nehta

AMT Model Review

Concept Definitions & Supporting Information

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Draft for Comment

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Document Information

Change History

Version	Date	Author	Comments
0.1	28 Oct 09	Margaret Prichard	Creation of document references NEHTA Editorial Rules v3.0
0.2	30 Oct 09	Margaret Prichard	Addition of Reference set and subpack information
0.3	3 Nov 09	Margaret Prichard	Additions following review by iSoft
0.4	4 Nov 09	Margaret Prichard	Revision following internal review
0.5	6 Nov 09	Margaret Prichard	Revision following internal review
0.6	9 Nov 09	Margaret Prichard	Revision following further review
0.7	12 Nov 09	Margaret Prichard	Additions following external consultation
0.8	23 Nov 09	Margaret Prichard	Revision following internal QC

1 Introduction

1.1 Document Purpose

This document aims to describe the concepts within the AMT in a technical way rather than an editorial context. For full editorial descriptions refer to *NEHTA AMT Editorial Rules v3.0*.

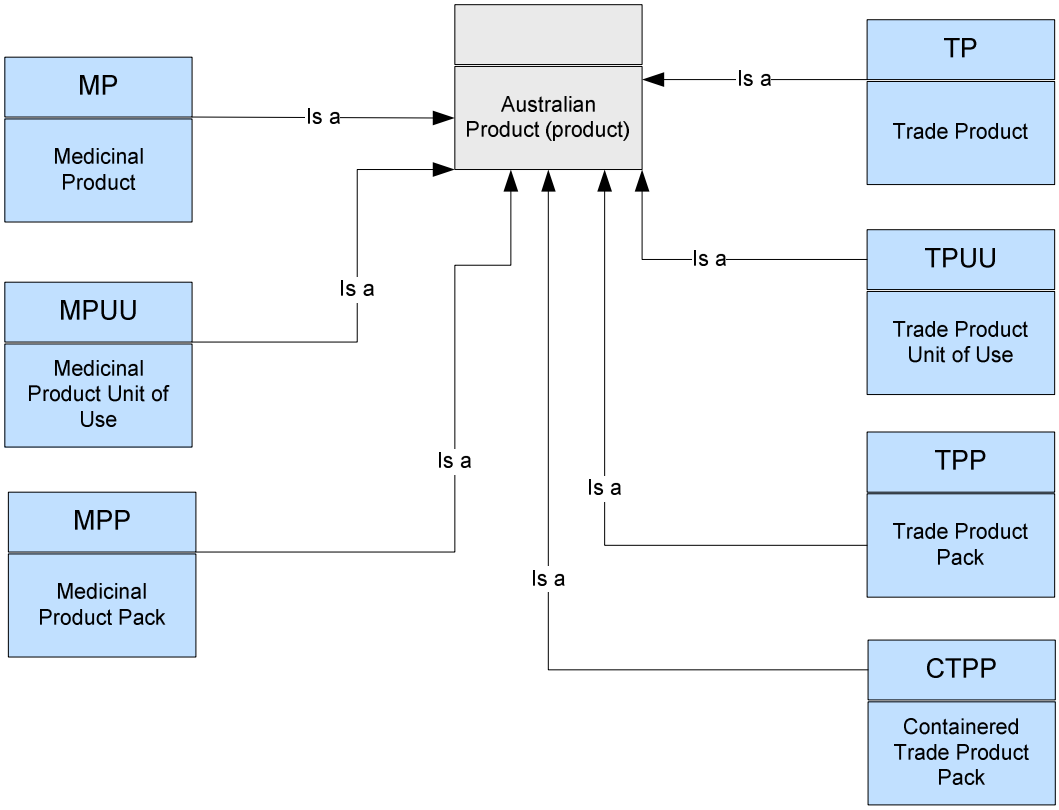
1.2 Intended Audience

The audience for this document is stakeholders involved in the AMT model review process.

