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Australian Medicines Terminology Editorial Rules

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Product or document version	Date	Release comments
2.0	8 July 2014	Update from v2 model to AMT v3.
2.1	21 Oct 2016	This update features the following revisions: • rule changes made as a result of discussion and review by the AMT Support Group; • routine review and clarification to existing rules, in particular updates to those rules pertaining to descriptions for multi-component and multipack products; • implementation of the Agency Clinical Interface Descriptions project work; and • substance name changes related to the TGA International Harmonisation of Ingredient Names project work. Technical information provided in other documents has been removed, along with the majority of examples which can be viewed within the terminology browser.
2.2	30 Nov 2017	This update features updates and additions to: • Sections 4.7 Trade Product Unit of Use (TPUU), 4.8 Trade Product Pack (TPP) and 4.9 Containered Trade Product Pack (CTPP) in relation to products where two different formulations exist with the same Trade Product name. • Section 4.8.2.1, TPP Fully Specified Name definition • Appendix E.1, Continuous semi-solid preparations • Appendix E.2, Dual strength representation • Appendix K.1, Vaccines, has had a major update with new rules applied
2.3	31 May 2018	This update features updates and additions to: • Section 4.6.2 in relation to the strength representation of Trade Products. • 4.6.3.2 TP Fully Specified Names rules examples • Appendix E, Strength formats and Appendix E2.2 for Acceptable synonyms • Appendix G, Form • Appendix J, Container Types • Appendix K.1, Vaccines – examples

Product or document version	Date	Release comments
2.4	31 October 2018	This update features updates and additions to: • Substance name changes related to the TGA International Harmonisation of Ingredient Names project work • 4.2.5.2 Combination packs • 6.1 Australian Qualifier definition • Appendix E – General strength formats • Appendix G – Form and Appendix H, Proprietary descriptions and equivalents • Appendix J – Container Types
2.5	30 April 2019	This update features updates and additions to: • 4.6.2 TP details • 4.7.2 TPUU descriptions • 4.8 Trade Product Pack (TPP) • 4.9.2.4 CTPP Preferred Term rules • Appendix B.1 Discernible therapeutic differences to the base (clinically significant modifications) • Appendix G – Form • Appendix E.1 Strength expression rules for specific medication forms • Appendix E.3 Strength expression rules for specific substances • Appendix K.8 Herbal preparations
2.6	31 October 2019	This update features updates and additions to: • 4.2.4 Multi-component • 4.5.2.1 MPP Fully Specified Name definition • 4.5.2.3 MPP Preferred Term definition • 4.7.1.2 Exceptions for products with “inert substance” ingredients • 4.8.2.2.2 TPP Preferred Term brief definition – multi-component TPP • 4.9.2 CTPP descriptions • Appendix E – General strength formats • Appendix G – Form • Appendix J – Container types • Appendix K.8 Herbal preparations
2.7	30 April 2020	This update features updates and additions to: • Appendix E – General strength formats • Appendix F – Units of measure • Appendix J – Container types
2.8	31 October 2020	This update features updates and additions to: • 4.5.2.3 MPP Preferred Term definition • 4.6.2 TP details for specific population • Appendix E – Acceptable synonyms • Appendix F – Units of measure

Product or document version	Date	Release comments
2.9	30 April 2021	This update features updates and additions to: • Appendix F – Units of measure • Appendix F – Proportions
3.0	31 October 2021	This update features updates and additions to: • Appendix G – Form • 4.6.2 TP details for strength representation

Table of contents

1 Introduction

1.1 Purpose

This document specifies the editorial rules for the Australian Medicines Terminology (AMT) and focuses on the naming conventions and rules associated with all description types for concepts[1] in the AMT v3 model.

1.2 Intended audience

This document is designed for use by those who wish to understand the process and rules necessary for the creation of AMT descriptions from a practical point of view. This may include:

- Terminologists
- Health informaticians
- Health sector managers
- Clinical software vendors

1.3 Scope

The AMT editorial rules are limited to the practical naming conventions and rules necessary for creating medicine descriptions for those products which are within scope for the AMT.

