



**Technical Specification (v2 model)
Guide**

Australian Medicines Terminology

2012-04-18

Final

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Acronyms

Acronym	Explanation
AMT	Australian Medicines Terminology
AO	Animal Origin
ARTG	Australian Register of Therapeutic Goods
ATC	WHO Anatomical Therapeutic Chemical Classification
BOSS	Basis Of Strength Substance
CT	Container Type
CTPP	Containered Trade Product Pack
CTV3	Clinical Terms Version 3 (Read Codes)
dm+d	UK Dictionary of Medicines and Devices
FSN	Fully Specified Name
GTIM	Global Trade Item Mapping
GTIN	Global Trade Item Number
HL7	Health Level 7
IAS	Ingredient Activity Status
ID	Identifier
IHTSDO	International Health Terminology Standards Development Organisation
ING	Ingredient Note: Ingredient (ING) and Substance (SUB) are used interchangeably in AMT v2 documentation.
MHM	MPP has MPUU
MP	Medicinal Product
MPP	Medicinal Product Pack
MPUU	Medicinal Product Unit of Use
MPUUSAI	MPUU Specific Active Ingredient
NCTIS	National Clinical Terminology & Information Service
NEHTA	National E-Health Transition Authority
NHS	National Health Service (UK)
NPC	National Product Catalogue
NPfIT	National Program for IT (UK)
PBS	Pharmaceutical Benefits Scheme

Acronym	Explanation
PF	Proprietary Form
PT	Preferred Term
RF1	Release Format 1 (SNOMED CT)
RF2	Release Format 2 (SNOMED CT)
RPBS	Repatriation Pharmaceutical Benefits Scheme
SCTID	SNOMED CT Identifier
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
SNOMED RT	Systematized Nomenclature of Medicine – Reference Terminology
SPO	Sponsor
TGA	Therapeutic Goods Administration
THT	TPP has TPUU
TP	Trade Product
TPG	Trade Product Group
TPP	Trade Product Pack
TPUU	Trade Product Unit of Use
TPUUPI	TPUU Pharmaceutical Ingredient
UTC	Coordinated Universal Time
UTF-8	Unicode Transformation Format (8-bit)
UML	Unified Modelling Language
UOM	Unit of Measure

1 Introduction

1.1 Purpose

This document specifies the data model for the AMT (v2 model), giving special attention to how the concepts, relationships and descriptions are linked together in the AMT.

This document should be read in conjunction with¹:

- *AMT UML Class Diagrams* [AMT2008]
- *AMT Editorial Rules (v2 model)* [AMT2011]
- *AMT v2 to v3 Migration Guide* [AMT2012]

Note: This Technical Specification is not a representation of the AMT distribution model. Instead, its primary purpose is to represent the data (i.e. the concepts, descriptions and relationships) incorporated into the AMT.

1.2 Intended audience

This guide is intended primarily for:

1. Health sector managers and analysts defining scope and requirements for clinical systems in their domains.
2. Health clinical software vendors with a specific interest in medicines management.

As such it assumes both a certain level of technical competence in data management and database design, and a familiarity with the use and nomenclature of medicines.

1.3 AMT purpose

The AMT delivers standardised identification of brand (trade) products and equivalent generic (medicinal) products along with associated components that are supported through standard naming conventions that accurately describe medicines.

The AMT may also be used for purposes other than eHealth messaging and system interoperability, for example within clinical systems delivering various aspects of electronic medications management, such as:

- Prescribing;
- Recording information about medicines (for example within an electronic patient record);
- Reviewing a consumer's medicines;
- Issuing medicines to a patient (including dispensing); and
- Administering medicines to a patient.

¹ Available from the NCTIS website (<https://nehta.org.au/aht/>).

1.4 AMT scope

In terms of product coverage, the scope of the AMT is to include medicinal products that are available in Australia for the treatment of human patients. The medicinal products to be addressed initially by the AMT will include:

- medicines registered with the TGA (AUST R); and
- medicines listed with the TGA (AUST L).

It is anticipated that the AMT will provide sufficient identification of medicines, products and components to support linkage with:

- PBS information; and
- regulatory bodies in Australia, such as the TGA Australian Register of Therapeutic Goods.

1.4.1 Out of scope

There is a wide range of knowledge about medicines that is not included in a medicines terminology. This information is provided by knowledge bases, (i.e. decision support) which can similarly be linked to product descriptions through the terminology.

Examples of information drawn from knowledge bases that are not considered to be within the scope of the AMT include, but are not limited to:

- Physiological equivalence
- Adverse effects
- Counselling instructions
- Cautionary and advisory label recommendations
- Contraindications
- Dose checking
- Drug-Drug interactions
- Drug-Allergy interactions
- Drug-Food interactions
- Indications
- Normal dose ranges
- Precautions for use
- Storage or supply chain related information

1.5 Acknowledgements

In authoring this document, the NCTIS would like to acknowledge the contributions made by: the NHS Dictionary of Medicines and Devices (dm+d) Team.

In addition, this work builds upon previous work by a number of groups and related initiatives including:

- A consultation draft of the Australian Medicines and Devices Terminology (AMDT) developed by the Department of Health and Ageing in conjunction with HL7 Australia and New Zealand.
- The design for the UK Dictionary of Medicines and Devices (dm+d), developed by the Connecting for Health Program.
- The design for the Australian Catalogue of Medicines (ACOM) which was guided by input from the Medicines Coding Council of Australia (MCCA).
- The *SNOMED CT User Guide* [SUG2012].

1.6 Questions and feedback

The National Clinical Terminology and Information Service (NCTIS) values your feedback about the usefulness of this document. We also encourage your comments or suggestions about AMT in general and this document in particular. Please direct your questions or feedback to terminologies@nehta.gov.au.

2 Overview of the AMT v2 model

2.1 Summary

The AMT data representation is based on the SNOMED CT international release data structures. SNOMED CT is a comprehensive and precise clinical reference terminology. More information on SNOMED CT is available from the International Health Terminology Standards Development Organisation (IHTSDO) website.²

Note: All references to AMT model in this document refer to AMT v2 model.

2.2 Conventions

The UML data models have been represented using visual aids as described below.

2.2.1 Concepts

Concepts (or groups of concepts) are represented as UML classes (named rectangles) and are colour coded as follows:

- Light green represents AMT grouper concepts which are parent concepts of the AMT hierarchies.
- Yellow represents the seven product types of AMT concepts.
- Blue represents the other (supporting) types of AMT concepts.
- Grey represents qualifier concepts within the AMT model only.

2.2.2 Relationships

Relationships are represented by lines joining the concepts. Hierarchical (IS A) relationships are represented by thick, blue lines, with an arrow at one end to indicate the direction of the hierarchy. All other (non-hierarchical) relationships are represented by labelled black lines.

A relationship, shown by a purple line, represents a relationship which does not appear in the SNOMED CT relationship table. Instead, these relationships are *implied* by referencing both the source and the target component's identifiers in some other way (e.g. through attributes).

The direction in which the relationship name is to be read is defined by small arrows next to the name. '►' indicates to read in forward direction. The forward direction is read from left to right and top to bottom. '◄' indicates to read in the reverse direction. The reverse direction is read from bottom to top and right to left.

2.2.3 Cardinality

Cardinality is defined in both directions, by use of the industry standard representation, that is:

- '1' denotes a cardinality of exactly one;
- '0..1' denotes a cardinality of zero to one;
- '0..*' denotes a cardinality of zero to many; and
- '1..*' denotes a cardinality of one to many.

Note: The cardinalities of the IS A relationships are not depicted on the diagrams, but instead are defined in the relationship tables in this document.

² <http://www.ihtsdo.org>.

2.2.4 Data Types

The data types and symbols shown in Table 1 are used in describing the description data types in this document.

Table 1: Description Data Types

Symbol	Data Type	Description
	Boolean	A Boolean is used to denote whether something is true or false. The AMT uses a '0' to represent 'False' and '1' to represent 'True'.
	DateTime	A date and (optionally) time, represented using ISO 8601 conventions, with no punctuation and no letter T between date and time, with a granularity up to the level of seconds.
	Integer	A number without a decimal (0, 1, 25, 173, 1032, etc). Integer values can be less than, equal to, or greater than zero.
	Real	A decimal number (e.g. 3.1417, 0.25, 1.8992, 6.0).
	Identifier	An identifier provides a means of uniquely identifying a SNOMED CT component. There are a number of types of identifiers used, including 'UUIDs' and 'SNOMED CT Ids (SCTIDs)'. The specific type of identifier will usually be indicated in brackets below this data type icon.
	String	A series of alphanumeric characters of any length.

2.2.5 Table header colours

Tables within this document have colour-coded heading rows for ease of recognition, as below.

Rules are coded green
Descriptions are coded blue
Examples are coded orange
Concepts are coded purple
Relationships are coded pink

This colour-coding is supplemented by the table captions (e.g. rules tables are identified as such), so this document is entirely legible in greyscale print.

2.2.6 SNOMED CT relationships

SNOMED CT relationships are sometimes represented as follows.

Character	Name	Description
←	IS A	The SNOMED CT IS A relationship, indicated by the direction of the arrow.

2.3 AMT products

The AMT has been conceptually designed to encompass seven (7) distinct 'product' concepts, each containing a set of logical data elements (or attributes) and each participating in a number of relationships (or associations) with other concepts. The main product concept groups are:

- Medicinal Product (MP);
- Medicinal Product Unit of Use (MPUU);
- Medicinal Product Pack (MPP);
- Trade Product (TP);
- Trade Product Unit of Use (TPUU);
- Trade Product Pack (TPP); and
- Containered Trade Product Pack (CTPP).

These seven product groups are also described as the seven AMT 'notable classes'. These concepts are diagrammatically represented in Figure 1.

Note: While the concept classes are described below, please see the *AMT Editorial Rules (v2 model)* [AMT2011] for the full definition of these classes.

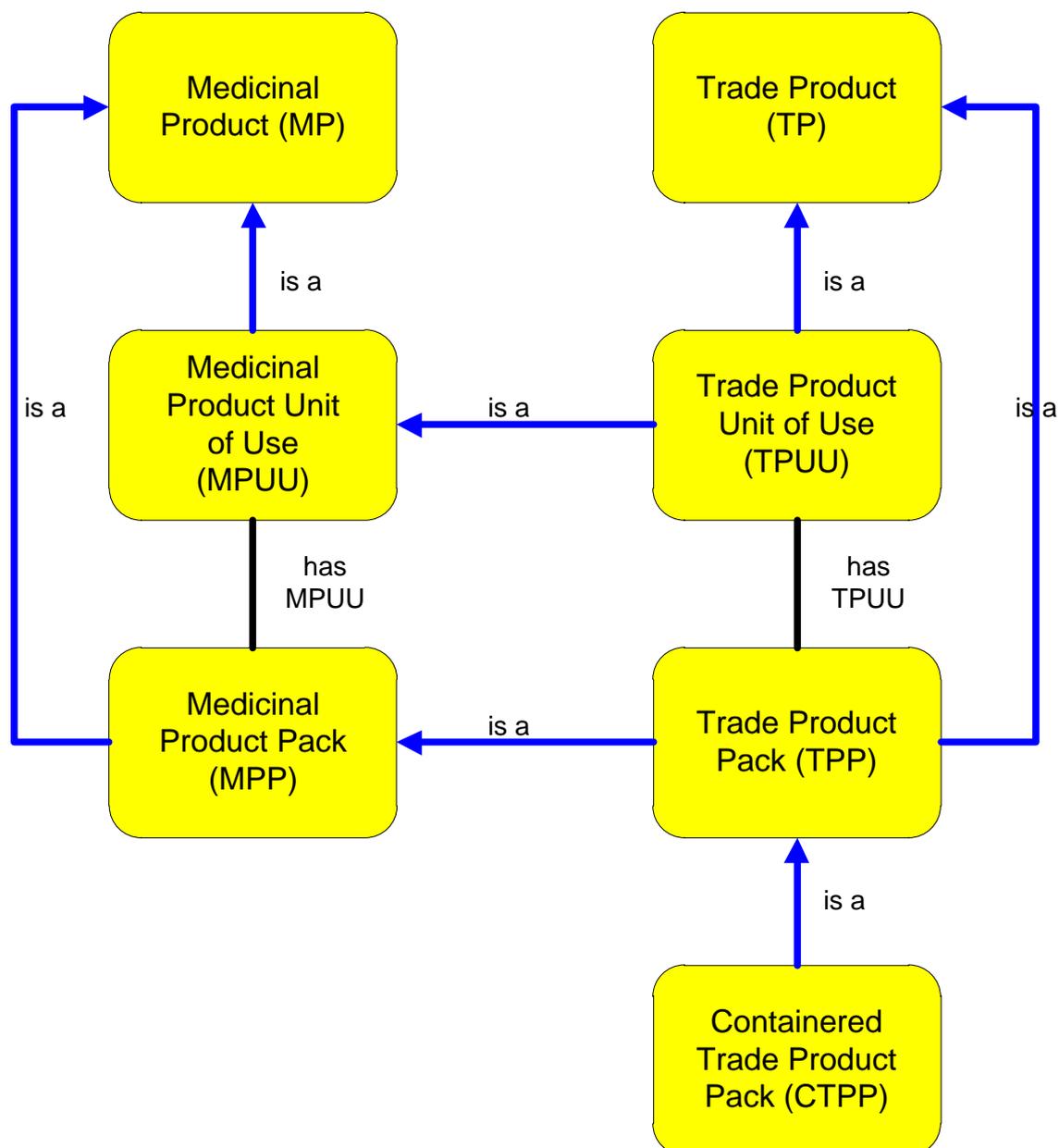


Figure 1: 'AMT Overview' model

2.3.1 Medicinal Product (MP)

A Medicinal Product (MP) is the abstract representation of the active ingredient(s) or substance(s) (devoid of strength and form), which when formulated as a medicinal product, is intended for use in the treatment of a patient. This includes medicines authorised by a health care professional as well as medicines for self-treatment.

The term 'medicines' may include over-the-counter preparations, vitamin preparations, complementary medicines as well as prescription-only medicines. A Medicinal Product will also define inactive (inert) ingredients where these are part of sequential multi-component products or diluents provided for the preparation of the actual administrable form of a product.

Note that the Medicinal Product name is derived from the base of the contained active ingredient concepts, with the following knowledge or rules incorporated:

- The precise ingredient (with salt) is specified, where this is therapeutically necessary or clinically significant.
- The Medicinal Product defines a group of products, which contain substances with the same active entity.

Note also that all Medicinal Product concepts will have a relationship to each of their active ingredients, using one or more HAS INGREDIENT relationships.

The list of Medicinal Products is designed for use in supporting 'generic prescribing' in a secondary care setting. For multi-ingredient products, the associated MP will generally include the individual substances. For multi-component products, the associated MP will be a 'composite MP', reflecting the Medicinal Product of each component according to formal concatenation rules.

2.3.2 Medicinal Product Unit of Use (MPUU)

A Medicinal Product Unit of Use (MPUU) is an abstract concept representing the properties of one or more clinically equivalent Trade Product Units of Use. Clinically equivalent TPUUs are those that have the same base active ingredient (or the same precise active ingredients, where the salt is therapeutically necessary), as well as the same strength, dose form, and administrable unit type, and where the TPUUs are considered as clinically and quantitatively equivalent. The MPUU will be represented by the associated MP's ingredient name(s), strength(s), form(s) and unit dose(s) (where appropriate). An MPUU will include single dose units of inactive (inert) ingredients (where these are part of sequential multi-component products) or diluents (provided for the preparation of the actual administrable form of a product).

A new MPUU will be created for each different strength of a registered medicinal product. If an existing product has a change of ingredient, such that it does not conform to the ingredients of the original MPUU, then a new MPUU will be created for the new product. The existing MPUU may have its status changed to an appropriate 'inactive' status.

Please note that all MPUU concepts will also have relationships to all of their active ingredients, as identified by the HAS SPECIFIC ACTIVE INGREDIENT relationship type.

2.3.3 Medicinal Product Pack (MPP)

A Medicinal Product Pack (MPP) is an abstract concept representing the properties of one or more quantitatively and clinically equivalent Trade Product Packs (TPP).

Note that for every Trade Product Pack, a corresponding MPP will exist. And every MPP may have one or more TPPs linked to it.

2.3.4 Trade Product (TP)

The Trade Product (TP) represents the product brand name or the grouping of products into a 'family', for either single component products that contain the same active ingredients or components of multi-component products which contain the same combination of active ingredients. This concept allows the recording of medications where only incomplete information is available. It will also allow the grouping of products for analysis. For example, a patient may be aware that they were previously prescribed 'Amoxil', but cannot be more specific about the form and strength. The Trade Product name will exclude suffixes that further define the item.

2.3.5 Trade Product Unit of Use (TPUU)

A Trade Product Unit of Use (TPUU) is a single dose unit of a finished dose form (unless the product is presented as a continuous dosage form, e.g. liquid or cream) that contains a specified amount of an active ingredient and is grouped within a particular Trade Product. A Trade Product Unit of Use will include single dose units of inactive (inert) ingredients where these are part of sequential multi-component products or diluents provided for the preparation of the actual administrable form of a product.

In other words, the TPUU represents one unit of a tangible, physical object that is taken, used or held by the patient, e.g. one tablet.

2.3.6 Trade Product Pack (TPP)

A Trade Product Pack (TPP) is the packaged product that is supplied for direct patient use. A TPP may contain multiple TPUU components, each of which may or may not be available for supply as an independent prescribable product.

Note that the TPP does not contain details of Container Type. (See Section 2.3.7 for more information.)

2.3.7 Containered Trade Product Pack (CTPP)

The Containered Trade Product Pack (CTPP) is the packaged product that is supplied for direct patient use and includes details of the Container Type. This defines the type of containers that immediately cover the medicine at the Trade Product Pack level. It does not include an article intended for ingestion. Examples include ampoule, bottle, blister pack, vial, etc.

2.4 Example AMT instance

A simple instance of the seven AMT product concepts is shown in Figure 2.

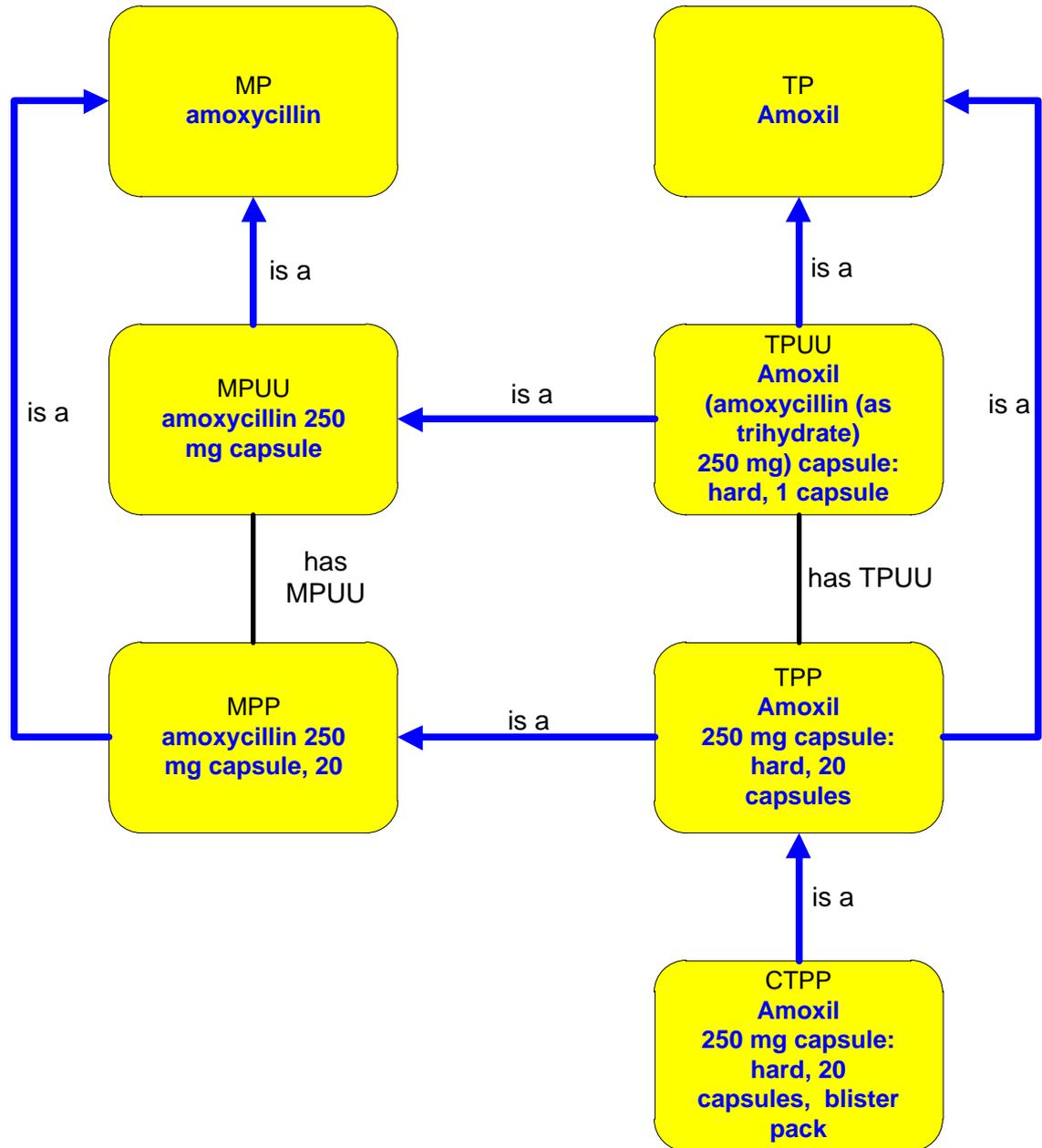


Figure 2: A simple instance of the AMT product concepts

3 AMT Concept Model

3.1 Overview

3.1.1 Purpose

The Australian Medicines Terminology (AMT) model shows those concepts, relationships and descriptions that are specifically relevant to the Australian medicines domain.