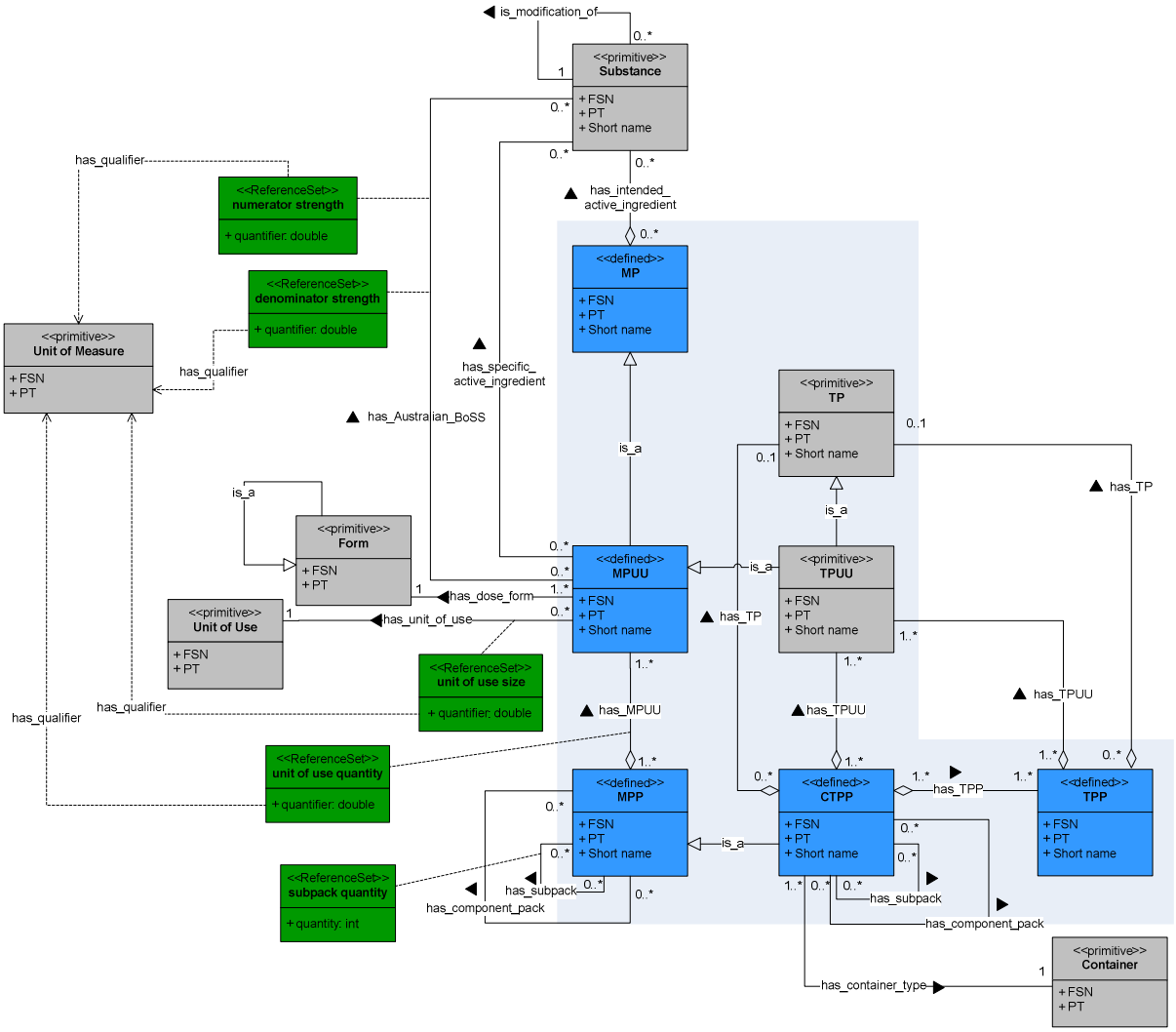
2 Concept Definitions

2.1 AMT Product Hierarchy

The representation of the AMT model below should be framed in the following context.



2.2 Concept Model



2.3 Trade Product

The Trade Product (TP) represents the product brand name for either

- single component products that contain the same base of an active ingredient or
- components of multi-component products which contain the same combination of bases of the active ingredients or
- generic products (Un-named, non brand product), the TP represents products that contain the same BoSS ingredient(s) that are supplied by the same sponsor

Grouping at the Trade Product level occurs at the base level of the ingredients, regardless of whether the salts are discernibly therapeutically different or not. For generic products, grouping occurs at the BoSS and sponsor levels. Trade Product is devoid of the form and strength.