1.4 Background

The AMT model was developed as a national medicines extension to the Australian Release of SNOMED CT® (SNOMED CT-AU). Input was received from a broad range of terminology experts and stakeholders including national and international terminologists, informaticians, clinicians, software vendors, health jurisdictions, the Pharmaceutical Benefits Division and the Therapeutic Goods Administration (TGA).

It has always been viewed as highly desirable to have the AMT model and editorial rules harmonised internationally as much as possible to encourage uptake of the AMT by software vendors, especially those multinational vendors offering their software for use in the acute care setting. The AMT editorial rules have their genesis in work undertaken by the National Health Service (UK) Dictionary of Medicines and Devices (dm+d) team. The Agency has further developed this work to reflect:

- the current AMT model;
- Australian clinical practice; and
- the complexity of many Australian products.

Changes to this document will occur to align with AMT model refinement, changes to the internal content authoring application, stakeholder and user feedback.

[1] See Section 3.3 for an explanation of clinical terminology concepts.

2 Notation

2.1 Extended Backus-Naur Form

The definitions are written using a notation for describing formal languages, called Extended Backus-Naur Form (EBNF). EBNF has been standardised by the ISO under the code ISO/IEC 14977:1996 [1], and uses the following characters.

Table 1: EBNF characters

Character	Name	Description
:=	Definition	The symbol on the left can be replaced by the expression on the right.
;	Terminating character	This identifies the end of a rule (called a “production rule”).
|	Logical OR	A choice, with alternative items separated by this symbol.
[…]	Option	Encloses optional items.
{ … }	Optional repetition	Encloses optional items that can be repeated zero or more times.
(…)	Arrangement in groups	Encloses items that need to be grouped together.
“ … ”	Double quotation	A terminal expression (that is, characters that appear exactly as shown).
(* … *)	Comment	Encloses a comment (that is, the characters inside are not part of the expression).
? … ?	Special sequence	A special sequence.
-	Exception	An exception to the rule.

The convention of using double quotation marks is extended to explanations within descriptions in this document.

For example: for generic products, the TP will consist of the TF_Name, which will be populated with the generic name, followed by the TF_Supplier, which will be populated by a “ ” and the sponsor/manufacturer/house brand name surrounded by “(” and “)”.

In natural language, the above statement would be equivalent to: For generic products, the TP will consist of the TF_Name, which will be populated with the generic name, followed by a space, and then the TF_Supplier, which will be populated by the sponsor/manufacturer/house brand name surrounded by curved brackets.

An example of the result of this would be: Methotrexate (Ebewe), where “Methotrexate” is the generic name, and “Ebewe” is the sponsor.

2.2 Tables

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

Table 2: Heading rows legend

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 (for example, rules tables are identified as such), so this document is entirely legible in greyscale print.

3 AMT model overview

The AMT provides descriptions of products using a taxonomy or hierarchical format, where each description type represents a different level of detail.

There are three main hierarchies of importance to those wishing to understand AMT content: *Australian substance*, *Australian qualifiers*, and *Australian products*. Each of these are discussed in detail in Chapters 5 and 6.

The hierarchies exist in a relational model, where each component of the model is shown in a box. The lines running between the boxes indicate a relationship between the two boxes and the cardinality ("1" or "*" (more than one)) represents the number of instances of one component in relation to another component.