3.1.2 Model summary

The AMT UML class diagrams³ include 12 connected sub-models (or 'pages'), which together describe the AMT model – namely:

- AMT Concept Hierarchy
- AMT Product hierarchy (top level)
- AMT Product Hierarchy (details)
- Medicinal Product (MP)
- Medicinal Product Unit of Use (MPUU)
- Medicinal Product Pack (MPP)
- MPUU/MPP Relationship Details
- Trade Product (TP)
- Trade Product Unit of Use (TPUU)
- Trade Product Pack (TPP)/Containerised Trade Product Pack (CTPP)
- TPUU/TPP Relationship Details
- Substance Concepts

Each of these is described below using the following headings (where applicable):

- **Overview** – an overview of the UML diagram, with a brief description.
- **Concepts** – an alphabetical list of all related concepts, with a brief definition of each.
- **Relationships** – an alphabetical list of the associated relationships, including the concepts involved, the relationship type and the relevant cardinalities.
- **Descriptions** – an alphabetical list of the descriptions introduced in the given model, with a brief definition of each.

3.2 AMT hierarchies

3.2.1 Overview

The 'AMT Concept Hierarchy' diagram (Figure 3) includes the AMT concept sub-hierarchies that are specifically relevant to the AMT. These sub-hierarchies include:

Australian product: These concepts are used to identify products including both abstract (medicinal) and trade representations at various levels of granularity.

Australian substance: These concepts represent the ingredient within medicinal products.

³ See NEHTA_0168_2008_AMT_UML_Class_Diagrams_v7.0.zip, available from the NCTIS site (<https://nehta.org.au/aht>).

Australian qualifier: These concepts are used in the AMT to provide the atomic data used to construct the name of each product and to provide additional information about each product.

Relationship details: These concepts will be used in the AMT to add more information about a relationship between two concepts – e.g. the relationship 'MPUU has specific active ingredient' requires that strength values be recorded.

Data representation concepts: These concepts are used to assist in the representation of the AMT data in SNOMED-like format and currently include Description Type concepts, Relationship Type concepts, Status Type concepts, Characteristic Type concepts and Refinability Type concepts.

The UML class diagram for the AMT Concept Hierarchy is depicted below.

AMT Concept Hierarchy

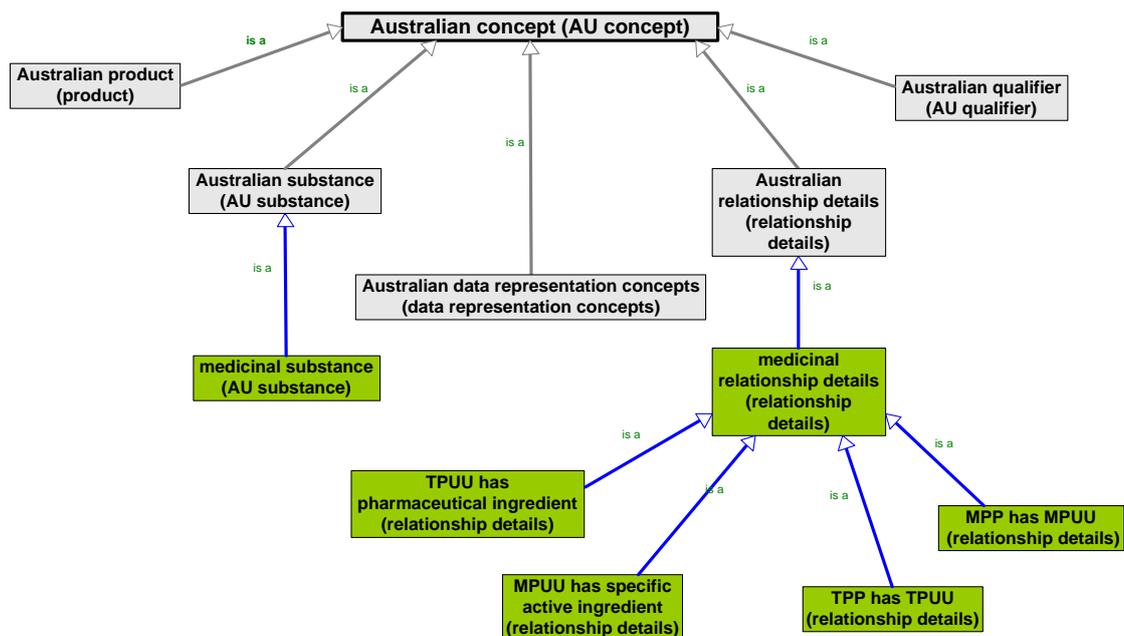


Figure 3: 'AMT Concept Hierarchy' model

3.2.2 Concepts

The subtypes (or children) of 'Australian concept' represented in the AMT Concept Hierarchy, together with their associated definitions, are shown in the following table.

Table 2: 'Australian Concept Hierarchy' concepts

Fully Specified Name	Definition
Australian concept (AU concept)	A clinical meaning that is uniquely identified by both a UUID and SCTID and is recommended for use in Australia, within one or more pre-defined clinical domains.
Australian data representation concepts (data representation concept)	Concepts used to assist in the representation of AMT data in the component model.
Australian product (product)	Products that are available in Australia for the treatment of human patients. These products are represented at a variety of levels of abstraction and granularity.
Australian qualifier (AU qualifier)	Concepts used in one or more domains to provide additional, qualifying information about the core domain concepts.
Australian relationship details (relationship details)	Concepts used to add more information about AMT relationships.
Australian substance (AU Substance)	A substance referred to in one of the Australian domain models, including medicinal ingredients contained within products.
Medicinal relationship details (relationship details)	Concepts that allow additional details to be recorded about specific relationships from the AMT.
Medicinal substance (AU substance)	A substance, which when formulated as a medicinal product, is intended for use in the treatment of a patient.
MPP has MPUU (relationship details)	A concept that allows quantity, size and preferred component order details to be recorded about a 'MPP has MPUU' relationship.
MPUU has specific active ingredient (relationship details)	A concept that allows strength and BOSS details to be recorded about a 'MPUU has specific active ingredient' relationship.
TPP has TPUU (relationship details)	A concept that allows quantity and size details to be recorded about a 'TPP has TPUU' relationship.
TPUU has pharmaceutical ingredient (relationship details)	A concept that allows activity status, strength, BOSS and biotech descriptor details to be recorded about a 'TPUU has pharmaceutical ingredient' relationship.

3.3 AMT Product hierarchy (top level)

3.3.1 Overview

The 'AMT Product hierarchy (top level)' class diagram shows the semantic hierarchy used to group each of the seven main AMT reference sets (e.g. 'Medicinal Product (MP)') under separate 'Australian product' grouper concepts.

The UML class diagram for the AMT Product hierarchy (top level) is shown in Figure 4.

AMT Product Hierarchy (Top level)

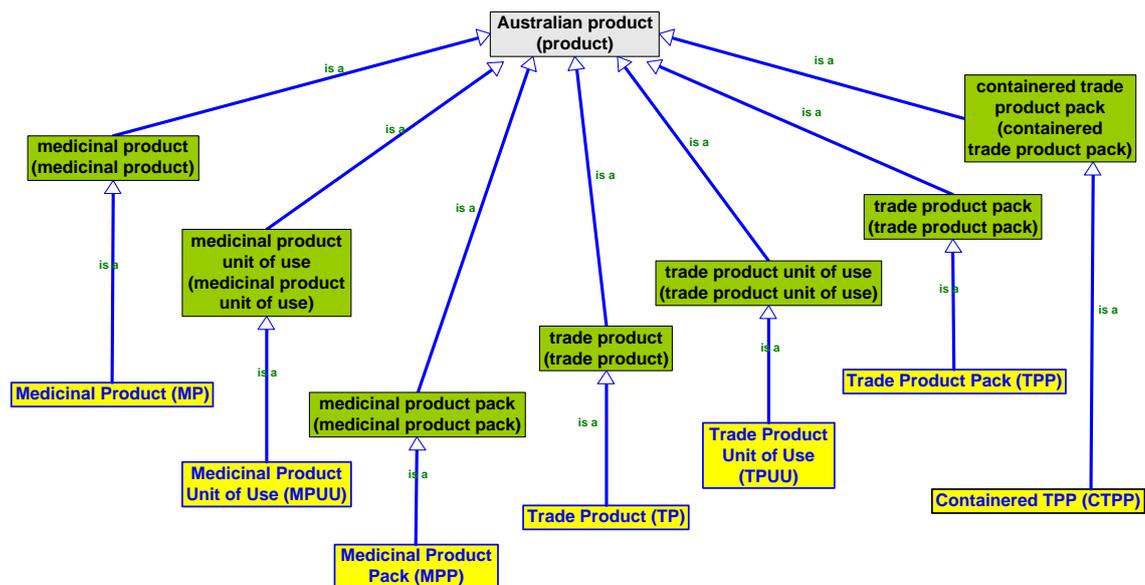


Figure 4: 'AMT Product hierarchy (top level)' model

3.3.2 Concepts

The concepts represented in the 'AMT Product hierarchy (top level)', together with their associated definitions, are shown in Table 3.

Note: Several entries in the following table appear to be duplicates. This is because the entry that contains a semantic tag (e.g. '(contained trade product pack)') corresponds to a grouper concept or class, whereas its counterpart entry without a semantic tag (e.g. '(CTPP)') refers to an instance of the class.

Table 3: AMT Product Hierarchy (top level)

Concept class	Grouper concept/ class FSN	Class Instance	Definition
Australian product	Australian product (product)		Concepts used to describe Medicinal products that are available in Australia for the treatment of human patients.
MP	medicinal product (medicinal product)		This concept is used to group the set of medicinal products within the Australian product hierarchy.

Concept class	Grouped concept/ class FSN	Class Instance	Definition
MP		medicinal product e.g. <i>amoxicillin</i>	A Medicinal Product is the abstract representation of the active ingredient(s) or substance(s) (devoid of strength and form), which when formulated as a medicinal product, is intended for use in the treatment of a patient.
MPUU	medicinal product unit of use (medicinal product unit of use)		This concept is used to group the set of medicinal product units of use within the Australian product hierarchy.
MPUU		medicinal product unit of use e.g. <i>amoxicillin</i> <i>250 mg capsule</i>	A Medicinal Product Unit of Use (MPUU) is an abstract concept representing the properties of one or more clinically equivalent Trade Product Units of Use – where 'clinical' is defined as having the same active ingredients, strength, dose form, and administrable unit type, and where the Trade Product Units of Use are considered to be clinically equivalent.
MPP	medicinal product pack (medicinal product pack)		This concept is used to group the set of medicinal product packs within the Australian product hierarchy.
MPP		medicinal product pack e.g. <i>amoxicillin</i> <i>250 mg capsule,</i> <i>20</i>	A Medicinal Product Pack (MPP) is an abstract concept representing the properties of one or more quantitatively and clinically equivalent Trade Product Packs (TPP).
TP	trade product (trade product)		This concept is used to group the set of trade products within the Australian product hierarchy.
TP		trade product e.g. <i>Amoxil</i>	A Trade Product represents the product brand name or the grouping of products into a 'family', for either single component products that contain the same active ingredients or multi-component products, which contain the same combination of active ingredients.

Concept class	Grouped concept/ class FSN	Class Instance	Definition
TPUU	trade product unit of use (trade product unit of use)		This concept is used to group the set of trade product units of use within the Australian product hierarchy.
TPUU		trade product unit of use e.g. <i>Amoxil (amoxicillin (as trihydrate) 250 mg) capsule: hard, 1 capsule</i>	A Trade Product Unit of Use (TPUU) is a single dose unit of a finished dose form (unless the product is presented as a continuous dosage form, e.g. liquid or cream) that contains a specified amount of an active ingredient substance and is grouped within a particular Trade Product.
TPP	trade product pack (trade product pack)		This concept is used to group the set of trade product packs within the Australian product hierarchy.
TPP		trade product pack e.g. <i>Amoxil 250 mg capsule: hard, 20 capsules</i>	A Trade Product Pack (TPP) is the packaged product that is supplied for direct patient use.
CTPP	containered trade product pack (containered trade product pack)		This concept is used to group the set of containered trade product packs within the Australian product hierarchy.
CTPP		containered trade product pack e.g. <i>Amoxil 250 mg capsule: hard, 20 capsules, blister pack</i>	This is the packaged product that is supplied for direct patient use and includes details of the Container Type. This defines the type of containers that immediately cover the medicine at the Trade Product Pack level.

3.4 AMT Product hierarchy (details)

3.4.1 Overview

The 'AMT Product Hierarchy (details)' class diagram shows the hierarchical relationships between the concepts contained in the seven main AMT reference sets (e.g. 'Medicinal Product (MP)').

The UML class diagram for 'AMT Product Hierarchy (details)' is shown in Figure 5.

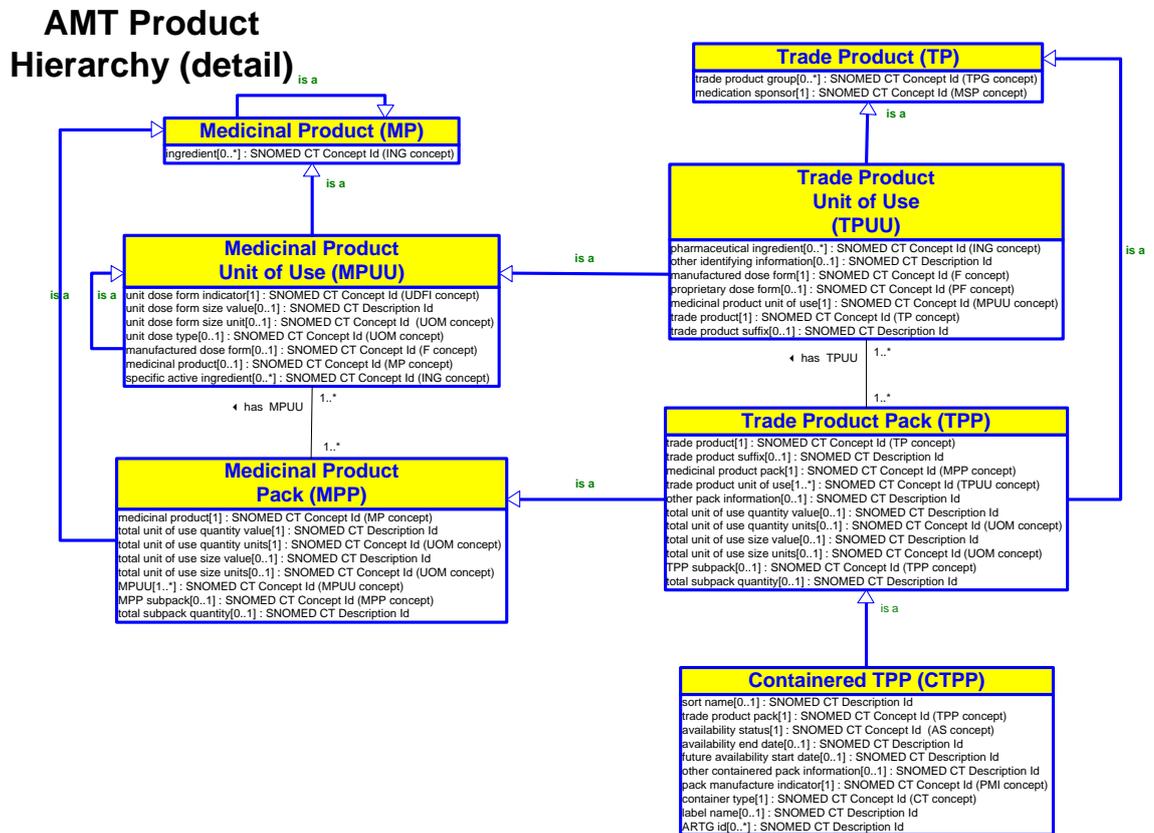


Figure 5: 'AMT Product Hierarchy (details)' model

3.4.2 Concepts

The concepts represented in the 'AMT Product Hierarchy (details) concepts' are as follows:

- Medicinal Product (MP)
- Medicinal Product Unit of Use (MPUU)
- Medicinal Product Pack (MPP)
- Trade Product (TP)
- Trade Product Unit of Use (TPUU)
- Trade Product Pack (TPP)
- Contained TPP (CTPP)

These concepts are defined in Table 3 above.

3.4.3 Relationships

The relationships that 'AMT Product Hierarchy (details)' concepts may participate in, together with their cardinality (C1 to C2/C2 to C1), are listed in Table 4.

Note: C1 refers to the source concept participating in a relationship, and C2 refers to the destination concept participating in the same relationship.

Table 4: 'AMT Product Hierarchy (details)' relationships

Concept 1 (C1)	Relationship Type	Concept 2 (C2)	Cardinality C1 to C2	Cardinality C2 to C1
Medicinal Product (MP)	is a	Medicinal Product (MP)	1	1..*
Medicinal Product Unit of Use (MPUU)	is a	Medicinal Product Unit of Use (MPUU)	1	1..*
Medicinal Product Unit of Use (MPUU)	is a	Medicinal Product (MP)	1	1..*
Medicinal Product Pack (MPP)	has MPUU	Medicinal Product Unit of Use (MPUU)	1..*	1..*
Medicinal Product Pack (MPP)	is a	Medicinal Product (MP)	1	1..*
Trade Product Unit of Use (TPUU)	is a	Trade Product (TP)	1	1..*
Trade Product Unit of Use (TPUU)	is a	Medicinal Product Unit of Use (MPUU)	1	1..*
Trade Product Pack (TPP)	has TPUU	Trade Product Unit of Use (TPUU)	1..*	1..*
Trade Product Pack (TPP)	is a	Trade Product (TP)	1	1..*
Trade Product Pack (TPP)	is a	Medicinal Product Pack (MPP)	1	1..*
Containerised TPP (CTPP)	is a	Trade Product Pack (TPP)	1	1..*

3.4.4 Descriptions

The description types associated with the concepts in the seven main AMT reference sets are described in Table 5.

Table 5: 'AMT Product Hierarchy (details)' descriptions

Description Type	Concept Class	Definition	Data Type	Cardinality
ARTG id	Containeder TPP (CTPP)	The associated identifier(s) from the Australian Register of Therapeutic Goods data.		0..*
other containeder pack information	Containeder TPP (CTPP)	Additional information about the CTPP to assist in further identifying the pack.		0..1
total subpack quantity	Medicinal Product Pack (MPP)	The total number of subpacks in the pack.		0..1
total unit of use quantity value	Medicinal Product Pack (MPP)	The numeric value associated with the total quantity of MPUUs in the MPP.		0..1
total unit of use size value	Medicinal Product Pack (MPP)	The numeric value associated with the smallest measurable amount of the product that is considered to be a unit for administration. This description is only used (where appropriate) for MPPs that contain only one type of MPUU.		0..1
unit dose form size value	Medicinal Product Unit of Use (MPUU)	The numeric value that represents the size of a single unit dose.		0..1
other pack information	Trade Product Pack (TPP)	Additional pack details that are required to avoid ambiguity in the constructed FSN and PT – e.g. 'sugar-free', 'preservative free', 'strawberry' (flavour).		0..1
total subpack quantity	Trade Product Pack (TPP)	The total number of subpacks within the TPP.		0..1
total unit of use quantity value	Trade Product Pack (TPP)	The numeric value associated with the total quantity of TPUUs in the TPP.		0..1

Description Type	Concept Class	Definition	Data Type	Cardinality
total unit of use size value	Trade Product Pack (TPP)	The numeric value associated with the smallest measurable amount of the product that is considered to be a unit for administration. This description is only used (where appropriate) for TPPs that contain only one type of MPUU.		0..1
trade product suffix	Trade Product Pack (TPP)	Any extension to a Trade Product name that further defines the product in terms of strength, form or presentation, e.g. for the product name 'Adalat Oros', 'Adalat' is the Trade Product name and 'Oros' is the Trade Product Suffix. This suffix will be sourced from the TGA ARTG Label Name.		0..1
other identifying information	Trade Product Unit of Use (TPUU)	Additional details that are required to avoid ambiguity in the constructed TPUU FSN and PT – e.g. 'sugar-free', 'preservative free', 'strawberry' (flavour).		0..1
trade product suffix	Trade Product Unit of Use (TPUU)	Any extension to a Trade Product name that further defines the product in terms of strength, form or presentation, e.g. for the product name 'Adalat Oros', 'Adalat' is the Trade Product name and 'Oros' is the Trade Product Suffix. This suffix be sourced from the TGA ARTG Label Name		0..1

3.5 Medicinal Product (MP)

3.5.1 Overview

The 'Medicinal Product (MP)' class diagram shows the hierarchical and non-hierarchical relationships that Medicinal Product concepts may participate in.

The UML class diagram for 'Medicinal Product (MP)' is shown in Figure 6.