2.3.1 TP Examples

Type of product	Preferred Term
Single Ingredient	Amoxil
	Morphine Sulfate (DBL)
	Morphine Tartrate (DBL)

Type of product	Preferred Term
Multi ingredient	Panadeine
	Panadeine Forte
	Amoxycillin and Clavulanic Acid (Apotex)
	Amoxycillin and Clavulanic Acid (GenRx)
Combination product	Triphasil
Multi component kit	Nexium
	Klacid
	Amoxil
	Nexium Hp7

2.4 Trade Product Unit of Use

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.

A Trade Product Unit of Use will include single dose units of inactive (inert) ingredients where these are part of sequential combination product (such as oral contraceptive) or diluents provided for the preparation of the actual administrable form of a product.

Note that this is the physical medicinal object or "each" unit, that is taken or held by the patient.

2.4.1 TPUU Examples

Type of product	Preferred Term
Single Ingredient	Amoxil (amoxycillin 500 mg) capsule
Multi ingredient	Panadeine Forte (paracetamol 500 mg + codeine phosphate 30 mg) tablet
Combination product	Triphasil (levonorgestrel 50 microgram + ethinyloestradiol 30 microgram) tablet
	Triphasil (levonorgestrel 75 microgram + ethinyloestradiol 40 microgram) tablet
	(Triphasil) levonorgestrel 125 microgram + ethinyloestradiol 30 microgram) tablet
	Triphasil (inert substance) tablet
Multi component kit	Nexium (esomeprazole 20 mg) tablet; enteric coated
	Klacid (clarithromycin 500 mg) tablet
	Amoxil (amoxicillin 500 mg) capsule

2.5 Containered Trade Product Pack

The Containered Trade Product Pack (CTPP) is the packaged product that is supplied for direct patient use and includes details of the container type as described by the TGA. The Container Type defines the **type of container that immediately covers** the unit of use, such as a blister pack for a tablet, or a sachet for a patch (which is then placed inside a box, the secondary package).

A Containered Trade Product Pack may contain a containered trade product pack. Recursive CTPPs will be created for products where items are contained in separate packaging within a multi component kit or where subpacks are described for products that contain more than one pack. *See section Subpack & Multi component pack*

Quantitatively and clinically equivalent CTPPs are those that have:

- Same Trade Product (or brand name)
- same base active ingredient (or the same precise active ingredients, where the salt is therapeutically necessary)
- same strength
- same dose form
- same pack size
- same container type

2.5.1 CTPP Examples

Type of product	Preferred Term
Single Ingredient	Amoxil 500 mg capsule, 20 blister pack
Multi ingredient	Panadeine Forte tablet, 20 blister pack
Combination product	Triphasil, 112 tablets [4x28 tablets], blister pack *Has a subpack* Triphasil, 28 tablets, blister pack
Multi component kit	Nexium Hp7, 1 pack, composite pack *Has three component packs* Nexium 20 mg tablet; enteric coated 14 , blister pack; Amoxil 500 mg capsule 28 blister pack; Klacid 500 mg tablet 14, blister pack

2.6 Trade Product Pack

A Trade Product Pack (TPP) is the abstract representation of a packaged product that is supplied for direct patient use. A TPP may contain multiple TPUU items, 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. This information is included in the Containered Trade Product Pack (CTPP).

2.6.1 TPP Examples

Type of product	Preferred Term
Single Ingredient	Amoxil 500 mg capsule, 20
Multi ingredient	Panadeine Forte tablet, 20
Combination product	Triphasil, 112 tablets [4x28 tablets]
Multi component kit	Nexium Hp7, 1 pack

2.7 Medicinal Product

A Medicinal Product (MP) is the abstract representation of the active ingredient(s), contained within a discrete unit of use, devoid of strength and form, which when formulated as a medicinal product, is intended for use in treating or preventing disease in human beings.