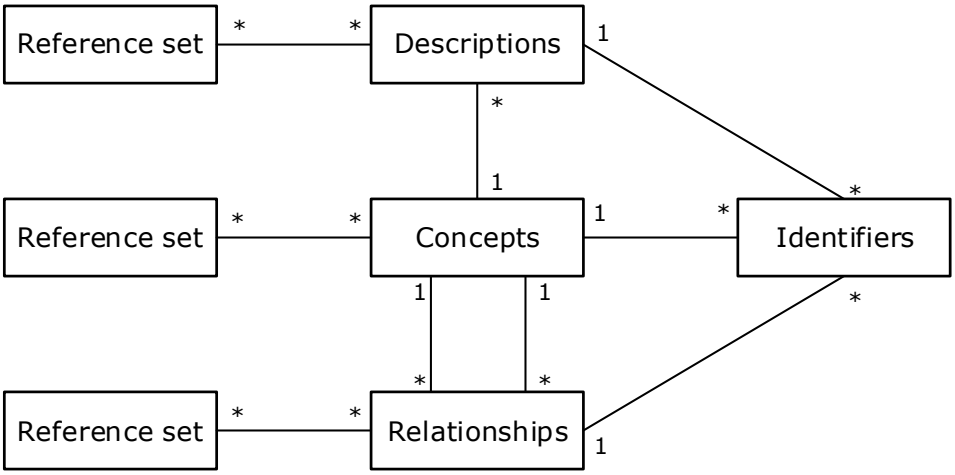

Figure 1: Diagram of a basic relational model

3.1 Identifiers

Every component of the model (description, concept and relationship type) has its own single unique identifier, which is assigned to it when it is created in the AMT. This identifier is a numeric sequence of 6 to 18 digits. Once created, an identifier always refers to the same component, and that component does not change meaning over its lifespan.

Unlike more traditional identifiers or codes, these identifiers in themselves carry no inherent meaning and cannot be used to derive any information about either the component itself, or about the hierarchy to which the component belongs.

3.2 Descriptions

Descriptions provide a human readable term for a given concept. They may be either a Fully Specified Name or a synonym. Synonyms may be further broken down into two types: the preferred synonym, which is known as the Preferred Term; and an acceptable synonym.

3.2.1 Fully Specified Name

The Fully Specified Name (FSN) is intended to provide an unambiguous way to identify that concept. The FSN does not necessarily represent the most commonly used or natural phrase for that concept. Each FSN ends with a "semantic tag" in parentheses, which indicates the hierarchy name or the level within a hierarchy to which the concept belongs.

For example:

- codeine + paracetamol (medicinal product)
- Panamax (paracetamol 500 mg) tablet, 50 tablets (trade product pack)
- container type (AU qualifier)
- flucloxacillin (AU substance)

3.2.2 Synonyms - Preferred Term

The Preferred Term (PT) is intended to capture the common word or phrase used by Australian clinicians to name that concept.

Unlike FSNs, PTs are not necessarily unique. Occasionally, the synonym for one concept may also be a synonym for a different concept. For example, “furosemide (frusemide)” may be the PT for both a Medicinal Product concept and a Substance concept.

3.2.3 Synonyms - acceptable synonym(s)

Acceptable synonyms represent any acceptable additional terms that are used by Australian clinicians to refer to the same concept as the FSN. Acceptable synonyms are optional, that is, not all concepts will have associated acceptable synonyms.

Acceptable synonyms, like PTs, are not required to be unique across concepts.

For example: within the AMT, the FSN for a Substance is “furosemide (AU substance)”, the PT is “furosemide (frusemide)” and an acceptable synonym is “furosemide”.

3.3 Concepts

In the context of this document, a “concept” is a clinical meaning identified by a unique numeric identifier that never changes. Each concept in the AMT has a single unique human readable FSN and one or more human readable synonyms, one of which is the designated Preferred Term. All other synonyms (where present) are designated as acceptable synonyms. All concepts are formally defined in terms of their relationships with other concepts. These “logical definitions” give explicit meaning which a computer can process and query on.

3.4 Relationships

Relationships are used to define how one concept is linked or related to another concept. Taken together, the relationships originating from a concept form a set of statements that define the meaning of the concept relative to the other concepts in the terminology.

Within the AMT model, the IS A relationships provide the bulk of the taxonomy (or hierarchy), while the HAS A relationships provide additional information about a given concept.

3.4.1 IS A relationships

The AMT uses a special type of relationship, known as IS A, to represent subtype/supertype (or child/parent) relationships between concepts. This relationship is used where a concept is wholly subsumed by another concept. This means that all of the relationships that are true for the parent, are automatically also true for the child.

A concept can have more than one IS A relationship to other concepts, either within the same hierarchy, or within a different hierarchy.

3.4.2 HAS A relationships

The AMT uses HAS A (attribute) relationships to show links from one concept to another concept, which provides further definition to the first concept.

A concept may have zero to many attribute relationships.

These relationship types are more fully represented in the full AMT model found in the *AMT v3 Technical Implementation Guide.* [2]

3.5 Reference sets

A reference set[2] is a file that groups terminology components together based on a common factor or provides additional information about terminology components. It is a flexible mechanism to support the evolution of the AMT and SNOMED CT-AU by allowing any form of extension to the terminology, linkages to other classifications and terminologies, and adding defining attributes for components.