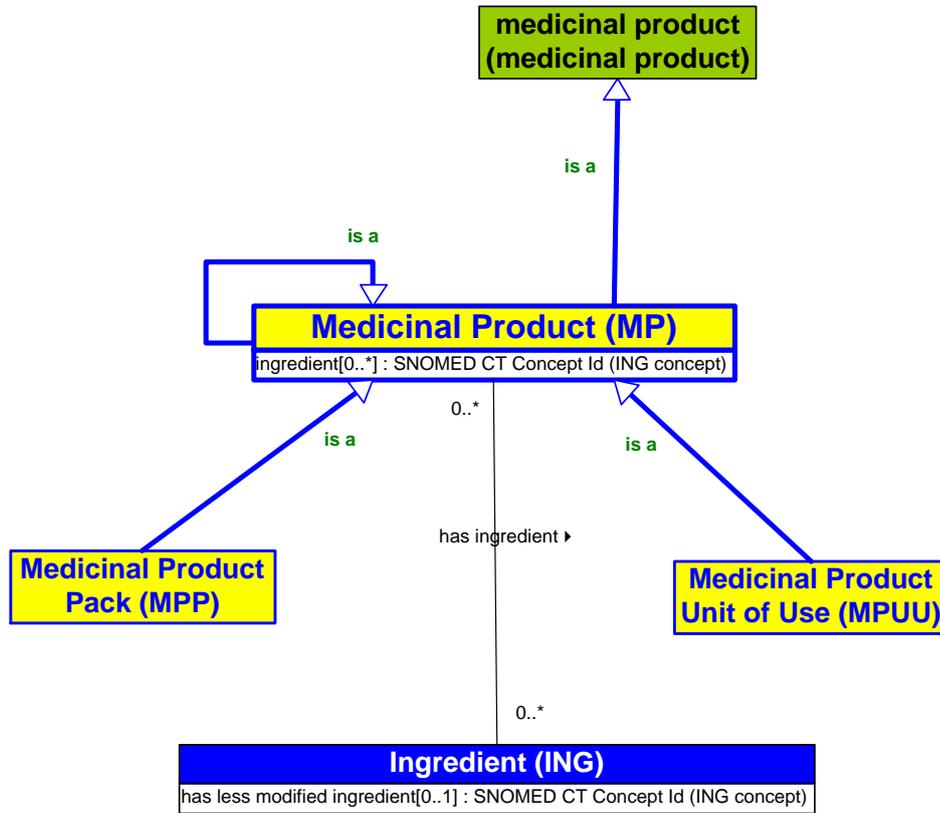


Figure 6: 'Medicinal Product (MP)' model

3.5.2 Concepts

The concepts that participate in relationships with 'Medicinal Product' concepts, together with their associated definitions are shown in Table 6.

Table 6: 'Medicinal Product (MP)' concepts

Concept class	Grouper concept/ class FSN	Class Instance	Definition
MP	medicinal product (medicinal product)		This concept is used to group the set of medicinal products within the Australian product hierarchy.
MP		medicinal product e.g. <i>amoxicillin</i>	A Medicinal Product is the abstract representation of the active ingredient(s) or substance(s) (devoid of strength and form), which when formulated as a medicinal product, is intended for use in the treatment of a patient.
Medicinal Product Unit of Use (MPUU)		medicinal product unit of use e.g. <i>amoxicillin 250 mg capsule</i>	A Medicinal Product Unit of Use (MPUU) is an abstract concept representing the properties of one or more clinically equivalent Trade Product Units of Use.
Medicinal Product Pack (MPP)		medicinal product pack e.g. <i>amoxicillin 250 mg capsule, 20</i>	A Medicinal Product Pack (MPP) is an abstract concept representing the properties of one or more quantitatively and clinically equivalent Trade Product Packs (TPP).
Ingredient (ING) ⁴			<p>A substance that is recognised in Australia as either:</p> <ul style="list-style-type: none"> • A chemical entity that may act as the actual active ingredient of a medicinal product – for example, heparin sodium, perindopril arginine or dexamethasone sodium phosphate; • The Basis of Strength Substance (BOSS) that may or may not be available as the actual ingredient – for example, perindopril or dexamethasone; • The 'clinically significant' portion of an actual ingredient – for example, diclofenac; or, • An excipient ingredient of medicinal products.

⁴ Ingredient (ING) and Substance (SUB) are used interchangeably in AMT v2 documentation.

3.5.3 Relationships

The relationships that 'Medicinal Product' concepts may participate in, together with their cardinality (C1 to C2/C2 to C1), are listed in Table 7.

Note: C1 refers to the source concept participating in a relationship, and C2 refers to the destination concept participating in the same relationship.

Table 7: 'Medicinal Product (MP)' relationships

Concept 1 (C1)	Relationship Type	Concept 2 (C2)	Cardinality C1 to C2	Cardinality C2 to C1
Medicinal Product (MP)	is a	Medicinal Product (MP)	1	1..*
Medicinal Product (MP)	is a	medicinal product (medicinal product)	1	1..*
Medicinal Product (MP)	has ingredient	Ingredient (ING)	0..*	0..*
Medicinal Product Unit of Use (MPUU)	is a	Medicinal Product (MP)	1	1..*
Medicinal Product Pack (MPP)	is a	Medicinal Product (MP)	1	1..*

3.6 Medicinal Product Unit of Use (MPUU)

3.6.1 Overview

The 'Medicinal Product Unit of Use (MPUU)' class diagram shows the hierarchical and non-hierarchical relationships that MPUU concepts may participate in.

The UML class diagram for 'Medicinal Product Unit of Use (MPUU)' is shown in Figure 7.

Medicinal Product Unit of Use (MPUU)

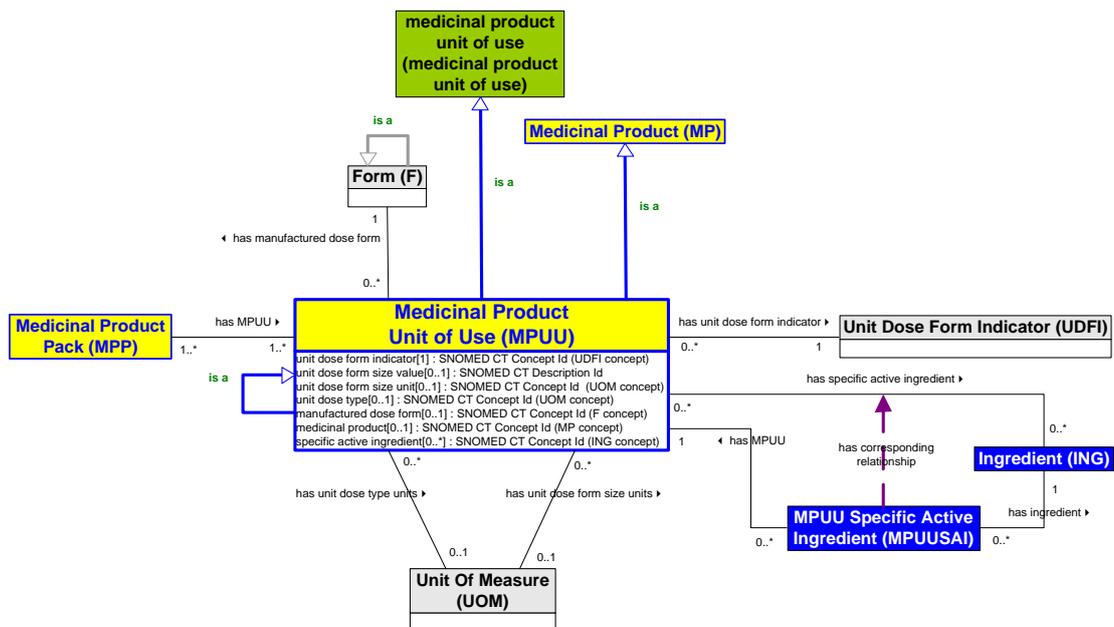


Figure 7: 'Medicinal Product Unit of Use (MPUU)' model

3.6.2 Concepts

The concepts that participate in relationships with 'Medicinal Product Unit of Use' concepts, together with their associated definitions, are shown in Table 8.

Table 8: 'Medicinal Product Unit of Use (MPUU)' concepts

Concept class	Groupier concept/ class FSN	Class Instance	Definition
Form			A qualifier concept that represents the dose formulation – for example, tablet, capsules or eye drops.

Concept class	Grouped concept/ class FSN	Class Instance	Definition
Ingredient (ING)			<p>A substance that is recognised in Australia as either:</p> <ul style="list-style-type: none"> • A chemical entity that may act as the actual active ingredient of a medicinal product – for example, heparin sodium, perindopril arginine or dexamethasone sodium phosphate; • The Basis of Strength Substance (BOSS) that may or may not be available as the actual ingredient – for example, perindopril or dexamethasone; • The 'clinically significant' portion of an actual ingredient – for example, diclofenac; or • An excipient ingredient of medicinal products.
MP		medicinal product e.g. <i>amoxicillin</i>	The abstract representation of the active ingredient(s) or substance(s) (devoid of strength and form), which when formulated as a medicinal product, is intended for use in the treatment of a patient.
MPP		medicinal product pack e.g. <i>amoxicillin 250 mg capsule, 20</i>	An abstract concept representing the properties of one or more quantitatively and clinically equivalent Trade Product Packs (TPP).
MPP	medicinal product unit of use (medicinal product unit of use)		This concept is used to group the set of medicinal product units of use within the Australian product hierarchy.
MPUU		medicinal product unit of use e.g. <i>amoxicillin 250 mg capsule</i>	An abstract concept representing the properties of one or more clinically equivalent Trade Product Units of Use.
MPUU Specific Active Ingredient (MPUUSAI)			A concept that records details about each ingredient in an MPUU (including strength, BOSS, BOSS strength etc.).

Concept class	Grouped concept/ class FSN	Class Instance	Definition
Unit Dose Form Indicator (UDFI)			A qualifier that identifies if an APUU describes a discrete unit dose form (e.g. tablet or capsule), a continuous substance where a consistent physically measurable unit or sub-unit cannot be identified (e.g. cream or eye drops), or a product where a unit dose form is not applicable.
Unit of Measure (UOM)			A 'unit' used to measure quantities of various kinds – e.g. 'millilitre', 'gram', 'centimetre', 'tablet'.

3.6.3 Relationships

The relationships that 'Medicinal Product Unit of Use (MPUU)' concepts may participate in, together with their cardinality (C1 to C2/C2 to C1), are listed in Table 9.

Note: C1 refers to the source concept participating in a relationship, and C2 refers to the destination concept participating in the same relationship.

Table 9: 'Medicinal Product Unit of Use (MPUU)' relationships

Concept 1 (C1)	Relationship Type	Concept 2 (C2)	Cardinality C1 to C2	Cardinality C2 to C1
Medicinal Product Unit of Use (MPUU)	has manufactured dose form (relationship type)	Form	1	0..*
Medicinal Product Unit of Use (MPUU)	has specific active ingredient (relationship type)	Ingredient (ING)	0..*	0..*
Medicinal Product Unit of Use (MPUU)	has unit dose form indicator (relationship type)	Unit Dose Form Indicator (UDFI)	1	0..*
Medicinal Product Unit of Use (MPUU)	has unit dose form size units (relationship type)	Unit of Measure (UOM)	0..1	0..*
Medicinal Product Unit of Use (MPUU)	has unit dose type units (relationship type)	Unit of Measure (UOM)	0..1	0..*
Medicinal Product Unit of Use (MPUU)	is a	Medicinal Product (MP)	1	1..*

Concept 1 (C1)	Relationship Type	Concept 2 (C2)	Cardinality C1 to C2	Cardinality C2 to C1
Medicinal Product Unit of Use (MPUU)	is a	medicinal product unit of use (medicinal product unit of use)	1	1..*
Medicinal Product Unit of Use (MPUU)	is a	Medicinal Product Unit of Use (MPUU)	1	1..*
Medicinal Product Pack (MPP)	has MPUU (relationship type)	Medicinal Product Unit of Use (MPUU)	1..*	1..*
Ingredient (ING)	has ingredient (relationship type)	MPUU Specific Active Ingredient (MPUUSAI)	0..*	1
MPUU Specific Active Ingredient (MPUUSAI)	has MPUU (relationship type)	Medicinal Product Unit of Use (MPUU)	1	0..*

3.6.4 Descriptions

The descriptions which may be associated with a Medicinal Product Unit of Use are described in Table 10.

Table 10: 'Medicinal Product Unit of Use (MPUU)' descriptions

Description Type	Associated Class	Definition	Data Type	Cardinality
unit dose form size value	Medicinal Product Unit of Use (MPUU)	The numeric value that represents the size of a single unit dose.		0..1

3.7 Medicinal Product Pack (MPP)

3.7.1 Overview

The 'Medicinal Product Pack (MPP)' class diagram shows the hierarchical and non-hierarchical relationships that MPP concepts may participate in.

The UML class diagram for 'Medicinal Product Pack (MPP)' is shown in Figure 8.

Medicinal Product Pack (MPP)

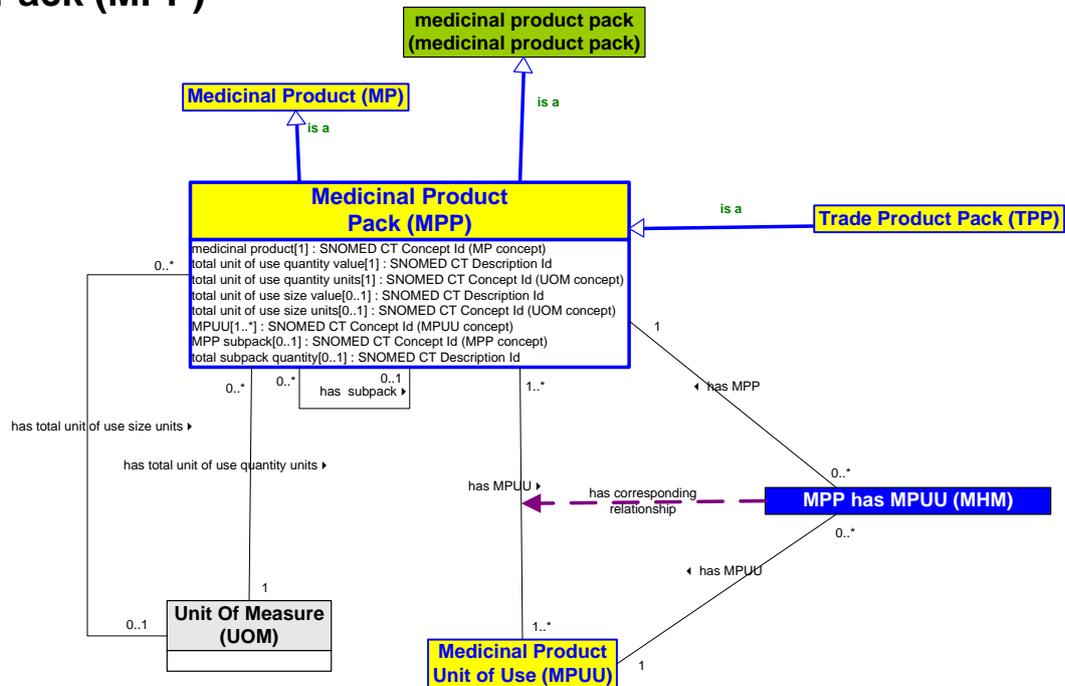


Figure 8: 'Medicinal Product Pack (MPP)' model

3.7.2 Concepts

The concepts that participate in relationships with 'Medicinal Product Pack' concepts, together with their associated definitions, are shown in Table 11.

Table 11: 'Medicinal Product Pack (MPP)' concepts

Concept class	Grouped concept/ class FSN	Class Instance	Definition
MP	medicinal product pack (medicinal product pack)		This concept is used to group the set of medicinal product packs within the Australian product hierarchy.
MP		medicinal product e.g. <i>amoxicillin</i>	The abstract representation of the active ingredient(s) or substance(s) (devoid of strength and form), which when formulated as a medicinal product, is intended for use in the treatment of a patient.

Concept class	Grouped concept/ class FSN	Class Instance	Definition
MPUU		medicinal product unit of use e.g. <i>amoxicillin</i> <i>250 mg capsule</i>	An abstract concept representing the properties of one or more clinically equivalent Trade Product Units of Use.
MPP		medicinal product pack e.g. <i>amoxicillin</i> <i>250 mg capsule,</i> <i>20</i>	An abstract concept representing the properties of one or more quantitatively and clinically equivalent Trade Product Packs (TPP).
TPP		trade product pack e.g. <i>Amoxil 250</i> <i>mg capsule: hard,</i> <i>20 capsules</i>	The packaged product that is supplied for direct patient use, independent of the container.
MPP has MPUU (MHM)			A concept representing the relationship between a specific Medicinal Unit of Use and a specific Medicinal Product Pack that contains it. This concept is used to record the quantity, size and preferred component order of the MPUU within the MPP.
Unit of Measure (UOM)			The units used to measure various quantities within the AMT.

3.7.3 Relationships

The relationships that 'Medicinal Product Pack (MPP)' concepts may participate in, together with their cardinality (C1 to C2/C2 to C1), are listed in Table 12.

Note: C1 refers to the source concept participating in a relationship, and C2 refers to the destination concept participating in the same relationship.

Table 12: 'Medicinal Product Pack (MPP)' relationships

Concept 1 (C1)	Relationship Type	Concept 2 (C2)	Cardinality C1 to C2	Cardinality C2 to C1
Medicinal Product Pack (MPP)	has MPUU (relationship type)	Medicinal Product Unit of Use (MPUU)	1..*	1..*
Medicinal Product Pack (MPP)	has subpack (relationship type)	Medicinal Product Pack (MPP)	0..1	0..*
Medicinal Product Pack (MPP)	has total unit of use quantity units (relationship type)	Unit of Measure (UOM)	1	0..*

Concept 1 (C1)	Relationship Type	Concept 2 (C2)	Cardinality C1 to C2	Cardinality C2 to C1
Medicinal Product Pack (MPP)	has total unit of use size units (relationship type)	Unit of Measure (UOM)	0..1	0..*
Medicinal Product Pack (MPP)	is a	Medicinal Product (MP)	1	0..*
Medicinal Product Pack (MPP)	is a	medicinal product pack (medicinal product pack)	1/	1..*
Trade Product Pack (TPP)	is a	Medicinal Product Pack (MPP)	1..*	1
MPP has MPUU (MHM)	has MPP (relationship type)	Medicinal Product Pack (MPP)	1	1..*
MPP has MPUU (MHM)	has MPUU	Medicinal Product Unit of Use (MPUU)	0..*	1

3.7.4 Descriptions

The descriptions which may be associated with a Medicinal Product Pack are described in Table 13.

Table 13: 'Medicinal Product Pack (MPP)' descriptions

Description Type	Associated Class	Definition	Data Type	Cardinality
total subpack quantity	Medicinal Product Pack (MPP)	The total number of subpacks in the pack.		0..1
total unit of use quantity value	Medicinal Product Pack (MPP)	The numeric value associated with the total quantity of MPUUs in the MPP.		0..1
total unit of use size value	Medicinal Product Pack (MPP)	The numeric value associated with the smallest measurable amount of the product that is considered to be a unit for administration. This description is only used (where appropriate) for MPPs that contain only one type of MPUU.		0..1

3.8 MPUU/MPP Relationship Details

3.8.1 Overview

The 'MPUU/MPP Relationship Details' class diagram shows the relationship details that are recorded for MPPs and MPUUs. In particular, this model shows:

- Quantity, size and preferred component order details recorded about the 'MPP has MPUU' relationship; and
- Strength, BOSS and preferred term order details recorded about the 'MPUU has specific active ingredient' relationship.

The UML class diagram for 'MPUU/MPP Relationship Details' is shown in Figure 9.

MPUU/MPP Relationship Details

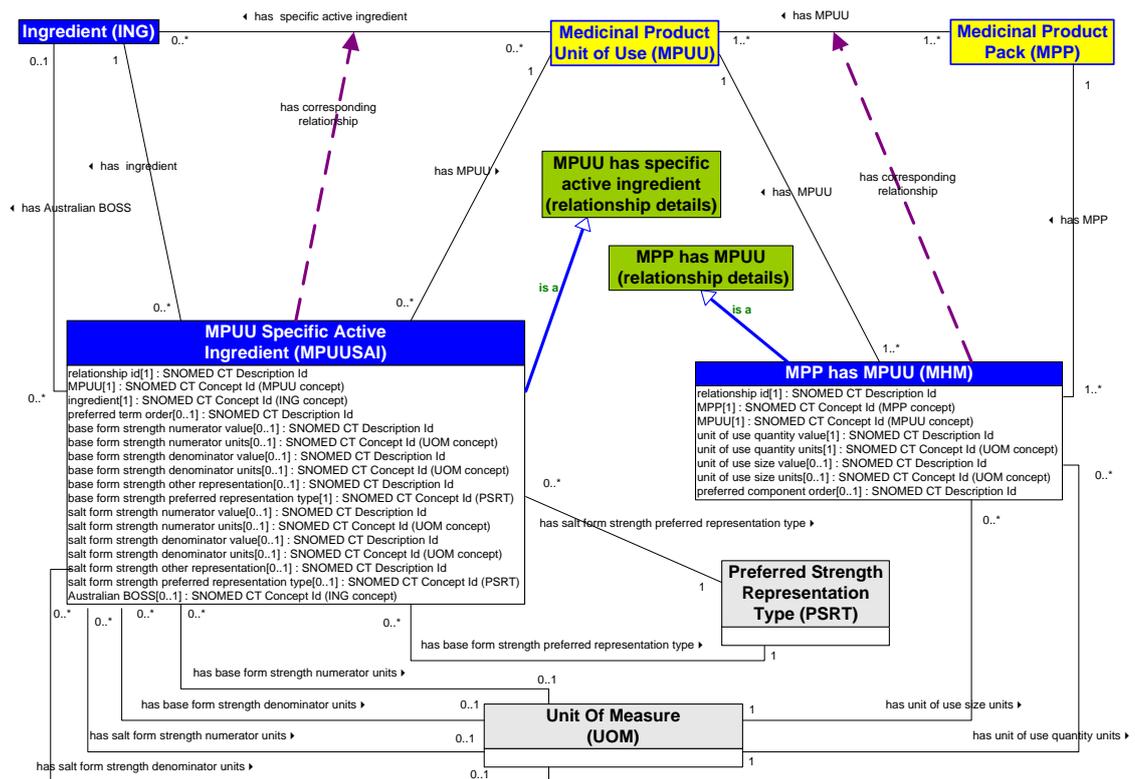


Figure 9: 'MPUU/MPP Relationship Details' model

3.8.2 Concepts

The concepts that participate in relationships with 'MPUU Specific Active Ingredient (MPUU_SAI)' concepts and 'MPP has MPUU (MHM)' concepts, together with their associated definitions, are shown in Table 14.