A single MP will describe items with multiple active ingredients when they are contained in one dose form, e.g. Triphasil. A single MP will not exist when the active ingredients do not exist in the same dose form, e.g. Nexium Hp7. A Medicinal Product will also define inactive (inert) ingredients where these are part of sequential combination products or diluents provided for the preparation of the actual administrable form of a product. (See examples below).

Medicinal Product name is derived from the base of the contained active ingredient concepts, with the following rules:

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

All Medicinal Product concepts will have a relationship to each of their active ingredients, using one or more 'has_intended_active_ingredient' relationships. The name 'has_intended_active_ingredient' reflects that this is the ingredient that has an intended therapeutic effect on the patient.

2.7.1 MP Examples

Type of product	Preferred Term
Single Ingredient	amoxycillin
Multi ingredient	paracetamol + codeine
Combination product	levonorgestrel + ethinyloestradiol inert substance
Multi component kit	esomeprazole clarithromycin amoxycillin

2.8 Medicinal Product Unit of Use

A Medicinal Product Unit of Use (MPUU) is an abstract concept representing the properties of one or more equivalent Trade Product Units of Use. More than one TPUU can be represented by one MPUU. Equivalent TPUUs are those that have:

- same base active ingredient (or the same precise active ingredients, where the salt is therapeutically necessary)
- same strength (for strength representation see *Section 5.1*)
- same dose form
- same administrable unit type

For continuous forms (e.g. liquids) an MPUU will not include the unit dose as this is variable. An MPUU will include single dose units of inactive (inert) ingredients (where these are part of sequential combination products) or diluents (provided for the preparation of the actual administrable form of a product).

MPUU concepts will also have relationships to all of their active ingredients, as identified by the 'has_Australian_BoSS' relationship and 'has_specific_active_ingredient' relationship. The name 'has_Australian_BoSS' is specifically defined to differentiate its national context from the International SNOMED CT release that has a 'has_reference_BoSS' relationship. AMT will always represent 'has_Australian_BoSS', this may be

directly populated from the 'has_reference_BoSS' or will be populated by any national decision to use a different substance against which to model strength.

2.8.1 MPUU Examples

Type of product	Preferred Term
Single Ingredient	amoxycillin 500 mg capsule
Multi ingredient	paracetamol 500 mg + codeine phosphate 30 mg tablet
Combination product	levonorgestrel 50 microgram + ethinyloestradiol 30 microgram tablet levonorgestrel 75 microgram + ethinyloestradiol 40 microgram tablet levonorgestrel 125 microgram + ethinyloestradiol 30 microgram tablet inert substance tablet
Multi component kit	esomeprazole 20 mg tablet clarithromycin 500 mg tablet amoxycillin 500 mg capsule

2.9 Medicinal Product Pack

A Medicinal Product Pack (MPP) is an abstract concept representing the properties of one or more quantitatively and clinically equivalent Containered Trade Product Packs (CTPP) devoid of container type. (*See section 2.5*)

Note that for every CTPP, a corresponding MPP will exist which may have one to many CTPPs linked to it. That is, a MPP is a grouper concept that may represent more than one brand of CTPP.

2.9.1 MPP Examples

Type of product	Preferred Term
Single Ingredient	amoxycillin 500 mg capsule, 20
Multi ingredient	paracetamol 500 mg + codeine phosphate 30 mg tablet, 20
Combination product	levonorgestrel 50 microgram + ethinyloestradiol 30 microgram tablet [24 tablets] & levonorgestrel 75 microgram + ethinyloestradiol 40 microgram tablet [20 tablets] & levonorgestrel 125 microgram + ethinyloestradiol 30 microgram tablet [40 tablets] & inert substance tablet [28 tablets], 112 [4x28 tablets]
Multi component kit	esomeprazole 20 mg tablet [14 tablets] & clarithromycin 500 mg tablet [14 tablets] & amoxicillin 500 mg capsule [28 capsules], 1 pack

3 Qualifiers

3.1 Unit of Measure

Unit of Measure is used to describe the units used to measure various quantities within the AMT. Units are sourced from the TGA.