The grouping together of a set of descriptions, concepts or relationships is the most common type of reference set, which is called a "Simple type reference set". An example is the *Medicinal product pack reference set*, which groups together all the concepts within the *Medicinal product pack* hierarchy. There are other reference set types that provide additional information about certain components. Examples are mapping between a proprietary code set to terminology, annotating text strings to a component, associating two terminology concepts (that are not linked via relationships), identifying concepts' Preferred Terms and acceptable terms, and representing numeric attributes of concepts.

Any number of reference sets can be used to support an AMT implementation. For ease of use, each of the AMT "Notable concept" hierarchies are provided in a convenient reference set without the implementer having to traverse the relationships to obtain the various product concepts.

For more detailed information on any of the above components, refer to the *AMT v3 Technical Implementation Guide*. [2]

3.6 The AMT model

The AMT may be viewed in its simplest form as a seven box model, comprising what are commonly referred to as the "seven notable concepts":

- Medicinal Product (MP) – a representation of the therapeutically active part of each substance in a product.
- Medicinal Product Unit of Use (MPUU) – a representation of the active substance, strength and dose form of a product.
- Medicinal Product Pack (MPP) - a representation of the active substance, strength, dose form and pack size of a product.
- Trade Product (TP) – a representation of the brand name of a product.
- Trade Product Unit of Use (TPUU) – a representation of the brand name, strength and dose form of a product.
- Trade Product Pack (TPP) – a representation of the brand name, strength, dose form and pack size of a product.
- Containered Trade Product Pack (CTPP) – a representation of the brand name, strength, dose form, pack size and container of a product.

These concepts and their principal relationships are diagrammatically represented in Figure 2.

[2] Colloquially referred to as a "refset".

The following figure represents both medicinal (generic) and trade (branded) descriptions at different levels of specificity, and may include information such as ingredient, strength, dosage form, pack size, and container type. Each level may be used to support different use cases. The left side of the diagram (shown in orange) represents the medicinal side of the model while the right side of the diagram (shown in blue) represents the trade side of the model.

The MP contains the least detailed description, and detail is gradually added as you move from the top left to the bottom right of the model diagram. The CTPP contains the most detailed information.

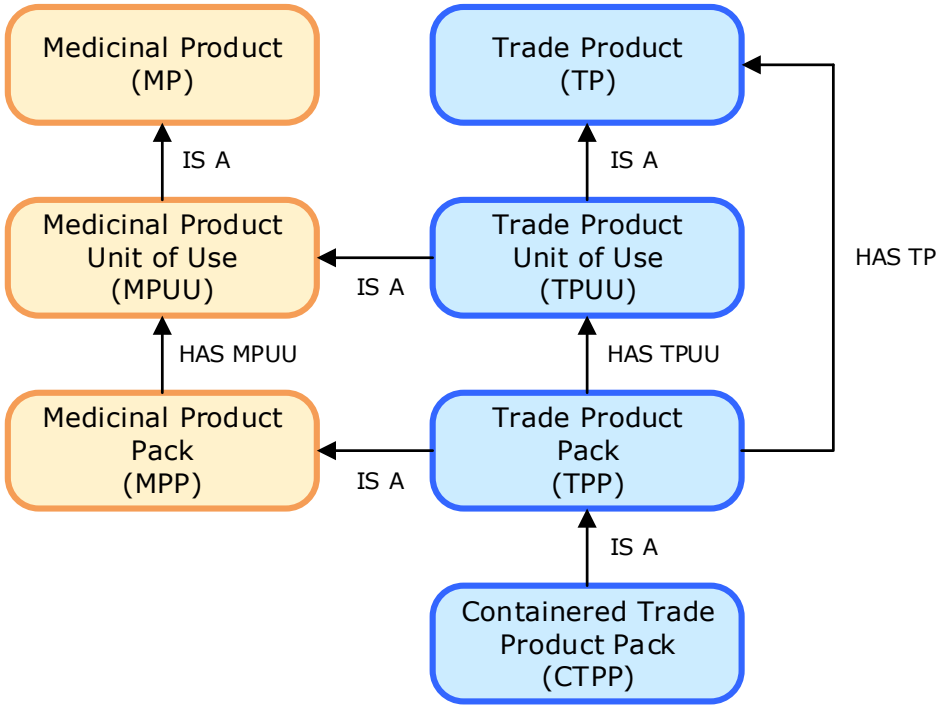

Figure 2: The AMT model (product concepts)

For further information on each of the seven notable concepts, refer to Chapter 4.