Table 14: 'MPUU/MPP Relationship Details' concepts

Fully Specified Name	Grouped concept/ class FSN	Class Instance	Definition
MPUU		medicinal product unit of use e.g. <i>amoxicillin 250 mg capsule</i>	An abstract concept representing the properties of one or more clinically equivalent Trade Product Units of Use.
MPP		medicinal product pack e.g. <i>amoxicillin 250 mg capsule, 20</i>	An abstract concept representing the properties of one or more quantitatively and clinically equivalent Trade Product Packs (TPP).
Ingredient (ING)			<p>A substance that is recognised in Australia as either:</p> <ul style="list-style-type: none"> • A chemical entity that may act as the actual active ingredient of a medicinal product – for example, heparin sodium, perindopril arginine or dexamethasone sodium phosphate; • The Basis of Strength Substance (BOSS) that may or may not be available as the actual ingredient – for example, perindopril or dexamethasone; • The 'clinically significant' portion of an actual ingredient – for example, diclofenac; or, • An excipient ingredient of medicinal products.
MPP has MPUU (MHM)			A concept representing the relationship between a specific Medicinal Unit of Use and a specific Medicinal Product Pack that contains it. This concept is used to record the quantity, size and preferred component order of the MPUU within the MPP.

Fully Specified Name	Grouping concept/ class FSN	Class Instance	Definition
MPP has MPUU (relationship details)			This concept is used to group the set of 'MPP has MPUU' concepts in the relationship details hierarchy.
MPUU has specific active ingredient (relationship details)			This concept is used to group the set of 'MPUU has specific active ingredient' concepts in the relationship details hierarchy.
MPUU Specific Active Ingredient (MPUUSAI)			These 'relationship details' concepts record the strength, BOSS and preferred term order of each active ingredient contained in each MPUU.
Preferred Strength Representation Type (PSRT)			<p>Preferred Strength Representation Type defines the order and combination of strength representations to include in the preferred term of the association medicinal products. Valid values include:</p> <ul style="list-style-type: none"> • alternate strength followed by numerator/denominator strength • alternate strength only • numerator/denominator strength • numerator/denominator strength followed by alternate strength.
Unit of Measure (UOM)			The units used to measure various quantities within the AMT.

3.8.3 Relationships

The relationships that ‘MPUU Specific Active Ingredient (MPUUSAI)’ concepts and ‘MPP has MPUU (MHM)’ concepts participate in, together with their cardinality (C1 to C2/C2 to C1), are listed in Table 15.

Note: C1 refers to the source concept participating in a relationship, and C2 refers to the destination concept participating in the same relationship.

Table 15: ‘MPUU/MPP Relationship Details’ relationships

Concept 1 (C1)	Relationship Type	Concept 2 (C2)	Cardinality C1 to C2	Cardinality C2 to C1
Medicinal Product Unit of Use (MPUU)	has specific active ingredient (relationship type)	Ingredient (ING)	0..*	0..*
Medicinal Product Pack (MPP)	has MPUU (relationship type)	Medicinal Product Unit of Use (MPUU)	1..*	1..*
MPP has MPUU (MHM)	has MPP (relationship type)	Medicinal Product Pack (MPP)	1	1..*
MPP has MPUU (MHM)	has MPUU (relationship type)	Medicinal Product Unit of Use (MPUU)	1	1..*
MPP has MPUU (MHM)	has unit of use quantity units (relationship type)	Unit of Measure (UOM)	1	0..*
MPP has MPUU (MHM)	has unit of use size units (relationship type)	Unit of Measure (UOM)	1	0..*
MPP has MPUU (MHM)	is a	MPUU in MPP details (relationship details)	1	1..*
MPUU Specific Active Ingredient (MPUUSAI)	has Australian BOSS (relationship type)	Ingredient (ING)	0..1	0..*
MPUU Specific Active Ingredient (MPUUSAI)	has base form strength denominator units (relationship type)	Unit of Measure (UOM)	0..1	0..*
MPUU Specific Active Ingredient (MPUUSAI)	has base form strength numerator units (relationship type)	Unit of Measure (UOM)	0..1	0..*
MPUU Specific Active Ingredient (MPUUSAI)	has preferred base form strength representation (relationship type)	Preferred Strength Representation Type (PSRT)	1	0..*
MPUU Specific Active Ingredient (MPUUSAI)	has ingredient (relationship type)	Ingredient (ING)	1	0..*

Concept 1 (C1)	Relationship Type	Concept 2 (C2)	Cardinality C1 to C2	Cardinality C2 to C1
MPUU Specific Active Ingredient (MPUUSAI)	has MPUU (relationship type)	Medicinal Product Unit of Use (MPUU)	1	0..*
MPUU Specific Active Ingredient (MPUUSAI)	has salt form strength denominator units (relationship type)	Unit of Measure (UOM)	0..1	0..*
MPUU Specific Active Ingredient (MPUUSAI)	has salt form strength numerator units (relationship type)	Unit of Measure (UOM)	0..1	0..*
MPUU Specific Active Ingredient (MPUUSAI)	has preferred salt form strength representation (relationship type)	Preferred Strength Representation Type (PSRT)	1	0..*
MPUU Specific Active Ingredient (MPUUSAI)	is a	MPUU has specific active ingredient (relationship details)	1	1..*

3.8.4 Descriptions

The descriptions, shown on the 'MPUU/MPP Relationship Details' model are listed in Table 16.

Table 16: 'MPUU/MPP Relationship Details' descriptions

Description Type	Associated Class	Definition	Data Type	Cardinality
relationship id	MPUU Specific Active Ingredient (MPUUSAI)	The SNOMED CT identifier of the 'MPUU has specific active ingredient' relationship that the relationship details concept refers to.	ID (SCTID)	1
preferred term order	MPUU Specific Active Ingredient (MPUUSAI)	The preferred order in which ingredients should be displayed in the MPUU's preferred term.	123	0..1
base form strength numerator value	MPUU Specific Active Ingredient (MPUUSAI)	The numeric value of the numerator of the active ingredient's base strength.	1234	0..1
base form strength denominator value	MPUU Specific Active Ingredient (MPUUSAI)	The numeric value of the denominator of the active ingredient's base strength.	1234	0..1

Description Type	Associated Class	Definition	Data Type	Cardinality
base form strength other representation	MPUU Specific Active Ingredient (MPUU_SAI)	The preferred strength representation format of the ingredient's base strength.		0..1
salt form strength numerator value	MPUU Specific Active Ingredient (MPUU_SAI)	The numeric value of the numerator of the active ingredient's salt strength.		0..1
salt form strength denominator value	MPUU Specific Active Ingredient (MPUU_SAI)	The numeric value of the denominator of the active ingredient's salt strength.		0..1
salt form strength other representation	MPUU Specific Active Ingredient (MPUU_SAI)	The preferred strength representation format of the ingredient's base strength.		0..1
relationship id	MPP has MPUU (MHM)	The SNOMED CT identifier of the 'MPP has MPUU' relationship that the relationship details concept refers to.	 (SCTID)	1
unit of use quantity value	MPP has MPUU (MHM)	The numeric value of the quantity of MPUUs in the given MPP.		1
unit of use size value	MPP has MPUU (MHM)	The smallest measurable amount of product considered to be a unit of medication for administration.		0..1
preferred component order	MPP has MPUU (MHM)	The preferred order in which MPUU components should appear in the MPP's preferred term.		0..1

3.9 Trade Product (TP)

3.9.1 Overview

The 'Trade Product (TP)' class diagram shows the hierarchical and non-hierarchical relationships that TP concepts may participate in.

The UML class diagram for 'Trade Product (TP)' is shown in Figure 10.

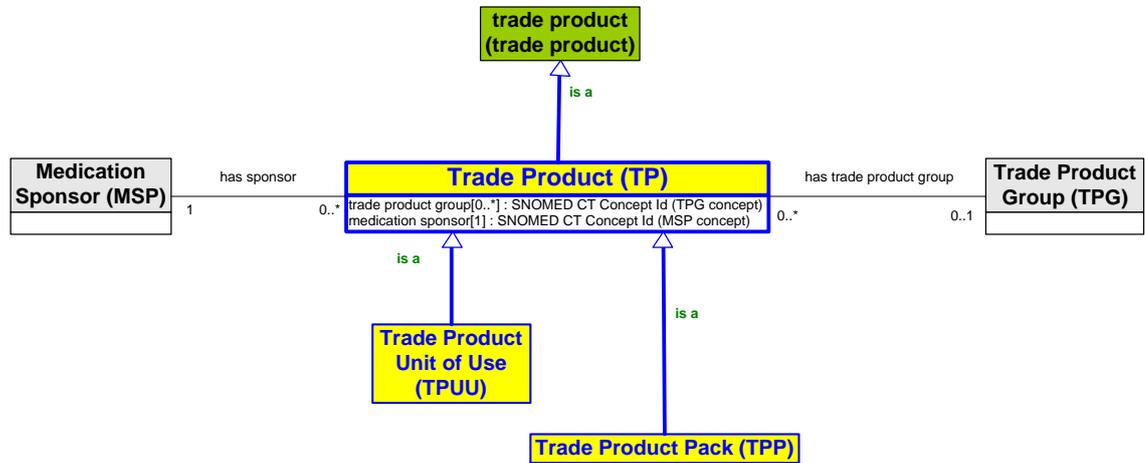


Figure 10: 'Trade Product (TP)' model

3.9.2 Concepts

The concepts that participate in relationships with 'Trade Product (TP)' concepts, together with their associated definitions, are shown in Table 17.

Table 17: 'Trade Product (TP)' concepts

Fully Specified Name	Groupier concept/ class FSN	Class Instance	Definition
TP	trade product (trade product)		This concept is used to group the set of trade products within the Australian Product hierarchy.
TP		trade product e.g. <i>Amoxil</i>	The Trade Product represents the product brand name or the grouping of products into a 'family', for either single component products that contain the same active ingredients or components of multi-component products, which contain the same combination of active ingredients.

Fully Specified Name	Grouped concept/ class FSN	Class Instance	Definition
TPUU		trade product unit of use e.g. <i>Amoxil (amoxicillin (as trihydrate) 250 mg) capsule: hard, 1 capsule</i>	A Trade Product Unit of Use (TPUU) is a single dose unit of a finished dose form (unless the product is presented as a continuous dosage form, e.g. liquid or cream) that contains a specified amount of an active ingredient substance and is grouped within a particular Trade Product.
TPP		trade product pack e.g. <i>Amoxil 250 mg capsule: hard, 20 capsules</i>	A Trade Product Pack (TPP) is the packaged product that is supplied for direct patient use, independent of the container.
Medication Sponsor (MSP)			An organisation that sponsors a medicinal product in the Australian marketplace.
Trade Product Group (TPG)			This qualifier concept allows for trade products sharing a common root trade product name to be grouped. For example, Canesten is the Trade Product Group description and provides links to Canesten Clotrimazole and Canesten Bifonazole.

3.9.3 Relationships

The relationships that 'Trade Product (TP)' concepts may participate in, together with their cardinality (C1 to C2/C2 to C1), are listed in Table 18.

Note: C1 refers to the source concept participating in a relationship, and C2 refers to the destination concept participating in the same relationship.

Table 18: 'Trade Product (TP)' relationships

Concept 1 (C1)	Relationship Type	Concept 2 (C2)	Cardinality C1 to C2	Cardinality C2 to C1
Trade Product (TP)	is a	trade product (trade product)	1	1..*
Trade Product (TP)	has sponsor (relationship type)	Medication Sponsor (MSP)	1	0..*
Trade Product (TP)	has trade product group (relationship type)	Trade Product Group (TPG)	0..1	0..*
Trade Product Unit of Use (TPUU)	is a	Trade Product (TP)	1	1..*
Trade Product Pack (TPP)	is a	Trade Product (TP)	1	1..*

3.10 Trade Product Unit of Use (TPUU)

3.10.1 Overview

The 'Trade Product Unit of Use (TPUU)' class diagram shows the hierarchical and non-hierarchical relationships that TPUU concepts may participate in.

The UML class diagram for 'Trade Product Unit of Use (TPUU)' is shown in Figure 11.

Trade Product Unit of Use (TPUU)

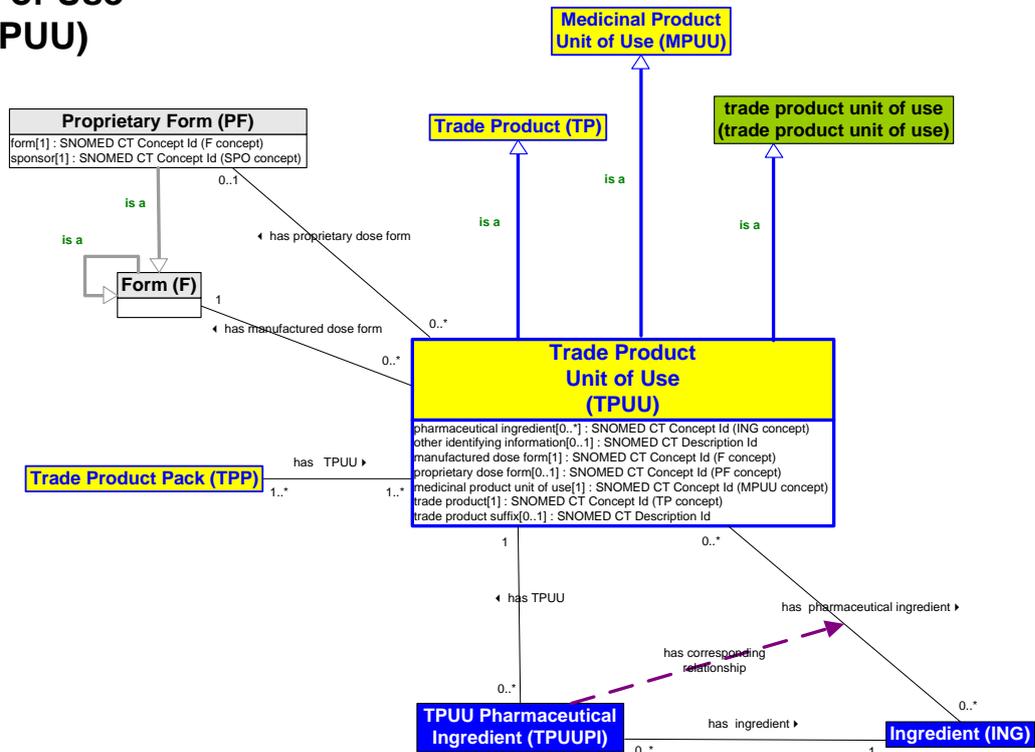


Figure 11: 'Trade Product Unit of Use (TPUU)' model

3.10.2 Concepts

The concepts that participate in relationships with 'Trade Product Unit of Use (TPUU)' concepts, together with their associated definitions, are shown in Table 19.

Table 19: 'Trade Product Unit of Use (TPUU)' concepts

Fully Specified Name	Groupier concept/ class FSN	Class Instance	Definition
MPUU		medicinal product unit of use e.g. <i>amoxicillin 250 mg capsule</i>	An abstract concept representing the properties of one or more clinically equivalent Trade Product Units of Use.

Fully Specified Name	Groupier concept/ class FSN	Class Instance	Definition
TP		trade product e.g. <i>Amoxil</i>	The product brand name or the grouping of products into a 'family', for either single component products that contain the same active ingredients or multi-component products, which contain the same combination of active ingredients.
TPUU	trade product unit of use (trade product unit of use)		This concept is used to group the set of trade product units of use within the Australian product hierarchy.
TPUU		trade product unit of use e.g. <i>Amoxil (amoxicillin (as trihydrate) 250 mg) capsule: hard, 1 capsule</i>	A single dose unit of a finished dose form (unless the product is presented as a continuous dosage form, e.g. liquid or cream) that contains a specified amount of an active ingredient substance and is grouped within a particular Trade Product.
TPP		trade product pack e.g. <i>Amoxil 250 mg capsule: hard, 20 capsules</i>	A Trade Product Pack (TPP) is the packaged product that is supplied for direct patient use, independent of the container.
TPUU Pharmaceutical Ingredient (TPUUPI)			These 'relationship details' concepts record the strength, BOSS and biotech descriptor of each pharmaceutical ingredient contained in each TPUU.

Fully Specified Name	Grouped concept/ class FSN	Class Instance	Definition
Ingredient (ING)			<p>A substance that is recognised in Australia as either:</p> <ul style="list-style-type: none"> • A chemical entity that may act as the actual active ingredient of a medicinal product – for example, heparin sodium, perindopril arginine or dexamethasone sodium phosphate; • The Basis of Strength Substance (BOSS) that may or may not be available as the actual ingredient – for example, perindopril or dexamethasone; • The 'clinically significant' portion of an actual ingredient – for example, diclofenac; or • An excipient ingredient of medicinal products.
Proprietary Form (PF)			<p>Forms that are privately owned and controlled by a product sponsor. For example, 'Caplet' or 'Tabsule'.</p>
Form			<p>The Form qualifier describes the dose formulation – for example, tablet, capsule or eye drops.</p>

3.10.3 Relationships

The relationships that 'Trade Product Unit of Use (TPUU)' concepts may participate in, together with their cardinality (C1 to C2/C2 to C1), are listed in Table 20.

Note: C1 refers to the source concept participating in a relationship, and C2 refers to the destination concept participating in the same relationship.

Table 20: 'Trade Product Unit of Use (TPUU)' relationships

Concept 1 (C1)	Relationship Type	Concept 2 (C2)	Cardinality C1 to C2	Cardinality C2 to C1
Trade Product Unit of Use (TPUU)	is a	Trade Product (TP)	1	1..*
Trade Product Unit of Use (TPUU)	is a	Medicinal Product Unit of Use (MPUU)	1	1..*
Trade Product Unit of Use (TPUU)	is a	trade product unit of use (trade product unit of use)	1	1..*
Trade Product Unit of Use (TPUU)	has proprietary dose form (relationship type)	Proprietary Form (PF)	0..1	0..*
Trade Product Unit of Use (TPUU)	has manufactured dose form (relationship type)	Form	1	0..*
Trade Product Pack (TPP)	has TPUU (relationship type)	Trade Product Unit of Use (TPUU)	1..*	1..*
TPUU Pharmaceutical Ingredient (TPUUPI)	has TPUU (relationship type)	Trade Product Unit of Use (TPUU)	1	0..*
TPUU Pharmaceutical Ingredient (TPUUPI)	has ingredient (relationship type)	Ingredient (ING)	1	0..*
Trade Product Unit of Use (TPUU)	has pharmaceutical ingredient (relationship type)	Ingredient (ING)	0..*	0..*

3.10.4 Descriptions

The descriptions, shown on the 'Trade Product Unit of Use (TPUU)' model, are listed in Table 21.

Table 21: 'Trade Product Unit of Use (TPUU)' descriptions

Description Type	Associated Class	Definition	Description Data Type	Cardinality
other identifying information	Trade Product Unit of Use (TPUU)	Additional details that are required to avoid ambiguity in the constructed description – e.g. 'sugar-free', 'preservative free', 'Strawberry' (flavour).		0..1
trade product suffix	Trade Product Unit of Use (TPUU)	The Trade Product Suffix is any extension to a Trade Product name that further defines the commercial product in terms of strength, form or presentation, e.g. for the product name Adalat Oros, 'Adalat' is the Trade Product name and 'Oros' is the Trade Product Suffix.		0..1

3.11 Trade Product Pack (TPP)/Containered Trade Product Pack (CTPP)

3.11.1 Overview

The 'Trade Product Pack (TPP)'/ 'Containered Trade Product Pack (CTPP)' class diagram shows the hierarchical and non-hierarchical relationships that TPP/CTPP concepts may participate in.

The UML class diagram is shown in Figure 12.