3.2 Form

The AMT includes a list of forms which may have a recursive is a relationship. This qualifier concept describes the dose formulation, for example, tablet, capsule or eye drop. The form may also be described in the terminology as a manufactured dose form. 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). Administrated dose forms are not specified, that is, the dose form when the product is administrated to the patient e.g. suspension for injection.

3.3 Unit of Use

The unit of use 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.

3.4 Container Type

This qualifier concept defines the type of container that immediately covers the medicine. It does not include an article intended for ingestion. Examples include ampoule, bottle, blister pack, vial etc. The name is derived from the TGA Approved Terminology for Medicines.

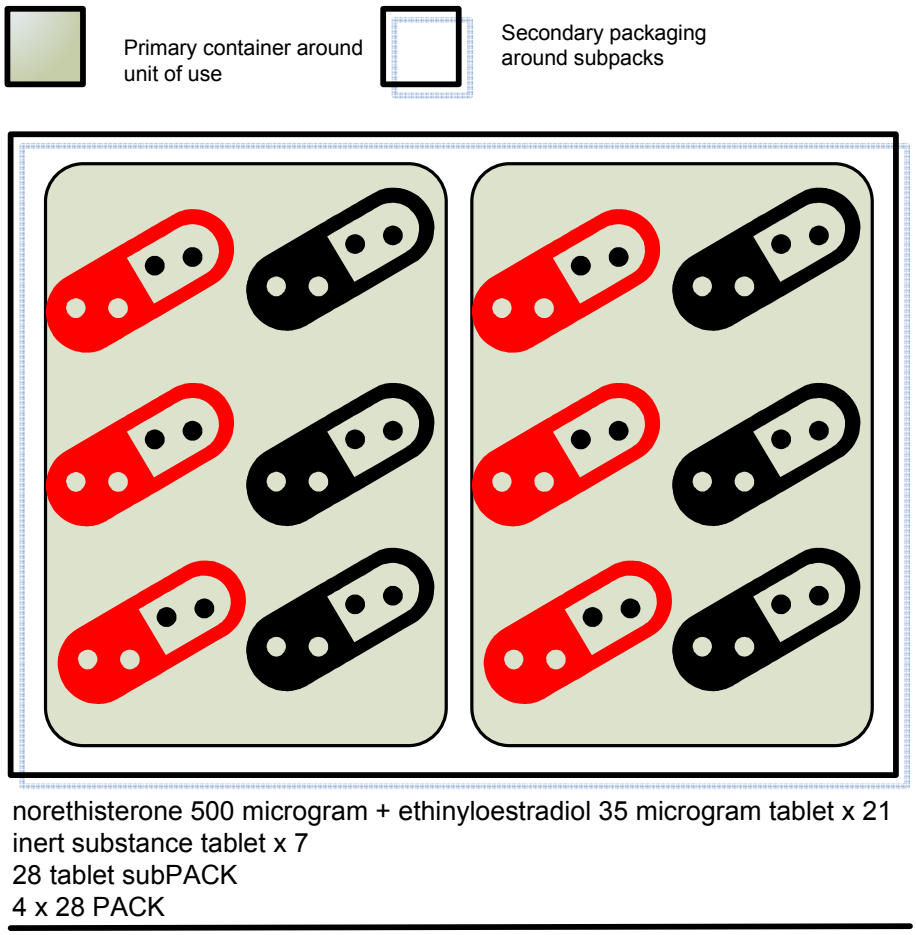
4 Subpack & Multi component pack

4.1 Subpack

A pack contains items (TPUUs) in a primary container, e.g. blister pack. These items may

- have the same ingredients, strength and form
- have the same ingredients, different strengths but similar form
- have different ingredients, strengths but similar form

When a product contains more than one of the same pack (that is, each pack has the **same items**) it is said to have subpacks. These subpacks are only represented for specific product categories. These currently include oral contraceptives and hormone replacement therapy products. These are differentiated by a representation within a Reference Set (*see section 5.4*)