4 Product concepts

The AMT has conceptually been designed to encompass seven 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 concepts and their principal relationships are diagrammatically represented below.

To view all "product concept" descriptions currently in the AMT, open the Shrimp Terminology Browser (at http://ontoserver.csiro.au/shrimp) and select the latest release of the "SNOMED Clinical Terms Australian extension".

4.1 Syntax

AMT terms are constructed using EBNF syntax. For further details on EBNF, refer to Section 2.1.

4.2 Product types

For inclusion in the AMT, a product is defined as a medicinal preparation that can be attributed to a specific sponsor (see Glossary) as defined by a trade product name, one or more active ingredients[3], strength, form, pack size and container type. This corresponds to the product concept of CTPP, which represents the product concept with the most specific level of detail in the AMT model. An exception to this is extemporaneous products which may not be attributable to a specific sponsor.

The model handles the following types of products:

- Single ingredient
- Multi-ingredient
- Single component
- Multi-component
- Subpacks
- Combination packs

[3] AMT product concepts are defined by substances that are contained in the *Substance* hierarchy. To align with current clinical practice, substances in this context are referred to as active ingredients.

Each of the types of products is represented at different levels of the AMT model.

Table 3: Product matrix

	Single ingredient/ Multi-ingredient/ Single component	Multi-component/ Subpacks and multipacks/ Combination packs
Medicinal Product (MP)	Yes	
Medicinal Product Unit of Use (MPUU)	Yes	
Medicinal Product Pack (MPP)	Yes	Yes
Trade Product (TP)	Yes	Yes
Trade Product Unit of Use (TPUU)	Yes	
Trade Product Pack (TPP)	Yes	Yes
Containered Trade Product Pack (CTPP)	Yes	Yes

The section below explains the differences between multi-ingredient products, multi-component products and products with subpacks and products with component packs.

Definitions and rules for each of the product concepts are included in this chapter.

4.2.1 Single ingredient

A single ingredient product is one in which there is only one active ingredient in each Unit of Use (that is, MPUU or TPUU).

Concept examples (FSN) of single ingredient products include:

MP: amoxicillin (medicinal product)

MPUU: amoxicillin 500 mg capsule (medicinal product unit of use)

TPUU: Amoxil (amoxicillin 500 mg) capsule (trade product unit of use)

4.2.2 Multi-ingredient

A multi-ingredient product is one where two or more ingredients are compounded together and cannot be separated, for example, amoxicillin and clavulanic acid (as in Augmentin Duo). A multi-ingredient product is one in which there are multiple active ingredients in each Unit of Use (that is, MPUU or TPUU).

Concept examples (FSN) of multi-ingredient products include:

MP: lamivudine + zidovudine (medicinal product)

MPUU: lamivudine 150 mg + zidovudine 300 mg tablet (medicinal product unit of use)

TPUU: Combivir (lamivudine 150 mg + zidovudine 300 mg) tablet (trade product unit of use)

4.2.3 Single component

A single component product is one which contains only one unique Unit of Use within the pack (that is, it may contain multiple identical units of use). Note that the example is a single ingredient, single component product.