Trade Product Pack (TPP)

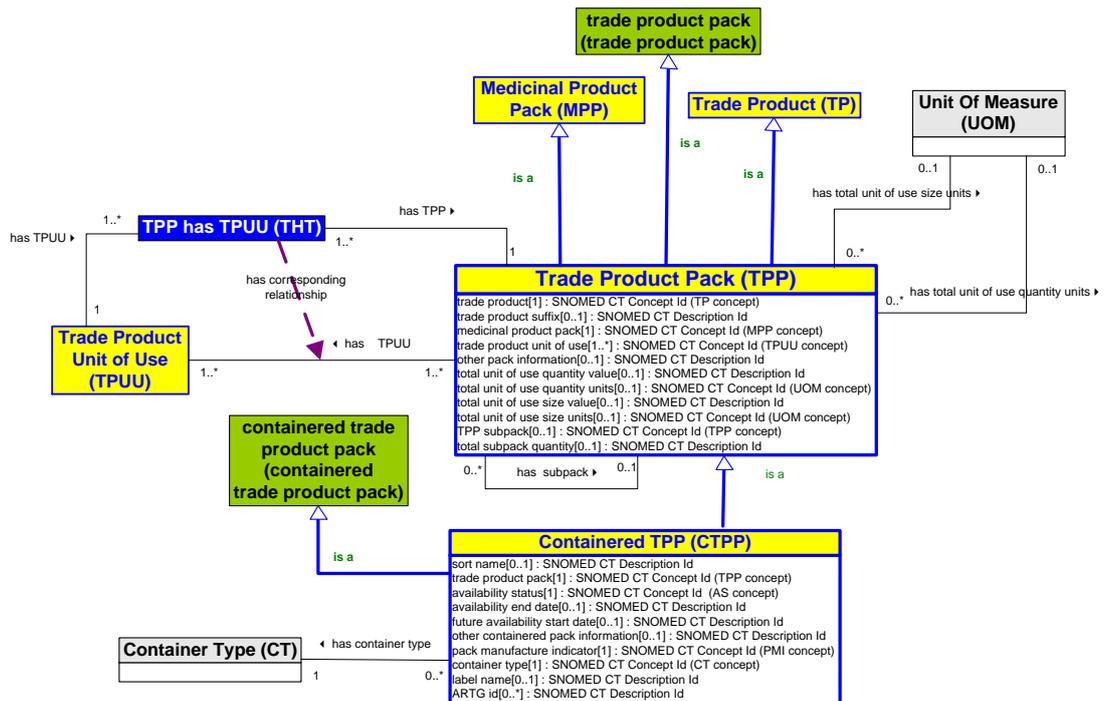


Figure 12: Trade Product Pack (TPP)/Containered Trade Product Pack (CTPP) model

3.11.2 Concepts

The concepts that participate in relationships with 'Trade Product Pack (TPP)'/ 'Containered Trade Product Pack (CTPP)' concepts, together with their associated definitions, are shown in Table 22.

Table 22: 'Trade Product Pack (TPP)'/ 'Containered Trade Product Pack (CTPP)' concepts

Concept class	Grouper concept/ class FSN	Class Instance	Definition
MPP		medicinal product pack e.g. <i>amoxicillin 250 mg capsule, 20</i>	An abstract concept representing the properties of one or more quantitatively and clinically equivalent Trade Product Packs (TPP).

Concept class	Grouped concept/ class FSN	Class Instance	Definition
TP		trade product e.g. <i>Amoxil</i>	The product brand name or the grouping of products into a 'family', for either single component products that contain the same active ingredients or multi-component products, which contain the same combination of active ingredients.
TPUU		trade product unit of use e.g. <i>Amoxil (amoxicillin (as trihydrate) 250 mg) capsule: hard, 1 capsule</i>	A Trade Product Unit of Use (TPUU) is a single dose unit of a finished dose form (unless the product is presented as a continuous dosage form, e.g. liquid or cream) that contains a specified amount of an active ingredient substance and is grouped within a particular Trade Product.
TPP	trade product pack (trade product pack)		This concept is used to group the set of trade product packs within the Australian product hierarchy.
TPP		trade product pack e.g. <i>Amoxil 250 mg capsule: hard, 20 capsules</i>	A Trade Product Pack (TPP) is the packaged product that is supplied for direct patient use, independent of the container.
	containered trade product pack (containered trade product pack)		This concept is used to group the set of containered trade product packs within the Australian product hierarchy.
CTPP		containered trade product pack e.g. <i>Amoxil 250 mg capsule: hard, 20 capsules, blister pack</i>	The packaged product that is supplied for direct patient use and includes details of the product's Container Type.
Container Type (CT)			A Container Type is a type of container that immediately covers a medicinal product. Examples include ampoule, bottle, blister pack, vial etc.

Concept class	Grouped concept/ class FSN	Class Instance	Definition
TPP has TPUU (THT)			A concept representing the relationship between a specific Trade Product Unit of Use and a Trade Product Pack that contains it. This concept is used to record the quantity and size of the MPUU within the MPP.
Unit of Measure (UOM)			The units used to measure various quantities within the AMT.

3.11.3 Relationships

The relationships that TPP/CTPP concepts may participate in, together with their cardinality (C1 to C2/C2 to C1), are listed in Table 23.

Note: C1 refers to the source concept participating in a relationship, and C2 refers to the destination concept participating in the same relationship.

Table 23: 'Trade Product Pack (TPP)'/ 'Containered Trade Product Pack (CTPP)' relationships

Concept 1 (C1)	Relationship Type	Concept 2 (C2)	Cardinality C1 to C2	Cardinality C2 to C1
Trade Product Pack (TPP)	is a	Medicinal Product Pack (MPP)	1	1..*
Trade Product Pack (TPP)	is a	trade product pack (trade product pack)	1	1..*
Trade Product Pack (TPP)	is a	Trade Product (TP)	1	1..*
Trade Product Pack (TPP)	has TPUU (relationship type)	Trade Product Unit of Use (TPUU)	1..*	1..*
Trade Product Pack (TPP)	has total unit of use size units (relationship type)	Unit of Measure(UOM)	0..1	0..*
Trade Product Pack (TPP)	has total unit of use quantity units (relationship type)	Unit of Measure(UOM)	0..1	0..*
Trade Product Pack (TPP)	has subpack (relationship type)	Trade Product Pack (TPP)	0..1	0..*
Containered TPP (CTPP)	is a	Trade Product Pack (TPP)	1	1..*

Concept 1 (C1)	Relationship Type	Concept 2 (C2)	Cardinality C1 to C2	Cardinality C2 to C1
Containeder TPP (CTPP)	is a	containeder trade product pack (containeder trade product pack)	1	1..*
Containeder TPP (CTPP)	has container type (relationship type)	Container Type (CT)	1	0..*
TPP has TPUU (THT)	has TPP (relationship type)	Trade Product Pack (TPP)	1	1..*
TPP has TPUU (THT)	has TPUU (relationship type)	Trade Product Unit of Use (TPUU)	1	1..*

3.11.4 Descriptions

The descriptions, shown on the TPP/CTPP model, are listed in Table 24.

Table 24: 'Trade Product Pack (TPP)'/ 'Containeder Trade Product Pack (CTPP)' descriptions

Description Type	Associated Class	Definition	Data Type	Cardinality
ARTG id	Containeder TPP (CTPP)	The associated identifier(s) from the Australian Register of Therapeutic Goods data.		0..*
availability end date ⁵	Containeder TPP (CTPP)	The date indicating the final date that the CTPP is available from the sponsor.		0..1
future availability start date ⁶	Containeder TPP (CTPP)	The date indicating when a CTPP will become available from its sponsor.		0..1
label name ⁷	Containeder TPP (CTPP)	The name of the product, as sourced from the National Product Catalogue (NPC).		0..1
other containeder pack information	Containeder TPP (CTPP)	Additional information about the CTPP to assist in further identifying the pack.		0..1

⁵ Although this description is included in the AMT v2 model, it has not been implemented.

⁶ Although this description is included in the AMT v2 model, it has not been implemented.

⁷ Although this description is included in the AMT v2 model, it has not been implemented.

Description Type	Associated Class	Definition	Data Type	Cardinality
sort name ⁸	Contained TPP (CTPP)	The name created to allow products to be correctly sorted alphabetically.		0..1
other pack information	Trade Product Pack (TPP)	Additional pack details that are required to avoid ambiguity in the constructed FSN and PT – e.g. 'sugar-free', 'preservative free', 'strawberry' (flavour).		0..1
total subpack quantity	Trade Product Pack (TPP)	The total number of subpacks within the TPP.		0..1
total unit of use quantity value	Trade Product Pack (TPP)	The numeric value associated with the total quantity of TPUUs in the TPP.		0..1
total unit of use size value	Trade Product Pack (TPP)	The numeric value associated with the smallest measurable amount of the product that is considered to be a unit for administration. This description is only used (where appropriate) for TPPs that contain only one type of MPUU.		0..1
trade product suffix	Trade Product Pack (TPP)	Any extension to a Trade Product name that further defines the product in terms of strength, form or presentation, e.g. for the product name 'Adalat Oros', 'Adalat' is the Trade Product name and 'Oros' is the Trade Product Suffix. This suffix will be sourced from the TGA ARTG Label Name.		0..1

⁸ Although this description is included in the AMT v2 model, it has not been implemented.

3.12 TPUU/TPP Relationship Details

3.12.1 Overview

The 'TPUU/TPP Relationship Details' class diagram shows the relationship details that are recorded for TPPs and TPUUs. In particular, this model shows:

- Quantity and size details recorded about the 'TPP has TPUU' relationship; and
- Strength, BOSS and biotech descriptor details recorded about the 'TPUU has pharmaceutical ingredient' relationship.

The UML class diagram for 'TPUU/TPP Relationship Details' is shown in Figure 13.

TPUU/TPP Relationship Details

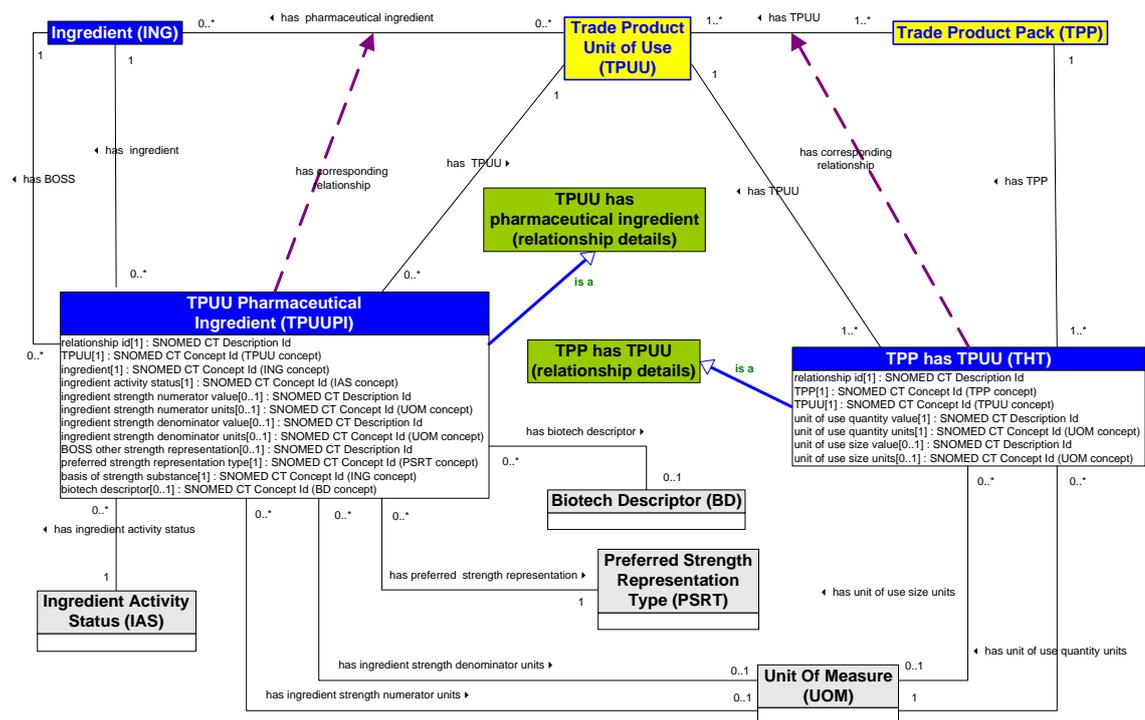


Figure 13: 'TPUU/TPP Relationship Details' model

3.12.2 Concepts

The concepts that participate in relationships with 'TPUU Pharmaceutical Ingredient (TPUUPI)' concepts and 'TPP has TPUU (THT)' concepts, together with their associated definitions, are shown in Table 25.

Table 25: 'TPUU/TPP Relationship Details' concepts

Fully Specified Name	Grouping concept/ class FSN	Class Instance	Definition
TPUU		trade product unit of use e.g. <i>Amoxil (amoxicillin (as trihydrate) 250 mg) capsule: hard, 1 capsule</i>	A Trade Product Unit of Use (TPUU) is a single dose unit of a finished dose form (unless the product is presented as a continuous dosage form, e.g. liquid or cream) that contains a specified amount of an active ingredient substance and is grouped within a particular Trade Product.
TPP		trade product pack e.g. <i>Amoxil 250 mg capsule: hard, 20 capsules</i>	A Trade Product Pack (TPP) is the packaged product that is supplied for direct patient use, independent of the container.
TPUU Pharmaceutical Ingredient (TPUUPI)			These 'relationship details' concepts record the strength, BOSS and biotech descriptor of each pharmaceutical ingredient contained in each TPUU.
TPP has TPUU (THT)			A concept representing the relationship between a specific Trade Product Unit of Use and a Trade Product Pack that it is contained in. This concept is used to record the quantity and size of the MPUU within the MPP.

Fully Specified Name	Grouped concept/ class FSN	Class Instance	Definition
Ingredient (ING)			<p>A substance that is recognised in Australia as either:</p> <ul style="list-style-type: none"> • A chemical entity that may act as the actual active ingredient of a medicinal product – for example, heparin sodium, perindopril arginine or dexamethasone sodium phosphate; • The Basis of Strength Substance (BOSS) that may or may not be available as the actual ingredient – for example, perindopril or dexamethasone; • The ‘clinically significant’ portion of an actual ingredient – for example, diclofenac; or • An excipient ingredient of medicinal products.
TPUU has pharmaceutical ingredient (relationship details)			<p>This concept is used to group the set of ‘TPUU has pharmaceutical ingredient’ concepts in the relationship details hierarchy.</p>
TPUU has TPP (relationship details)			<p>This concept is used to group the set of ‘TPP has TPUU’ concepts in the relationship details hierarchy.</p>
Ingredient Activity Status (IAS)			<p>This qualifier concept indicates if an ingredient is an active ingredient or excipient. At this stage Herbal and Proprietary Ingredients are not included. Valid values are:</p> <ul style="list-style-type: none"> • active • excipient

Fully Specified Name	Grouping concept/ class FSN	Class Instance	Definition
Biotech Descriptor (BD)			<p>Biotech Descriptors represent a product derived from a genetically engineered cell line which has been developed in order to express a therapeutically recombinant protein.</p> <p>Note: Released BD data has not been fully maintained, and so may not be suitable for production use. Contact the NCTIS for guidance.</p>
Preferred Strength Representation Type (PSRT)			<p>Preferred Strength Representation Type defines the order and combination of strength representations to include in the preferred term of the association medicinal products. Valid values include:</p> <ul style="list-style-type: none"> • alternate strength followed by numerator/denominator strength • alternate strength only • numerator/denominator strength • numerator/denominator strength followed by alternate strength.
Unit of Measure (UOM)			<p>The units used to measure various quantities within the AMT.</p>

3.12.3 Relationships

The relationships that 'TPUU Pharmaceutical Ingredient (TPUUPI)' concepts and 'TPP has TPUU (THT)' concepts may participate in, together with their cardinality (C1 to C2/C2 to C1), are listed in Table 26.

Note: C1 refers to the source concept participating in a relationship, and C2 refers to the destination concept participating in the same relationship.

Table 26: 'TPUU/TPP Relationship Details' relationships

Concept 1 (C1)	Relationship Type	Concept 2 (C2)	Cardinality C1 to C2	Cardinality C2 to C1
TPUU Pharmaceutical Ingredient (TPUUPI)	is a	TPUU has pharmaceutical ingredient (relationship details)	1	1..*
TPUU Pharmaceutical Ingredient (TPUUPI)	has BOSS (relationship type)	Ingredient (ING)	1	0..*
TPUU Pharmaceutical Ingredient (TPUUPI)	has ingredient (relationship type)	Ingredient (ING)	1	0..*
TPUU Pharmaceutical Ingredient (TPUUPI)	has TPUU (relationship type)	Trade Product Unit of Use (TPUU)	1	0..*
TPUU Pharmaceutical Ingredient (TPUUPI)	has biotech descriptor (relationship type)	Biotech Descriptor (BD)	0..1	0..*
TPUU Pharmaceutical Ingredient (TPUUPI)	has preferred strength representation (relationship type)	Preferred Strength Representation Type (PSRT)	1	0..*
TPUU Pharmaceutical Ingredient (TPUUPI)	has ingredient strength denominator units (relationship type)	Unit of Measure (UOM)	0..1	0..*
TPUU Pharmaceutical Ingredient (TPUUPI)	has ingredient strength numerator units (relationship type)	Unit of Measure (UOM)	0..1	0..*
TPUU Pharmaceutical Ingredient (TPUUPI)	has ingredient activity status (relationship type)	Ingredient Activity Status (IAS)	1	0..*

Concept 1 (C1)	Relationship Type	Concept 2 (C2)	Cardinality C1 to C2	Cardinality C2 to C1
Trade Product Unit of Use (TPUU)	has pharmaceutical ingredient (relationship type)	Ingredient (ING)	0..*	0..*
TPP has TPUU (THT)	has TPUU (relationship type)	Trade Product Unit of Use (TPUU)	1	1..*
Trade Product Pack (TPP)	has TPUU (relationship type)	Trade Product Unit of Use (TPUU)	1..*	1..*
TPP has TPUU (THT)	has TPP (relationship type)	Trade Product Pack (TPP)	1	1..*
TPP has TPUU (THT)	is a	TPP has TPUU (relationship details)	1	1..*
TPP has TPUU (THT)	has unit of use size units (relationship type)	Unit of Measure (UOM)	1	0..*
TPP has TPUU (THT)	has unit of use quantity units (relationship type)	Unit of Measure (UOM)	1	0..*

3.12.4 Descriptions

The descriptions, shown on the 'TPUU/TPP Relationship Details' model, are listed in Table 27.

Table 27: 'TPUU/TPP Relationship Details' descriptions

Description Type	Associated Class	Definition	Data Type	Cardinality
relationship id	TPUU Pharmaceutical Ingredient (TPUUPI)	The SNOMED CT identifier of the 'TPUU has pharmaceutical ingredient' relationship that the relationship details concept refers to.	ID (SCTID)	1
ingredient strength numerator value	TPUU Pharmaceutical Ingredient (TPUUPI)	The numeric value of the numerator of the ingredient's strength.	1234	0..1
ingredient strength denominator value	TPUU Pharmaceutical Ingredient (TPUUPI)	The numeric value of the denominator of the ingredient's strength.	1234	0..1

Description Type	Associated Class	Definition	Data Type	Cardinality
BOSS other strength representation	TPUU Pharmaceutical Ingredient (TPUUPI)	The preferred strength representation format of the ingredient's BOSS strength.	ABC B	0..1
relationship id	TPP has TPUU (THT)	The SNOMED CT identifier of the 'TPP has TPUU' relationship that the relationship details concept refers to.	ID (SCTID)	1
unit of use quantity value	TPP has TPUU (THT)	The numeric value of the quantity of the given TPUU contained in the given TPP.	1234	1
unit of use size value	TPP has TPUU (THT)	The numeric value of the size of the given TPUU in the given TPP. This description is only used when the TPP contains only one type of TPUU.	1234	0..1

3.13 Substance Concepts

3.13.1 Overview

The 'Substance' class diagram shows the hierarchical and non-hierarchical relationships that Substance concepts may participate in.

The UML class diagram for 'Substance' is shown in Figure 14.

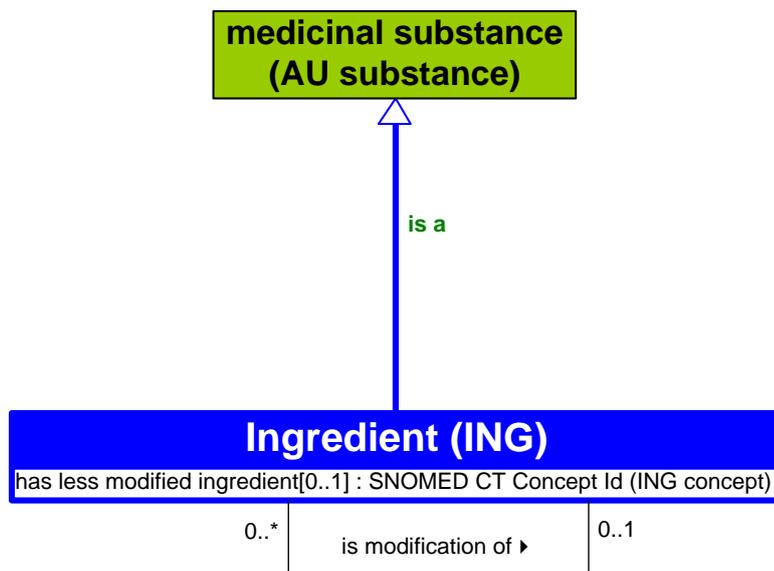


Figure 14: 'Substance Concepts' model

3.13.2 Concepts

The concepts that participate in relationships with 'Substance' concepts, together with their associated definitions, are shown in Table 28.