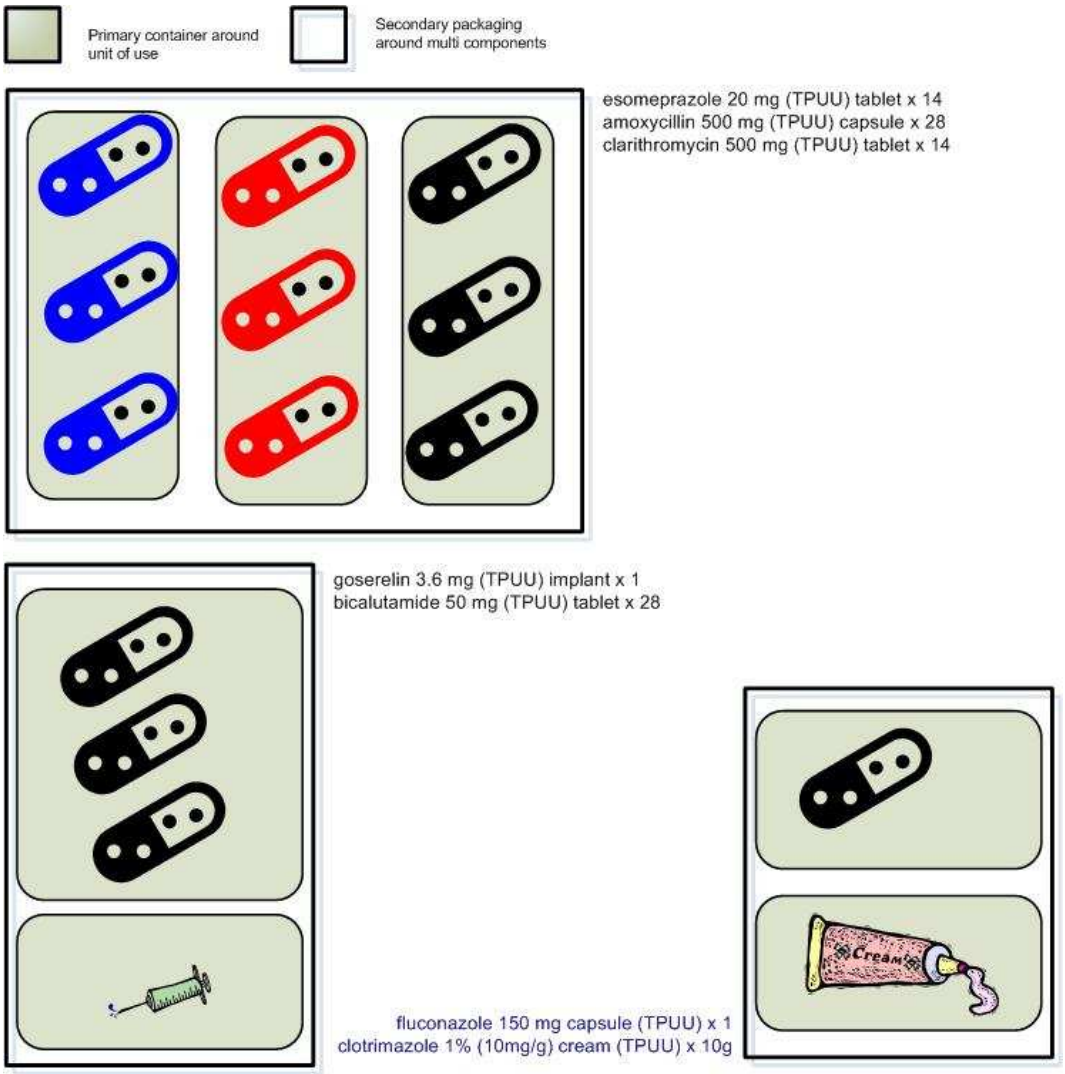


4.2 Multi Component Packs

A product pack that contains items (TPUUs) in separate primary packaging is said to be multi component.

These items may

- have similar forms
- have different forms



5 Reference sets – DRAFT

This is a draft list of suggested reference sets for inclusion with the AMT release based on direct feedback received from the Model Review Working Group or as a consequence of the requirement to remain consistent with the SNOMED CT international pharmacy model currently entering external review. Listing here does not indicate that they have been approved for inclusion.

5.1 Strength

Strengths are consistently represented by the combination of a numerator and denominator where the denominator is normalised to a unitary level.

Consistent with the IHTSDO recommendations the definition of the denominator falls into five types. The values of these units of measure will be represented in the release.

1. Premeasured. This includes forms such as ampoule and pre-filled syringe where a dose is predetermined or pre-packaged. This is represented as "1 each".
2. Measured. This includes forms where the strength is represented as a quantifiable strength and has a quantifiable unit of use (e.g. Tablet). For example "per mL", "per g".
3. Indivisible. This includes forms that have an invariable amount such as metered dose, actuation or premeasured injection. This is represented as "1 metered dose".
4. Continuous. This includes forms where it is continuously measured such as large liquid volumes or bulk powders. These are represented as "per L" or "per g" or some other appropriate SI unit.
5. Continuous Release Patches. Where **quantifiable**, these are expressed as a unit of time. For example, "per 1 hour", "per 1 minute".

5.2 Unit of Use Quantity

This reference set expresses the number of units of MPUU within the pack or subpack (MPP). It is qualified by a unit of measure.

5.3 Unit of Use Size

This reference set contains the unit of use size for a MPUU. It is qualified by a unit of measure when the unit of use does not appropriately qualify the size. For example, a unit of use of ampoule would require a unit of use size *nn* and a qualifier of *mL*.

E.g. Iron 100mg/2mL injection has a unit of use size of 2 and a unit of measure qualifier of mL.

5.4 Prescribable

This reference set contains CTTP that are able to be prescribed. That is, it does not contain subpacks only the parent pack, multi component packs, only the parent pack.

5.5 Subpack Quantity

This reference set contains the number of subpacks that are in a pack. For example Triphasil pack has 4 subpacks of 28 tablets in each subpack (4 x 28).

5.6 Is_Device

This reference set identifies the TPPUU concept IDs associated with a product identified as "Device" by the TGA.

5.7 MPUU_TradePrescribe

This reference set contains MPUUs that are deemed (by the editorial committee) to be clinical inappropriate to be presented as a 'generic' item and require reference to a Trade concept when used.

5.8 MPUU_Names

This reference set contains MPUUs that can be utilised at a generic level that is, it contains less than three active ingredients.

5.9 MP

This reference set contains those MP concepts as defined by the AMT editorial committee as being the single instance of MP to be used in Australia. For example, amoxycillin would only appear as amoxycillin not as amoxycillin trihydrate. This will also only contain items with less than three ingredients to assist with the use of the class as an interface terminology.

5.10 Licence ID

This reference set provides a link to the ARTG Licence ID which is the primary identifier for all therapeutic goods included in the ARTG. Further details will be released at a later date.

5.11 GTIN

This reference set provides a link to the GTIN. Further details will be released at a later date.

5.12 ATC Code

This reference set provides an indication of the associated ATC code for the MPUU and in certain cases for the MPP. Further details will be released at a later date.

6 Definitions, Acronyms & Abbreviations

Term	Explanation
AMT	Australian Medicines Terminology
AMT Editorial Committee	Committee of experts in the clinical domain
ATC	Anatomic Therapeutic and Chemical classification
BoSS	Basis of Strength Substance
CTIRG	Clinical Terminology & Information Reference Group
CTPP	Contained Trade Product Pack
FSN	Fully Specified Name
GTIN	Global Trade Item Number
IHTSDO®[1]	International Health Terminology Standards Development Organisation®
MP	Medicinal Product
MPP	Medicinal Product Pack
MPUU	Medicinal Product Unit of Use
NPC	National Product Catalogue
PBS	Pharmaceutical Benefits Scheme
PT	Preferred Term
RefSets	Reference sets as described by IHTSDO
TP	Trade Product
TPP	Trade Product Pack
TPUU	Trade Product Unit of Use
SI	International System of Units
SNOMED CT® – AU	SNOMED CT® Australian Release
SNOMED CT®	Systematized Nomenclature of Medicine–Clinical Terms®
TGA	Therapeutic Goods Administration
UML	Unified Modeling Language
WHO	World Health Organisation

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