Note: The term 'Ingredient' is deprecated and has been replaced by 'Substance'.

Table 28: 'Substance' concepts

Concept class	Grouped concept/ class FSN	Class Instance	Definition
Ingredient (ING)			<p>A substance that is recognised in Australia as either:</p> <ul style="list-style-type: none"> • A chemical entity that may act as the actual active ingredient of a medicinal product – for example, heparin sodium, perindopril arginine or dexamethasone sodium phosphate; • The Basis of Strength Substance (BOSS) that may or may not be available as the actual ingredient – for example, perindopril or dexamethasone; • The 'clinically significant' portion of an actual ingredient – for example, diclofenac; or • An excipient ingredient of medicinal products.
medicinal substance (AU substance)			This concept groups the set of medicinal substances within the Australian substance hierarchy.

3.13.3 Relationships

The relationships that 'Substance' concepts may participate in, together with their cardinality (C1 to C2/C2 to C1), are listed in Table 29.

Note: C1 refers to the source concept participating in a relationship, and C2 refers to the destination concept participating in the same relationship.

Table 29: 'Substance' relationships

Concept 1 (C1)	Relationship Type	Concept 2 (C2)	Cardinality C1 to C2	Cardinality C2 to C1
Ingredient (ING)	is a	medicinal substance (AU substance)	1	1..*
Ingredient (ING)	is modification of (relationship type)	Ingredient (ING)	0..1	0..*

4 Release

4.1 Distribution format

Data associated with a release are provided in three UTF-8 encoded, tab-delimited text files.

4.1.1 Concepts table

The file is structured similarly to the Concepts file (RF1 format) as distributed in the SNOMED CT International Release, details of which can be found in the *SNOMED CT Technical Implementation Guide* [STIG2012]. There are some additional fields that NCTIS is providing in conjunction with Australian-developed content. Additional fields are shown in dark red and italics.

Field number	Column Tag	Content
1	CONCEPTID	SNOMED CT identifier##
2	CONCEPTSTATUS	integer(enum) – see SNOMED CT Technical Reference Guide
3	FULLYSPECIFIEDNAME	string – see ++
4	CTV3ID	string
5	SNOMEDID	string
6	ISPRIMITIVE	boolean – see SNOMED CT Technical Reference Guide
7	<i>CONCEPTUUID</i>	<i>UUID – see **</i>
8	<i>CONCEPTSTATUSUUID</i>	<i>UUID – see **</i>
9	<i>EFFECTIVETIME</i>	<i>datetime [YYYY-MM-DD-HH:MM:SS]^ ^</i>

Notes:

##	64-bit integer. This identifier should be used for the storing and sending of AMT concepts.
++	The max length of this field is 32,000 characters and may include XHTML
**	A UUID consists of 32 hexadecimal digits, displayed in 5 groups separated by hyphens, for a total of 36 characters.
^^	The EFFECTIVETIME field is currently defaulted to 28 of September 2007.

4.1.2 Descriptions table

This file is structured similarly to the Descriptions file (RF1 format) as distributed in the SNOMED CT International Release, details of which can be found in the *SNOMED CT Technical Implementation Guide* [STIG2012]. There are some additional fields that NEHTA are providing in conjunction with Australian-developed content. Additional fields are shown in dark red and italics.

Field number	Column Tag	Content
1	DESCRIPTIONID	SNOMED CT identifier##
2	DESCRIPTIONSTATUS	integer(enum) – see SNOMED CT Technical Reference Guide
3	CONCEPTID	SNOMED CT identifier##
4	TERM	string – see ++
5	INITIALCAPITALSTATUS	boolean – see SNOMED CT Technical Reference Guide
6	DESCRIPTIONTYPE	integer(enum) – see SNOMED CT Technical Reference Guide
7	LANGUAGECODE	string
8	<i>DESCRIPTIONUUID</i>	<i>UUID – see **</i>
9	<i>DESCRIPTIONSTATUSUUID</i>	<i>UUID – see **</i>
10	<i>CONCEPTUUID</i>	<i>UUID – see **</i>
11	<i>DESCTIPTIONTYPEUUID</i>	<i>UUID – see **</i>
12	<i>CASESENSITIVITY</i>	<i>boolean</i>
13	<i>LANGUAGECODEUUID</i>	<i>UUID – see **</i>
14	<i>EFFECTIVETIME</i>	<i>datetime [YYYY-MM-DD-HH:MM:SS]^ ^</i>

Notes:

##	64-bit integer. This identifier should be used for the storing and sending of AMT concepts.
++	The max length of this field is 32,000 characters and may include XHTML
^^	The EFFECTIVETIME field is currently defaulted to 28 of September 2007.
**	A UUID consists of 32 hexadecimal digits, displayed in 5 groups separated by hyphens, for a total of 36 characters.

4.1.3 Relationships table

This file is structured similarly to the Relationships file (RF1 format) as distributed in the SNOMED CT International Release, details of which can be found in the *SNOMED CT Technical Implementation Guide* [STIG2012]. There are some additional fields that NEHTA are providing in conjunction with Australian developed content. Additional fields are shown in dark red and italics.

Field number	Column Tag	Content
1	RELATIONSHIPID	SNOMED CT Identifier##
2	CONCEPTID1	SNOMED CT Identifier##
3	RELATIONSHIPTYPE	SNOMED CT Identifier##
4	CONCEPTID2	SNOMED CT Identifier##
5	CHARACTERISTICTYPE	integer(enum) – see SNOMED CT Technical Reference Guide
6	REFINABILITY	integer(enum) – see SNOMED CT Technical Reference Guide
7	RELATIONSHIPGROUP	Integer – see SNOMED CT Technical Reference Guide
8	<i>RELATIONSHIPUUID</i>	<i>UUID – see **</i>
9	<i>CONCEPTUUID1</i>	<i>UUID – see **</i>
10	<i>RELATIONSHIPTYPEUUID</i>	<i>UUID – see **</i>
11	<i>CONCEPTUUID2</i>	<i>UUID – see **</i>
12	<i>CHARACTERISTICTYPEUUID</i>	<i>UUID – see **</i>
13	<i>REFINABILITYUUID</i>	<i>UUID – see **</i>
14	<i>RELATIONSHIPSTATUSUUID</i>	<i>UUID – see **</i>
15	<i>EFFECTIVETIME</i>	<i>datetime [YYYY-MM-DD-HH:MM:SS]^ ^</i>

Note:

##	64-bit integer. This identifier should be used for the storing and sending of AMT concepts.
^ ^	The EFFECTIVETIME field is currently defaulted to 28 of September 2007.
**	A UUID consists of 32 hexadecimal digits, displayed in 5 groups separated by hyphens, for a total of 36 characters.

4.2 Reference sets

Reference sets are a mechanism used to identify a subset of content from a source dataset, in this case AMT. These are a part the SNOMED CT Release Format 2 (RF2) specifications.

Each reference set file has a header row containing field names for each of the columns. The names of the standard fields are the field names as detailed in the *SNOMED CT Technical Implementation Guide* [STIG2012].

The additional fields are named 'Attribute 1', 'Attribute 2', 'Attribute 3', etc. Alternatively, where only one Reference Set is released in a file, the additional fields may also be given names matching those provided in the Reference Set's Descriptor.

4.2.1 Attribute value

These files provide a simple mechanism to identify and implement AMT components of each of the seven notable classes.

Attribute value reference sets have the following fields.⁹

Field	Data type	Purpose
id	UUID	A 128 bit unsigned integer, uniquely identifying the reference set member.
effectiveTime	Time	Specifies the inclusive date at which this change becomes effective.
active	Boolean	Specifies whether the member's state was active or inactive from the nominal release date specified by the effectiveTime field.
moduleId	SctId	Identifies the member version's module. Set to a child of Module within the metadata hierarchy.
refSetId	SctId	Set to a child of Attribute value type in the metadata hierarchy.
referencedComponentId	SctId	A reference to the AMT component being tagged with a value.
valueId	SctId	Set to a grandchild of Attribute value .

⁹ For further information, see the reference set specifications included in the *SNOMED CT Technical Implementation Guide* [STIG2012].

5 Extracting information

5.1 Strength detail

When extracting atomic strength details from the v2 release files, a Basis of strength substance (BoSS) representing a base ingredient must have an associated base strength. A BoSS representing a salt ingredient must have an associated salt strength.

The following guidance should be used, which uses the BoSS relationship to determine the correct strength details to be displayed.

1. Filter relationshipStatusUUID field for only relationships that have active statuses i.e.
 - i) 2faa9261-8fb2-11db-b606-0800200c9a66 (current)
 - ii) 854552b2-74b7-3f68-81fc-3211950d2ba9 (unreviewed)
2. Using the MPUU, find the source concept of the following relationship, which will be the MPUUSAI i.e. in the relationship file
 - i) conceptId1 = MPUUSAI
 - ii) relationshipType = 'has MPUU' (30348011000036104)
 - iii) conceptId2 = MPUU
3. If multiple source concepts are found i.e. multiple MPUUSAI per MPUU, retain only the MPUUSAI concepts that have a 'has Australian BOSS' relationship i.e. the existence of the following in the relationship file
 - i) conceptId1 = MPUUSAI
 - ii) relationshipType = 'has Australian BOSS' (30364011000036101)
 - iii) conceptId2 = Substance
4. The conceptId2 from the previous step represents a Substance (BoSS) concept.

We now need to determine if the Substance is a base or salt.

If the following relationship exists, then the Substance (BoSS) is a salt; if not, it is a base:

- conceptId1 = Substance
 - relationshipType = 'is modification of' (30394011000036104)
 - conceptId2 = Substance
- a. If Substance (BoSS) is found to be a salt, salt strength should be displayed with the following components:
 - salt form strength numerator value (mandatory)
 - target of 'has salt form strength numerator units' relationship (mandatory)

You have a choice of using plural units or singular units here¹⁰

 - salt form strength denominator value (optional)

¹⁰ Refer to *AMT Editorial rules (v2 model)* [AMT2011].

- target of 'has salt form strength denominator units' relationship (optional)
You have a choice of using plural units or singular units here ¹¹
 - salt form strength other representation (optional)¹²
- b. If Substance (BoSS) is found to be a base, base strength should be displayed with the following components:
- base form strength numerator value (mandatory)
 - target of 'has base form strength numerator units' relationship (mandatory)
You have a choice of using plural units or singular units here ¹³
 - base form strength denominator value (optional)
 - target of 'has base form strength denominator units' relationship (optional)
You have a choice of using plural units or singular units here ¹⁴
 - base form strength other representation (optional)¹⁵

5.2 Extracting active relationships

The following is guidance on how to extract AMT v2 relationships with an active status.

- In the relationship file, filter RelationshipStatusUUID field for rows that have an active status i.e. those with the following values:
 - 2faa9261-8fb2-11db-b606-0800200c9a66 (current)
 - 854552b2-74b7-3f68-81fc-3211950d2ba9 (unreviewed)
- Using the information in Section 3, determine which type of relationship is of interest in the relationship file:
 - Source concept (ConceptID1 field)
 - Destination concept (ConceptID2 field)
 - Relationship type (RelationshipType field)
- For example, if the object of interest is the Form concept at the Trade Product Unit of Use level then the TPUU HAS MANUFACTURED DOSE FORM relationship should be used.
 - Source concept (ConceptID1 field) is a Trade Product Unit of Use (TPUU) concept.
 - Destination concept (ConceptID2 field) is a Form (qualifier) concept.
 - Relationship type (RelationshipType field) is the 'HAS MANUFACTURED DOSE FORM' relationship type.
- To determine the source concept (ConceptID1 field):
 - Find all children concepts (instances) of the parent TPUU concept |30425011000036101 trade product unit of use| by
 - Joining the relationship and description files, with ConceptID1 (relationship file) = ConceptID (description file).

¹¹ Refer to *AMT Editorial rules (v2 model)* [AMT2011].

¹² Refer to *AMT Editorial rules (v2 model)* [AMT2011].

¹³ Refer to *AMT Editorial rules (v2 model)* [AMT2011].

¹⁴ Refer to *AMT Editorial rules (v2 model)* [AMT2011].

¹⁵ Refer to *AMT Editorial rules (v2 model)* [AMT2011].

- Find all concepts (ConceptID) containing the string '%(trade product unit of use)' in the Term field, in the description file.
- Next, determine the Relationship type (RelationshipType field):
 - In the relationship file, filter rows with the value of '30523011000036108', which is the concept identifier for the 'HAS MANUFACTURED DOSE FORM' relationship type.
- The resulting destination concepts (ConceptID2 field) participating in these relationships should be Form concepts:
 - To extract the human readable Preferred Term descriptions of the Form concepts with an active status (which is suitable for implementation)
 - Join the relationship and description files, with ConceptID2 (relationship file) = ConceptID (description file).
 - Filter rows with DescriptionStatus field value of '0' (current).
 - Implement the Term field for all resulting concepts (ConceptID), in the description file. The ConceptID field should be retained as the primary identifier of the concept and the Term field as the string.

5.3 Extracting specific AMT description types and relationship types

- To determine the concept identifiers for specific AMT description types and relationship types, search for these concepts in the AMT Viewer:
 - AMT description types:
 - Note the SNOMED CT UUID identifier for the description type concept e.g. '16a28981-61ab-300d-b2aa-e0e3dc0f872a' for the 'trade product suffix' description type concept.
 - In the description file, find this value in the DescriptionTypeUUID field.
 - The resulting rows reflect descriptions of the trade product suffix description type.
 - Filter for all active descriptions.
 - AMT relationship types:
 - Note the SNOMED CT integer ID for the relationship type concept e.g. '30465011000036106' for the HAS CONTAINER TYPE relationship type concept.
 - In the relationship file, find this value in the RelationshipType field.
 - The resulting rows reflect relationships of the HAS CONTAINER TYPE relationship type.
 - Filter for all active relationships.

6 AMT maintenance

6.1 Between releases

- A comparison of the most recent AMT release files with the previous release files.
- Any additions and changes are appended/updated in the implemented data.

6.2 History mapping reference set

The AMT now makes use of SNOMED CT status guidelines for concepts, their associated descriptions, and relationships. This means that the AMT release files now contain inactive components. To assist with this change there is an additional text file that describes these changes in status, provided in a machine-readable format. The file currently does not conform to SNOMED CT reference set specifications, but does use elements of what will be delivered as a reference set in future releases.

Releases of the concept file now contain rows with a status of '5 (Erroneous)'; in future releases this may also include other statuses. The description file also contains rows with a status of '8 (concept Retired)'. The additional text file supplied will contain information that will inform the user as to which concepts should now 'replace' these inactive concepts.

Note: Strictly speaking, concepts are not directly replaced, so much as retired and then substituted with new ones. That is, the referencedComponentID is retired, and substituted by the targetComponentID.

The fields present in this file will be as follows.

Field	Field Type	Description
refSetID	SNOMED CT Identifier##	Concept ID for the description of the change that has been made. It will be equivalent to REPLACED BY. ¹⁶
referencedComponentID	SNOMED CT Identifier##	ID for concept that has been retired.
targetComponentID	SNOMED CT Identifier##	ID for what the changed concept now is. For example, if a concept has been retired as a result of being erroneous, then this will be the concept ID for the concept that has 'replaced' it.

Note:

##	64-bit integer. This identifier should be used for the storing and sending of AMT concepts.
----	---

¹⁶ Other historical associations exist in SNOMED CT. See the RF2 specifications in the *SNOMED CT Technical Implementation Guide* [STIG2012] for details.

To utilise this file:

1. Extract the referencedComponentId field.
2. Compare referencedComponentId field with Id field as implemented for concepts in the system.
 - a. If no corresponding concepts are found in the implementation, the process stops at this step.
 - b. If corresponding concepts are found in the implementation, continue to the next step.
3. Extract the targetComponentId field.
4. Two options exist should a user find a retired concept with a replacement. The chosen approach is based on a user's requirements for the implementation:
 - a. Any retired concepts (as specified in the referencedComponentId field) are removed completely from use in the implementation. The associated concepts (as specified in the targetComponentId field) replace the removed concepts and become of active use.
 - b. Any retired concepts (as specified in the referencedComponentId field) are reflected as inactive for use in the implementation. The associated concepts (as specified in the targetComponentId field) are added as additional concepts and become of active use.
5. When a retired concept with a replacement is processed, its associated descriptions and relationships must also be processed if they have changed.

7 References

- [AMT2008] National E-Health Transition Authority, *Australian Medicines Terminology UML Class Diagrams*, v7.0, 05 March 2008, NEHTA, Sydney. Available from: https://nehta.org.au/aht/index.php?option=com_docman&task=catt_view&gid=21&Itemid=40
- [AMT2011] National E-Health Transition Authority, *Australian Medicines Terminology Editorial Rules (v2 model)*, 23 December 2011, NEHTA, Sydney. Available from: https://nehta.org.au/aht/index.php?option=com_docman&task=catt_view&gid=21&Itemid=40
- [AMT2012] National E-Health Transition Authority, *Australian Medicines Terminology v2 to v3 Migration Guide*, 29 February 2012, NEHTA, Sydney. Available from: https://nehta.org.au/aht/index.php?option=com_docman&task=catt_view&gid=21&Itemid=40
- [STIG2012] International Health Terminology Standards Development Organisation, *SNOMED CT Technical Implementation Guide*, January 2012, IHTSDO, Copenhagen. Available from: www.snomed.org/doc
- [SUG2012] International Health Terminology Standards Development Organisation, *SNOMED CT User Guide*, January 2012, IHTSDO, Copenhagen. Available from: www.snomed.org/doc

Appendix A: AMT components

A.1 Component

A.1.1 Definition

A component is anything in AMT that can be identified by an SNOMED CT Id and a UUID. Each component is a uniquely identifiable instance of one of the following component types:

- Concept
- Description
- Relationship
- Reference Set
- Reference Set Member

A.1.2 Attributes

The attributes of the Component class are listed in Table 30, together with their definitions, data types and cardinalities.

Table 30: Attributes of the Component Class

Name	Definition	Data Type	Cardinality
ComponentUUID	The 'Universally Unique Identifier' (UUID) that is used to identify each Component.	ID (UUID)	1
ComponentID	A unique SNOMED CT identifier (SCTID) that is used to identify each Component. ComponentIDs include ConceptIDs, DescriptionIDs, RelationshipIDs, ReferenceSetIDs, ReferenceSetMemberIDs and IDMappingIDs.	ID (SCTID)	1
ComponentStatusUID	A concept that represents the status of the component – that is, whether or not the component is in active use and, if not, indicates the reason for its withdrawal from current use.	ID (UUID)	1

Name	Definition	Data Type	Cardinality
ComponentStatus	An enumerated value that indicates the status of the component – that is, whether the component is in active use and, if not, the reason for its withdrawal from current use.	 (enumeration)	1
EffectiveTime ¹⁷	The time (UTC) at which the component representation becomes effective. Once effective, the component representation remains valid until it is superseded.		1

A.1.3 Data rules

The data rules for the Component Class are outlined in Table 31.

Table 31: Data Rules for the Component Class

Data Element	Constraints/Data Definition
ComponentUUID	All Components must have exactly one ComponentUUID.
ComponentUUID	All ComponentUUIDs must be unique.
ComponentID	All Components must have exactly one ComponentID (i.e. SNOMED CT id).
ComponentID	All ComponentIDs must be unique.
ComponentID	Each ComponentID is a SNOMED CT identifier (SCTID) that complies with the SNOMED data type format. The permitted characters for a SCTID are the digits 0-9. The minimum permitted length is 6 digits; the maximum length is 18 digits. The ComponentID is either an international release SCTID or an Australian extension SCTID. It includes a partition-identifier that indicates the type of component being identified. Australian extension SCTIDs include the namespace identifier '1000036'.
ComponentStatusUUID	Each ComponentStatusUUID must be a ComponentUUID that identifies some concept in the ' <i>Australian concept ← Australian data representation concept ← Australian status type</i> ' hierarchy.

¹⁷ Due to technical limitations AMT data has never populated this EFFECTIVETIME field, leaving it set to 28 September 2007.

Data Element	Constraints/Data Definition
<p>ComponentStatus</p>	<p>The valid values for ComponentStatus are:</p> <ul style="list-style-type: none"> 0 (Current): The component is in current use and is considered active. 1 (Retired): The component has been withdrawn without a specified reason. 2 (Duplicate): The component has been withdrawn from current use because it duplicates another component of the same type. 3 (Outdated): The component has been withdrawn from current use because it is no longer recognized as valid, or is no longer in general clinical use. 4 (Ambiguous): The component has been withdrawn from current use because it is inherently ambiguous. This status can only be used for concept components. 5 (Erroneous): The component has been withdrawn from current use as it contains an error. 6 (Limited): The component is of limited clinical value. Components with this status are still valid for current use. 7 (Inappropriate): The (description) component has been withdrawn as it should not refer to the associated concept. This status applies only to description components. 8 (Concept retired): The (description) component is valid for the associated concept, but the concept has been made non-current (i.e. the associated concept has ComponentStatus 1, 2, 3, 4, 5 or 10) 10 (Moved elsewhere): The component has been moved to an extension, to a different extension, or to the international release. If the component is a concept, a 'moved to' relationship should be used to locate the namespace to which the concept has been moved. If the component is of any other type, a reference will indicate the namespace to which the component has been moved. 11 (Pending Move): The component will be moved to an extension, to a different extension, or to the international release. <p>Note that components with a ComponentStatus of 0, 6, 8 or 11 are considered to be active, while those with a ComponentStatus of 1, 2, 3, 4, 5, 7 or 10 are considered to be inactive.</p>
<p>EffectiveTime</p>	<p>The EffectiveTime date/time should be represented using ISO 8601 conventions, with no punctuation, and no letter 'T' between date and time, with a granularity up to the level of seconds.</p>

A.2 Concept

A.2.1 Definition

A concept is a clinical meaning that is identified by a unique identifier, and represented by a unique human readable Fully Specified Name (FSN).

Concepts can be formally defined in terms of their relationships with other concepts. These 'logical definitions' give explicit meaning which a computer can process and query on.

Every concept also has a set of terms that name the concept in a human-readable way.

A.2.2 Attributes

The attributes of the Concept class, together with their definitions, data types and cardinalities, is listed in Table 4. Note that Concepts also share (by inheritance) those attributes of the Component class – e.g. all concepts have a ComponentUUID.

Table 32: Attributes of the Concept Class

Name	Definition	Data Type	Cardinality
FullySpecifiedName	<p>A phrase that describes the concept uniquely and in a manner that is intended to be unambiguous. Typically, the Fully Specified Name will not be a term that would be used in a clinical record. Instead, it may be stylized to ensure that it has a single, unambiguous meaning.</p> <p>Each Fully Specified Name (FSN) contains a suffix (called the 'semantic tag') that indicates the primary AMT hierarchy that the term's concept belongs to.</p> <p>Every FSN term that is used to populate this attribute must also exist as a description component.</p>		1
CTV3ID	Blank field – not used.		0..1
SNOMEDID	Blank field – not used.		0..1

Name	Definition	Data Type	Cardinality
IsPrimitive	<p>This attribute indicates whether a concept is primitive or fully defined by its defining relationships. A concept may be primitive because:</p> <ul style="list-style-type: none"> its only stated defining characteristics are IS A relationships; or an aspect of its meaning is not fully expressed by existing relationships. <p>If a concept is primitive it cannot be checked for equivalence with another concept expression or post-coordinated expression.</p>		1

A.2.3 Data rules

The data rules for the Concept class is listed in Table 33.

Table 33: Data Rules for the Concept Class

Data Element	Constraints/Data Definition
ComponentStatus	<p>The valid values for the ComponentStatus of a concept are:</p> <ul style="list-style-type: none"> 0 (Current) 1 (Retired) 2 (Duplicate) 3 (Outdated) 4 (Ambiguous) 5 (Erroneous) 6 (Limited) 10 (Moved elsewhere) 11 (Pending Move)
FullySpecifiedName	All concepts must have exactly one FullySpecifiedName.
FullySpecifiedName	Every FullySpecifiedName must be unique, within the Namespace in which it resides.
FullySpecifiedName	The FSN must comply with all FSN description constraints and data definitions – including that it must be provided in XHTML fragment form (i.e. without <html>), encoded using UTF-8. The maximum length of a FSN is 32,000 characters.

A.3 Description

A.3.1 Definition

A description is a human-readable term or name that is associated with the concept that it describes. Each description is identified by a unique UUID and SNOMED CT ID.

Each SNOMED CT concept may be associated with multiple alternative descriptions, including a Fully Specified Name, a Preferred Term and Synonyms. Each concept has exactly one Fully Specified Name, exactly one Preferred Term (for a particular language or dialect), and potentially multiple synonyms.

A.3.1.1 Fully Specified Name (FSN)

Each concept has one unique FSN intended to provide an unambiguous way to name a concept. The purpose of the FSN is to uniquely identify a concept and to clarify its meaning, not necessarily to present the most commonly used or natural phrase for that concept. Each FSN ends with a 'semantic tag' in parentheses at the end of the concept. The semantic tag indicates the primary concept hierarchy to which the concept belongs.

A.3.1.2 Preferred Term (PT)

Each concept has one preferred term, which is meant to capture the common word or phrase used by clinicians to name that concept.

Unlike FSNs, Preferred Terms are not necessarily unique. Occasionally, the Preferred Term for one concept may also be a Synonym or the Preferred Term for a different concept, in a different part of the semantic hierarchy.

A.3.1.3 Synonym

Synonyms are additional terms that represent the same concept as referred to by the FSN. Synonyms, like Preferred Terms, are not required to be unique between concepts.

A.3.2 Attributes

The attributes of the Description class, together with the associated definitions, data types and cardinalities, are listed in Table 34. Note that Descriptions also share (by inheritance) those attributes from the Component class – e.g. all descriptions have a ComponentUUID.

Table 34: Attributes of the Description Class

Name	Definition	Data Type	Cardinality
ConceptUUID	The UUID of the concept to which this description applies.	ID (UUID)	1
ConceptID	The unique SNOMED CT ID of the concept to which this description applies.	ID (SCTID)	1
Term	The text of the term used to describe the associated concept.	ABC	1

Name	Definition	Data Type	Cardinality
CaseSensitivity	Indicates whether or not the capitalisation of the entire term is significant.		1
InitialCapitalStatus	Indicates whether or not the capitalisation status of the first character of the term is significant. Capitalisation of characters other than the first character is, by default, always regarded as significant.		1
DescriptionTypeID	A concept which represents the type of the description – for example, ‘Fully Specified Name’, ‘Preferred Term’ or ‘Synonym’. This attribute allows additional, non-standard description types (e.g. ‘Short Name’) to be added within the AMT.	ID (UUID)	1
DescriptionType	Indicates whether the Term is a Fully Specified name, a Preferred Term or a Synonym.	 (enumeration)	1
LanguageID	A concept which represents the language/dialect for this term.	ID (UUID)	0..1
LanguageCode	A string, which specifies the language/dialect for this term – e.g. ‘en’.		0..1

A.3.3 Data rules

The data rules for the Description Class are outlined in Table 35.

Table 35: Data Rules for the Description Class

Data Element	Constraints/Data Definition
Term	All descriptions must have exactly one Term, which is valid in one or more languages or dialects.
Term	Some terms may be applied to more than one concept. In this case each instance of a term must be represented by a separate row in the Descriptions Table with the same term text but with different Description and Concept identifiers.
Term	Each term is provided in XHTML fragment form (i.e. without an ‘<html>’ header), encoded using UTF-8. The maximum length of a term is 32,000 characters.

Data Element	Constraints/Data Definition
DescriptionType	All descriptions must have exactly one DescriptionType.
DescriptionType	The valid values for DescriptionType are: 0 (Unspecified) 1 (Preferred) 2 (Synonym) 3 (Fully Specified Name)

A.4 Relationship

A.4.1 Definition

A relationship is a component that represents an association between two concepts. Relationships are identified by both a ComponentUUID and a ComponentID, and are distributed as rows in the Relationship table. A relationship is assigned only when that relationship is always known to be true.

Each relationship refers to three distinct concepts. Two of these concepts are the concepts logically associated by the relationship, and the third represents the relationship type by which the other two concepts are associated.

A relationship also contains an indication of its characteristic type. This distinguishes between:

- **defining relationships** – which state things that are always true about the first concept;
- **qualifying relationships** – which offer options for qualifying a concept;
- **historical relationships** – which refer from an inactive concept to an active concept that duplicates, corrects, replaces or disambiguates it; and
- **additional (or other) relationships.**

A.4.1.1 IS A relationships

IS A relationships are also known as 'Supertype-Subtype relationships' or 'Parent-Child relationships'. IS A relationships are the basis of the SNOMED CT's hierarchies.

A concept can have more than one IS A relationship to other concepts – that is, subtype relationships can be multi-hierarchical. Every active SNOMED CT concept (except the 'SNOMED CT concept' and 'Australian concept' root concepts) has at least one IS A relationship to a supertype concept.

Relationship types can themselves be represented in a hierarchical structure. For example, the AMT relationship type 'has strength units (relationship type)' has an IS A relationship to the relationship type 'has units (relationship type)'. Data retrieval algorithms can be constructed to recognise these relationship type hierarchies, and to retrieve all relationships whose type belongs to a particular hierarchy (e.g. all 'has units' relationships).

A.4.2 Attributes

The attributes of the Relationship class are listed in Table 36, together with their associated definitions, data types and cardinalities. Please note that Relationships also share (by inheritance) those attributes from the Component class – e.g. all relationships have a ComponentUUID.

Table 36: Attributes of the Relationship Class

Name	Definition	Data Type	Cardinality
ConceptUUID1	The UUID of the concept which is the source of the relationship.	ID (UUID)	1
ConceptID1	The SNOMED CT identifier of the concept which is the source of the relationship.	ID (SCTID)	1
RelationshipTypeUUID	The UUID of the concept that represents the type of relationship between the two related concepts.	ID (UUID)	
RelationshipType	The SNOMET CT Identifier of the Concept which represents the type of relationship between the two related concepts.	ID (SCTID)	1
ConceptUUID2	The UUID of the concept which is the target of the relationship.	ID (UUID)	
ConceptID2	The SNOMED CT Identifier of the concept which is the target of the relationship.	ID (SCTID)	1
CharactereristicTypeD	The UUID of the concept which represents the characteristic type of the relationship.	ID (UUID)	0..1
ChararcteristicType	An indication of whether the relationship specifies a defining characteristic of the source concept, a qualification of the source concept, an historical relationship or an additional relationship.	1²3 (enumerated)	0..1
RefinabilityID	The UUID of the concept which represents the refinability of the target concept in this relationship.	ID (UUID)	0..1
Refinability	An indication of whether it is possible to refine the target concept when this relationship is used as a template for clinical data entry.	1²3 (enumerated)	0..1

Name	Definition	Data Type	Cardinality
RelationshipGroup	An integer value that expresses an association between two or more relationships.	123	0..1

A.4.3 Data rules

The data rules for the Relationship Class are outlined in Table 37.

Table 37: Data Rules for the Relationship Class

Data Element	Constraints/Data Definition
RelationshipType	All relationships must have exactly one RelationshipType.
CharacteristicType	The valid values for the CharacteristicType of a relationship are: 0 (Defining) 1 (Qualifier) 2 (Historical) 3 (Additional)
Refinability	The valid values for the Refinability of a relationship are: 0 (Not refinable) 1 (Optional) 2 (Mandatory)

A.5 AMT semantic hierarchies

The top-level semantic hierarchies positioned under 'Australian concept' include the following:

- *Product concepts*
Concepts in the 'Australian product' hierarchy will include medicinal products that are available in Australia for the treatment of human patients. These products are represented at a variety of levels of abstraction and granularity.
For example, 'amoxicillin 250 mg capsule, 20 capsules (medicinal product pack)'.
- *Substance concepts*
Concepts in the 'Australian substance' hierarchy currently include medicinal ingredients contained within products.
- *Data representation concepts*
Concepts in the 'Australian data representation concept' hierarchy are concepts that are used to assist in the representation of AMT data in the component model.
- *Relationship details concepts*

Concepts in the 'Australian relationship details' hierarchy are used to add more information about AMT relationships.

For example, 'amoxicillin 250 mg capsule HAS SPECIFIC ACTIVE INGREDIENT amoxicillin' is the preferred term of a relationship details concept that records the strength of 'amoxicillin' in the 'amoxicillin 250 mg capsule' medicinal product unit of use.

- *Qualifiers*

Concepts in the 'Australian qualifier' hierarchy will be used in one or more of the domain models to provide additional, qualifying information about the core domain concepts.

For example, 'tablet dose form (AU qualifier)' and 'milligram unit (AU qualifier)'

A.5.1 Australian concept

A.5.1.1 Model

The UML model, shown in Figure 15 outlines the Australian concept hierarchy.

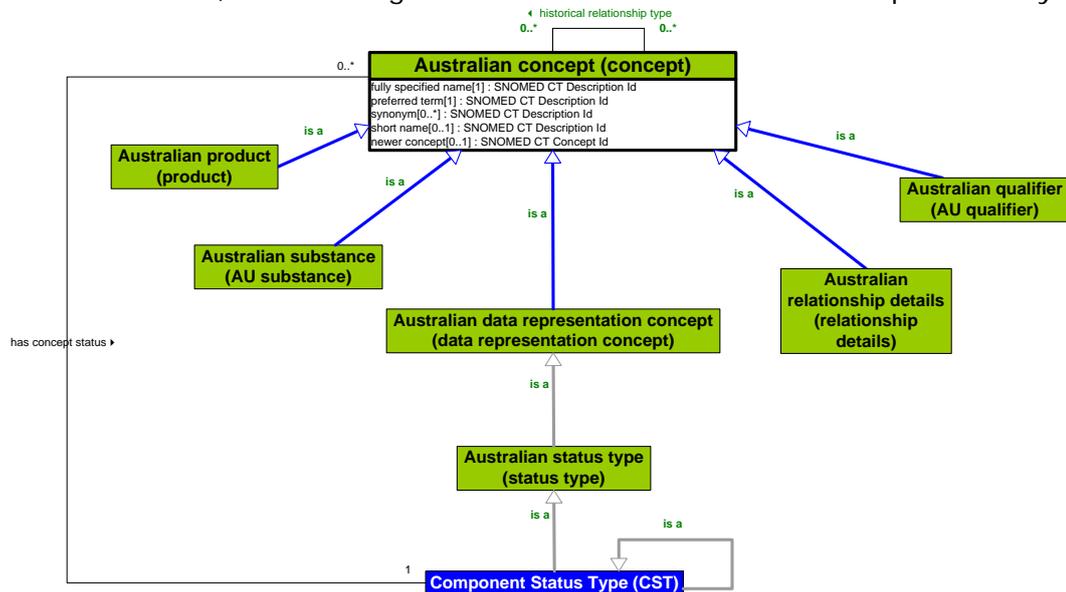


Figure 15: 'Australian Concept' model

A.5.1.2 Related Concepts

The concepts that participate in relationships with 'Australian concept' are shown in Table 38, together with their associated definitions.

Table 38: 'Australian Concept' related concepts

Fully Specified Name	Definition
Australian concept (concept)	A clinical meaning that is uniquely identified by both a UUID and SCTID and is recommended for use in Australia, within one or more pre-defined clinical domains.
Australian data representation concept (data representation concept)	Concepts used to assist in the representation of AMT data in the component model. These concepts currently include (but are not limited to): <ul style="list-style-type: none"> • Australian description type concepts; • Australian relationship type concepts; • Australian status type. concepts; • Australian characteristic type concepts; and • Australian language concepts.
Australian product (product)	Products that are available in Australia for the treatment of human patients. These products are represented at a variety of levels of abstraction and granularity.
Australian qualifier (AU qualifier)	Concepts used in one or more domains to provide additional, qualifying information about the core domain concepts.
Australian relationship details (relationship details)	Concepts used to add more information about AMT relationships.
Australian substance (AU Substance)	A substance referred to in one of the Australian domain models, including medicinal ingredients contained within products.
Australian status type (status type)	Concepts used to represent the Australian status of a component.
Component Status Type (CST)	The set of concepts that are children of 'Australian status type (status type)' and that represent the status of a component.

A.5.2 Australian data representation concepts

A.5.2.1 Definition

Australian Data Representation Concepts are used to assist in the representation of the AMT data in SNOMED CT-like format and currently include:

- Australian characteristic type (characteristic type);
- Australian data type (data type);
- Australian description type (description type);
- Australian domain (domain);
- Australian identifier type (identifier type);

- Australian language (language);
- Australian mapping reason (mapping reason);
- Australian mapping type (mapping type);
- Australian originator (originator);
- Australian realm (realm);
- Australian reference set type (reference set type);
- Australian refinability type (refinability type);
- Australian relationship type (relationship type); and
- Australian status type (status type).

A.5.2.2 Model

The UML model in Figure 16 shows the Australian data representation concept hierarchy.

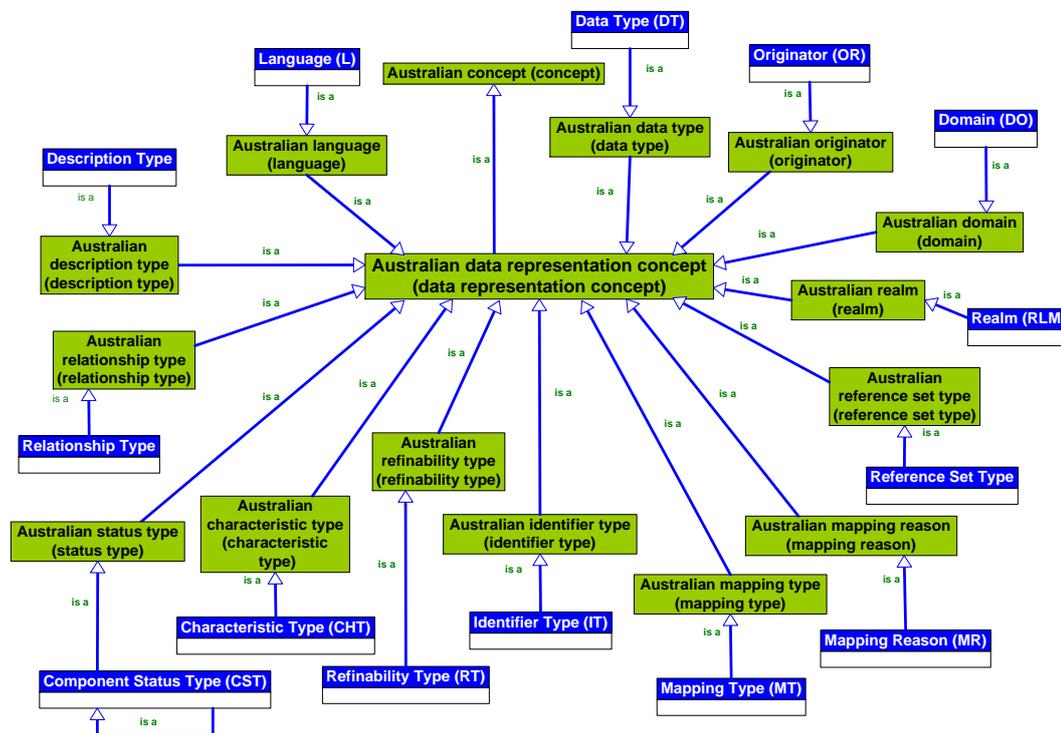


Figure 16: 'Australian Data Representation Concept' model

A.5.2.3 Concepts

The concepts that participate in relationships with 'Australian data representation concept' (in particular, its children) are shown in Table 39, together with their associated definitions.

Table 39: 'Australian Data Representation Concept' related concepts

Name	Definition
Australian characteristic type (characteristic type)	'Australian characteristic type' represents the characteristic types of relationships within the AMT (e.g. 'defining', 'qualifying', 'historical', 'additional').
Australian data type (data type)	'Australian data type' represents the valid data types used within the AMT (e.g. integer, datetime, string).

Name	Definition
Australian description type (description type)	'Australian description type' represents the type of a description contained in the AMT (e.g. fully specified name, synonym).
Australian domain (domain)	'Australian domain' represents the clinical domain within which a particular reference set is used.
Australian identifier type (identifier type)	'Australian identifier type' represents the concept used to describe the Identifier types used within the Australian context.
Australian language (language)	Concept used to describe a language used within the Australian context.
Australian mapping reason (mapping reason)	Concept used to define the reasons for decisions made when mapping SNOMED CT concepts to other terminologies or classifications within the Australian context.
Australian mapping type (mapping type)	Concepts used to define the type of mapping made when mapping concepts to other terminologies or classifications within the Australian context.
Australian originator (originator)	Concept used to define the creator of a reference set within the Australian context.
Australian realm (realm)	Concept used to describe the Australian jurisdictions to which a reference set applies.
Australian reference set type (reference set type)	Concept used to describe the types of sets of components that are appropriate for a specific case within the Australian context.
Australian refinability type (refinability type)	Concept used to identify the refinability type of relationships within the Australian context. The concepts are used to indicate whether it is possible to refine the target concept. There are three possible values: Not Refinable, Optional and Mandatory.
Australian relationship type (relationship type)	The nature of a relationship between two concepts. The Relationship Type field indicates the Concept ID for the concept in SNOMED CT that forms the relationship between the two other concepts (ConceptID1 and ConceptID2) within the Australian context.
Australian status type (status type)	Concept used to group the set of 'Australian status type' relationship type concepts; asserts an interaction between two concepts that indicates a non-defining, qualifying attribute.

A.5.2.4 Australian Description Type

A.5.2.4.1 Definition

This concept is used to group the set of description type concepts which may be used in an identified Australian clinical domain. These description type concepts represent both the 'standard' SNOMED CT description types (e.g. fully specified name and synonym) and a set of 'extended' SNOMED CT description types (e.g. 'sort name').

A.5.2.4.2 *Child concepts*

The concepts that participate in relationships with 'Australian description type', or its children, are shown in Table 40, together with their associated definitions.

Table 40: 'Australian Description Type' children concepts

Name	Definition
abbreviated name (description type)	An abbreviated or shortened name of a concept – e.g. abbreviated Medication Product name.
ARTG id (description type)	An Australian Register of Therapeutic Goods Identifier from the Therapeutic Goods Administration (TGA).
Australian date time based property (description type)	A concept that groups together those description types that are date-time based properties – e.g. 'availability end date'.
Australian integer based property (description type)	A concept that groups together those description types that are integer-based properties – e.g. 'total unit of use quantity value'.
Australian property description type (description type)	A concept that groups together those description types that represent properties of a concept.
Australian real based property (description type)	A concept that groups together those description types that are numeric, real-based (i.e. decimal) properties – e.g. 'ingredient strength numerator value'.
Australian string based property (description type)	A concept that groups together those description types that are string-based (i.e. with alphanumeric characters) properties – e.g. 'other identifying information'.
availability end date (description type)	The last date that a product is expected to be available for prescribing.
base form strength denominator value (description type)	The denominator value of the strength of the base of the ingredient in the given medicinal product.
base form strength numerator value (description type)	The numerator value of the strength of the base of the ingredient in the given medicinal product.
base form strength other representation (description type)	A representation of the strength of the ingredient's base substance in the given medicinal product, that differs from the associated numerator/denominator format.
BOSS other strength representation (description type)	A representation of the strength of the ingredient in the given medicinal product, that differs from the associated numerator/denominator format, and which uses the same Basis of Strength Substance.
entry term (description type)	A term that is entered through the user interface of a clinical information system to refer to the associated concept.

Name	Definition
explanation (description type)	A term that provides some explanation or further details about the associated concept.
external reference (description type)	A term that describes a reference to an object outside SNOMED CT (e.g. a URL).
fully specified name (description type)	A phrase that describes the concept uniquely and in a manner that is intended to be unambiguous.
future availability start date (description type)	The date on which a product will become available for prescribing, dispensing or administering.
ingredient strength denominator value (description type)	The denominator value of the strength of the ingredient in the given medicinal product.
ingredient strength numerator value (description type)	The numerator value of the strength of the ingredient in the given medicinal product.
label name (description type)	The name of the product, sourced from the National Product Catalogue.
other containered pack information (description type)	Additional information about a CTPP that helps to distinguish it from other packs.
other identifying information (description type)	Additional information about a TPUU that helps to distinguish it from other TPUUs.
other pack information (description type)	Additional information about a TPP that helps to distinguish it from other TPPs.
plural name (description type)	A term used to describe more than one of the given concept.
preferred component order (description type)	A number indicating the order in which the given unit of use appears in the preferred term for the pack.
preferred term (description type)	The term preferred by users when referring to the concept.
preferred term order (description type)	A number indicating the order in which the substance appears in the preferred term of the unit of use (if relevant).
product data availability date (description type)	The date on which data about the product is expected to become available.
relationship id (description type)	The UUID that uniquely identifies the relationship that the Relationship Details concept refers to.

Name	Definition
salt form strength denominator value (description type)	The denominator value of the strength of the salt-form of the ingredient in the given medicinal product.
salt form strength numerator value (description type)	The numerator value of the strength of the salt-form of the ingredient in the given medicinal product.
salt form strength other representation (description type)	A representation of the strength of the ingredient's salt substance in the given medicinal product, that differs from the associated numerator/denominator format.
short name (description type)	A term containing no more than 60 characters used as a shorter alternative for naming a concept.
sort name (description type)	A term that allows concepts to be sorted correctly alphabetically. Leading zeros are included, where necessary, to ensure that numbers sort appropriately.
symbolic name (description type)	A symbolic-representation of the name of the concept.
synonym (description type)	Additional terms that are used to refer to the concept that differ from the FSN.
total subpack quantity (description type)	The number of subpacks contained in the pack.
total unit of use quantity value (description type)	The numeric value of the total number of units of use in the pack.
total unit of use size value (description type)	The numeric value of the size of the unit of use in a single-component pack.
trade product suffix (description type)	An extension to the trade product name that further identifies the product in terms of strength, form or presentation.
unabbreviated singular name (description type)	A term that represents the name of a single instance of the concept, which is not abbreviated or shortened in any way.
unit dose form size value (description type)	The numeric value of the size of a single unit dose form of the product.
unit of use quantity value (description type)	The numeric value of the quantity of units of use contained within a pack.
unit of use size value (description type)	The numeric value of the size of the unit of use contained within a pack.

A.5.2.5 Australian Refinability Type

A.5.2.5.1 Definition

These concepts are used to identify the refinability type of relationships in the Australian Extension. The concepts are used to indicate whether it is possible to refine the target concept; there are three values possible:

- mandatory (refinability type)
- not refinable (refinability type)
- optional (refinability type)

A.5.2.6 Australian Relationship Type

A.5.2.6.1 Definition

Australian Relationship Type concepts are those types of relationships that are relevant in an identified Australian clinical domain. The SCTIDs of these relationship type concepts are used to populate the 'RelationshipType' field of the SNOMED CT Relationship table.

A.5.2.6.2 Model

The three UML models, shown in Figure 17, Figure 18 and Figure 19, outline the Australian relationship type concept hierarchy.

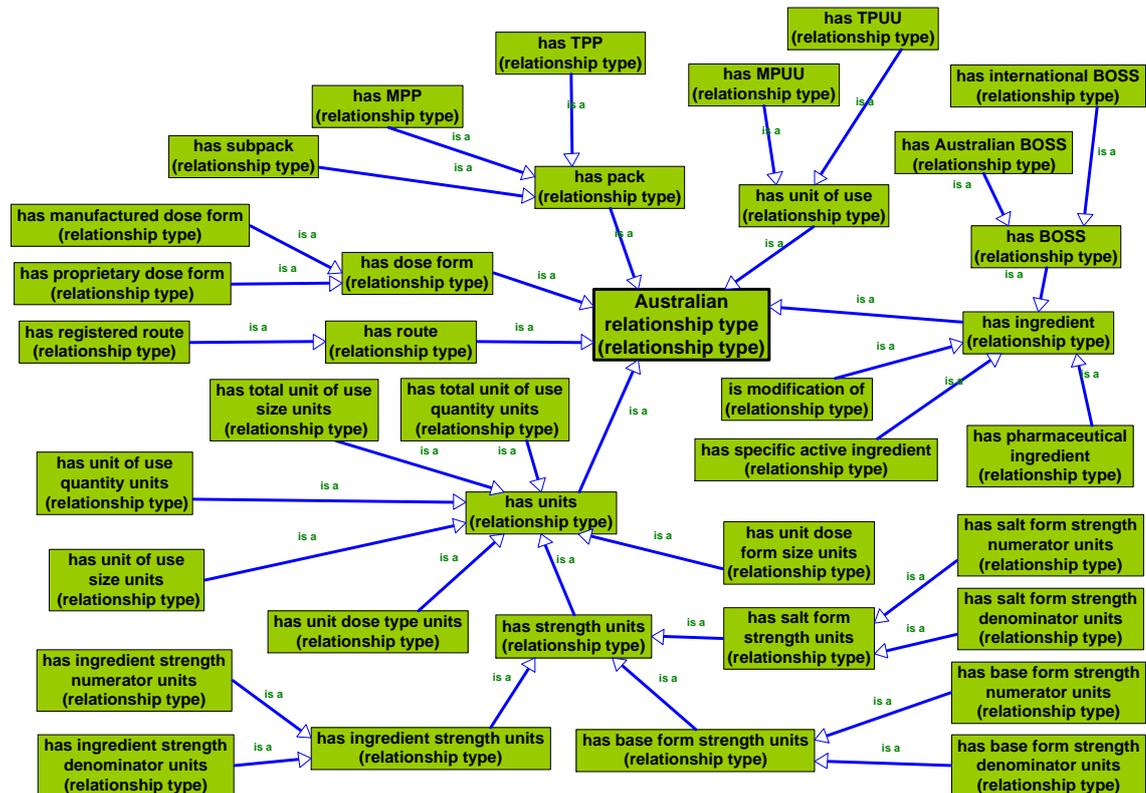


Figure 17: 'Australian Relationship Type (1)' model

Relationship Type Concepts (2)

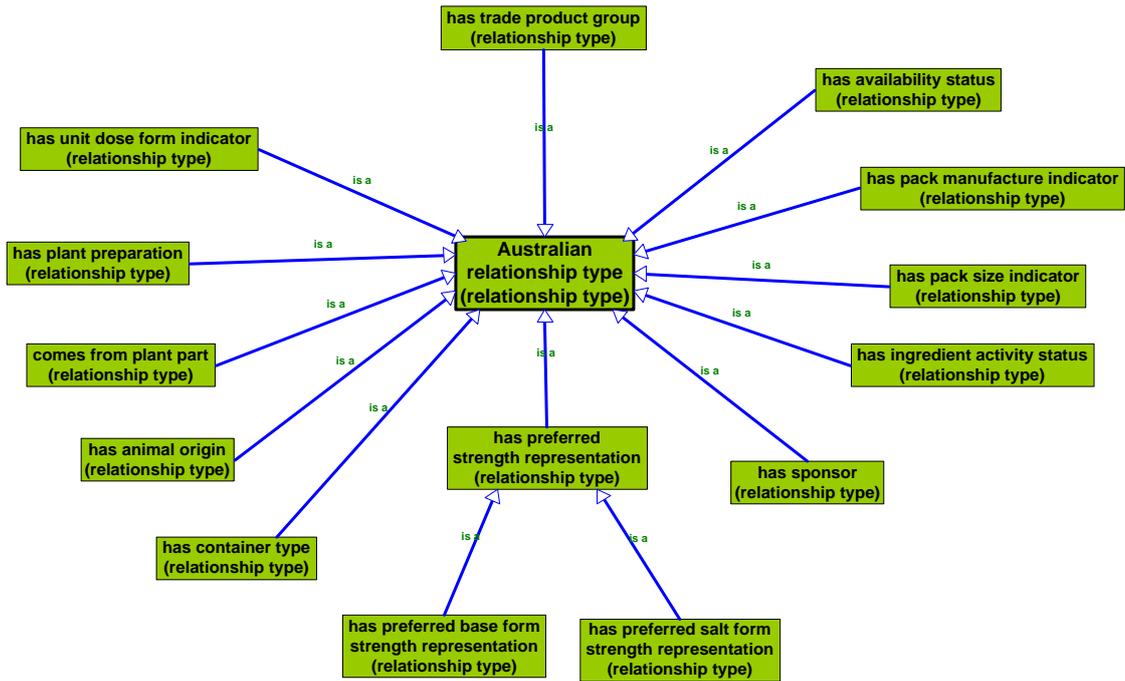


Figure 18: 'Australian Relationship Type (2)' model

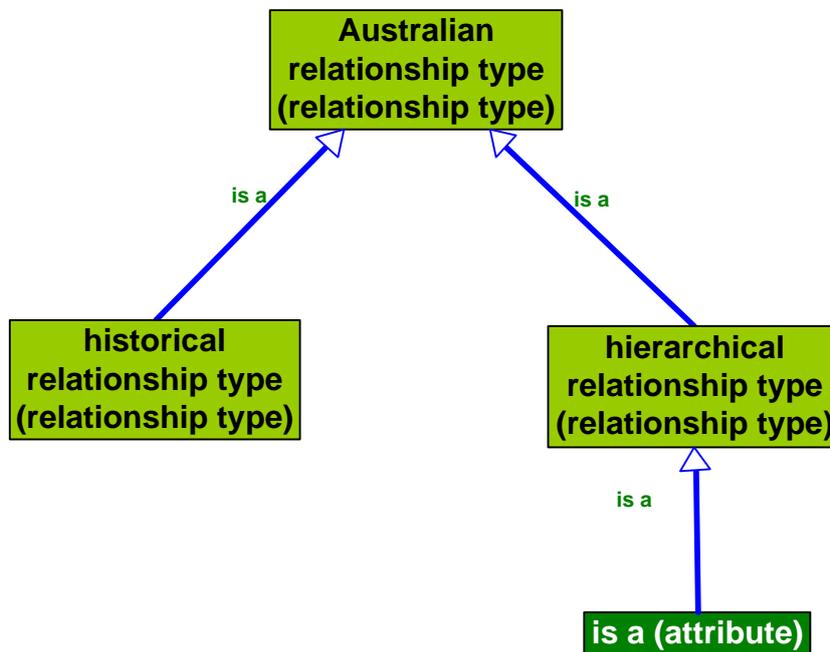


Figure 19: 'Australian Relationship Type (3)' model

A.5.2.7 Australian Status Type

A.5.2.7.1 Definition

This concept is used to identify the status of a concept and description in the Australian Extension.

A.5.3 Australian Product

A.5.3.1 Definition

Australian Products are medicinal products that are available in Australia for the treatment of human patients. The concepts in the 'Australian Product' hierarchy are used to identify products available for prescribing, dispensing or administering, at various levels of abstraction.

The 'Australian Product' hierarchy has been conceptually designed to encompass seven distinct 'product' concept types – namely:

- Medicinal Product (MP) – e.g. 'amoxicillin';
- Medicinal Product Unit of Use (MPUU) – e.g. 'amoxicillin 500 mg capsule';
- Medicinal Product Pack (MPP) – e.g. 'amoxicillin 500 mg capsule, 20';
- Trade Product (TP) – e.g. 'Amoxil';
- Trade Product Unit of Use (TPUU) – e.g. 'Amoxil (amoxicillin (as trihydrate) 500 mg) capsule: hard, 1 capsule';
- Trade Product Pack (TPP) – e.g. 'Amoxil 500 mg capsule: hard, 20 capsules'; and
- Containered Trade Product Pack (CTPP) – e.g. 'Amoxil 500 mg capsule: hard, 20 capsules, bottle'.

A.5.4 Australian Substance

A.5.4.1 Definition

Australian substances are those that are recognised in Australia as either:

- Chemical entities that may act as the actual active ingredients of medicinal products – for example, heparin sodium, perindopril arginine or dexamethasone sodium phosphate;
- The Basis of Strength Substance (BOSS) that may or may not be available as the actual ingredient – for example, perindopril or dexamethasone;
- The 'clinically significant' portion of an actual ingredient – for example, diclofenac; or
- A substance to which an allergy or adverse reaction may be recorded;

A.5.5 Australian Relationship Details

A.5.5.1 Definition

Australian Relationship Details are concepts that are used to add more information about a relationship that exists between two concepts in the Australian context.

A.5.6 Australian Qualifier

A.5.6.1 Definition

Australian Qualifiers are concepts used to qualify other concepts. These concepts will be used in the various AMT clinical domains either to provide the atomic data used to construct a concept name, or to provide additional information about a concept.

A.5.6.2 Concepts

The concepts that participate in relationships with ‘Australian qualifier’ (namely its children) are shown together with their associated definitions in Table 41.

Table 41: ‘Australian Qualifier’ concepts

Name	Description/Definition
Australian qualifier (AU qualifier)	This concept is used to group the set of Australian qualifier concepts within the extended SNOMED CT hierarchy.
animal origin (AU qualifier)	This concept is used to group the set of Animal Origin concepts within the Australian qualifier hierarchy.
Animal Origin (AO)	Animal Origin defines the animal from which an ingredient originates. Their names are derived from the TGA Approved Terminology for Medicines.
availability status (AU qualifier)	This concept is used to group the set of Availability Status concepts within the Australian qualifier hierarchy.
Availability Status (AS)	Availability Status is used to define whether or not a CTPP is available for prescribing in Australia. Valid members are: <ul style="list-style-type: none"> • available; and • available only as a component or subpack.
biotech descriptor (AU qualifier)	This concept is used to group the set of Biotech Descriptors in the Australian qualifier hierarchy.
Biotech Descriptor (BD)	Biotech Descriptors represent a product derived from a genetically engineered cell line which has been developed in order to express a therapeutically recombinant protein.
container type (AU qualifier)	This concept is used to group the set of Container Types in the Australian qualifier hierarchy.
Container Type (CT)	A Container Type is a type of container that immediately covers a medicinal product. It does not include an article intended for ingestion. The name of the Container Type is derived from the TGA Approved Terminology for Medicines. Examples include ampoule, bottle, blister pack, vial etc.
form (AU qualifier)	This concept is used to group the set of Forms in the Australian qualifier hierarchy.

Name	Description/Definition
Form	<p>The Form qualifier describes the dose formulation – for example, tablet, capsule or eye drops. Note that medications can pass through different physical forms during the journey from the end of the manufacturing process (the manufactured dose form), through to the point where the medicine is administered to the patient (the orderable dose form).</p> <p>Notes:</p> <ul style="list-style-type: none"> • Orderable dose forms are the dose forms the person writing a prescription expects the patient to take. • Manufactured dose forms are the forms in which the product is manufactured and transported (i.e. the dose form created by the manufacturer, e.g. powder for reconstitution as suspension). • As the dose form is a defining characteristic of medication and is linked with knowledge regarding medicine administration, it is important that there is a standard defining list of dose forms. • Form names are derived from the Dosage Forms specified in the TGA Approved Terminology for Medicines. Additional dosages may be defined, however, to meet the requirements of clinical practice.
ingredient activity status (AU qualifier)	<p>This concept is used to group the set of Ingredient Activity Statuses in the Australian qualifier hierarchy.</p>
Ingredient Activity Status (IAS)	<p>This qualifier concept indicates if an ingredient is an active ingredient or excipient. At this stage, Herbal and Proprietary Ingredients are not included. Valid values are:</p> <ul style="list-style-type: none"> • active • excipient
medication sponsor (AU qualifier)	<p>This concept is used to group the set of Medication Sponsors in the Australian qualifier hierarchy.</p>
Medication Sponsor (MSP)	<p>An organisation that sponsors a medicinal product in the Australian marketplace.</p>
organisation (AU qualifier)	<p>This concept is used to group the set of Organisations in the Australian qualifier hierarchy.</p>
Organisation (ORG)	<p>An organisation is a company, business or other organised group that has some association with the Australian healthcare domain.</p>
pack manufacture indicator (AU qualifier)	<p>This concept is used to group the set of Pack Manufacture Indicators in the Australian qualifier hierarchy.</p>
Pack Manufacture Indicator (PMI)	<p>The Pack Manufacture Indicator is used to describe whether the pack is in its original form or if the product has been re-packaged. Valid values are:</p> <ul style="list-style-type: none"> • original manufacture pack • repackaged pack
pack size indicator (AU qualifier)	<p>This concept is used to group the set of Pack Size Indicators in the Australian qualifier hierarchy.</p>

Name	Description/Definition
Pack Size Indicator (PSI)	<p>The Pack Size Indicator indicates if the medicinal product pack contains a single administrable dose or multiple unit doses. Valid values are:</p> <ul style="list-style-type: none"> • multiple unit dose pack • unit dose pack
plant part (AU qualifier)	<p>This concept is used to group the set of Plant Parts in the Australian qualifier hierarchy.</p>
Plant Part (PP)	<p>Plant Part defines the part of a plant that is used to manufacture some product. Plant Part descriptions are derived from the TGA Approved Terminology for Medicines.</p>
plant preparation (AU qualifier)	<p>This concept is used to group the set of Plant Preparation techniques in the Australian qualifier hierarchy.</p>
Plant Preparation (PPN)	<p>Plant Preparation defines the preparation techniques used to prepare a substance for medicinal use – for example, extract or infusion. Plant Preparation descriptions are derived from the TGA Approved Terminology for Medicines.</p>
preferred strength representation type (AU qualifier)	<p>This concept is used to group the set of Preferred Strength Representation Types in the Australian qualifier hierarchy.</p>
preferred strength representation type (PSRT)	<p>Preferred Strength Representation Type defines the order and combination of strength representations to include in the preferred term of the association medicinal products. Valid values include:</p> <ul style="list-style-type: none"> • alternate strength followed by numerator/denominator strength • alternate strength only • numerator/denominator strength • numerator/denominator strength followed by alternate strength
proprietary form (AU qualifier)	<p>This concept is used to group the set of proprietary forms in the Australian qualifier hierarchy.</p>
Proprietary Form (PF)	<p>Proprietary Forms are those forms that are privately owned and controlled by a product sponsor. For example, 'Caplet' or 'Tabsule'.</p>
route of administration (AU qualifier)	<p>This concept is used to group the set of routes of administration in the Australian qualifier hierarchy.</p>
Route of Administration (RA)	<p>Route is used to describe the set of registered routes of administration for medicinal products in the AMT. For example, 'Oral', 'Intravenous'.</p>
trade product group (AU qualifier)	<p>This concept is used to group the set of trade product groups in the Australian qualifier hierarchy.</p>
Trade Product Group (TPG)	<p>This qualifier concept allows for trade products sharing a common root trade product name to be grouped. For example, Canesten is the Trade Product Group description and provides links to Canesten Clotrimazole and Canesten Bifonazole.</p>

Name	Description/Definition
unit dose form indicator (AU Qualifier)	This concept is used to group the set of unit dose form indicators in the Australian qualifier hierarchy.
Unit Dose Form Indicator (UDFI)	<p>The unit dose form indicator (UDFI) identifies if an APUU describes a discrete unit dose form, e.g. tablet or capsule; a continuous substance where a consistent physically measurable unit or sub-unit cannot be identified, e.g. cream or eye drops; or a product where a unit dose form is not applicable. Valid values are:</p> <ul style="list-style-type: none"> • continuous • discrete • unit dose form not applicable
unit of measure (AU qualifier)	This concept is used to group the set of unit of measures in the Australian qualifier hierarchy.
Unit of Measure (UOM)	<p>Unit of Measure is used to describe the units used to measure various quantities within the AMT. Units of Measure are used to describe the following:</p> <ul style="list-style-type: none"> • Base form strength numerator units • Base form strength denominator units • Salt form strength numerator units • Salt form denominator units • Ingredient strength numerator units • Ingredient strength denominator units • Total unit of use quantity units • Pack quantity units • Unit dose form size units • Unit dose type units