Concept examples (FSN) of single component products include:

MP: amoxicillin (medicinal product)

MPUU: amoxicillin 500 mg capsule (medicinal product unit of use)

MPP: amoxicillin 500 mg capsule, 20 capsules (medicinal product pack)

TPUU: Amoxil (amoxicillin 500 mg) capsule (trade product unit of use)

TPP: Amoxil (amoxicillin 500 mg) capsule, 20 capsules (trade product pack)

MP: lamivudine + zidovudine (medicinal product)

MPUU: lamivudine 150 mg + zidovudine 300 mg tablet (medicinal product unit of use)

MPP: lamivudine 150 mg + zidovudine 300 mg tablet, 60 tablets (medicinal product pack)

TPUU: Combivir (lamivudine 150 mg + zidovudine 300 mg) tablet (trade product unit of use)

TPP: Combivir (lamivudine 150 mg + zidovudine 300 mg) tablet, 60 tablets (trade product pack)

4.2.4 Multi-component

A multi-component product is one which contains two or more different units of use within the same pack (that is, the MPP has multiple MPUUs; the CTPP or TPP has multiple TPUUs). One of the components may be an inert substance in the case of a diluent supplied in the same packaging with the active component.

Note that when a product has two different units of use and one of these units of use is an inert diluent, the product will be modelled as a multi-component product and not as a combination product.

Concept examples (FSN) of multi-component products include:

MP: codeine + paracetamol + phenylephrine (medicinal product)

chlorphenamine + paracetamol + phenylephrine (medicinal product)

MPUU: codeine phosphate hemihydrate 9.5 mg + paracetamol 500 mg + phenylephrine hydrochloride 5 mg tablet (medicinal product unit of use)

chlorphenamine maleate 2 mg + paracetamol 500 mg + phenylephrine hydrochloride 5 mg tablet (medicinal product unit of use)

MPP: chlorphenamine maleate 2 mg + paracetamol 500 mg + phenylephrine hydrochloride 5 mg tablet [12 tablets] (&) codeine phosphate hemihydrate 9.5 mg + paracetamol 500 mg + phenylephrine hydrochloride 5 mg tablet [36 tablets], 48 tablets (medicinal product pack)

TPUU: Codral Day and Night Cold and Flu (Day) (codeine phosphate hemihydrate 9.5 mg + paracetamol 500 mg + phenylephrine hydrochloride 5 mg) tablet (trade product unit of use)

Codral Day and Night Cold and Flu (Night) (chlorphenamine maleate 2 mg + paracetamol 500 mg + phenylephrine hydrochloride 5 mg) tablet (trade product unit of use)

TPP: Codral Day and Night Cold and Flu (chlorphenamine maleate 2 mg + paracetamol 500 mg + phenylephrine hydrochloride 5 mg) tablet [12 tablets] (&) (codeine phosphate hemihydrate 9.5 mg + paracetamol 500 mg + phenylephrine hydrochloride 5 mg) tablet [36 tablets], 48 tablets (trade product pack)

Note that MPUUs and TPUUs may never be multi-component, as they always represent a single Unit of Use component. These will have a relationship to single component MPs and TPs.

However, MPPs, TPs, TPPs and CTPPs may be multi-component.

MPs may never be multi-component; however, they can reflect an individual component of a multi-component product.

4.2.4.1 Dual chamber products

A dual chamber product is a multi-component product which contains two units of use joined together within the one container type. Each component is defined as a 'chamber' unit of use, even though it cannot be separated from the other, or physically handled. The two chambers contain separate ingredients, one of which may be an inert substance. These two chambers are mixed within the container before the final dose is ready to be administered.

Concept examples (FSN) of dual chamber products include:

MP	inert substance (medicinal product) leuprorelin (medicinal product)
MPUU	inert substance diluent, 1.5 mL chamber (medicinal product unit of use) leuprorelin acetate 7.5 mg modified release injection, 7.5 mg chamber (medicinal product unit of use)
MPP	inert substance diluent [1 x 1.5 mL chamber] (&) leuprorelin acetate 7.5 mg modified release injection [1 x 7.5 mg chamber], 1 dual chamber syringe (medicinal product pack)
TPUU	Lucrin Depot (inert substance) diluent, 1.5 mL chamber (trade product unit of use) Lucrin Depot (leuprorelin acetate 7.5 mg) modified release injection, 7.5 mg chamber (trade product unit of use)
TPP	Lucrin Depot (inert substance) diluent [1 x 1.5 mL chamber] (&) (leuprorelin acetate 7.5 mg) modified release injection [1 x 7.5 mg chamber], 1 dual chamber syringe (trade product pack)
CTPP	Lucrin Depot (inert substance) diluent [1 x 1.5 mL chamber] (&) (leuprorelin acetate 7.5 mg) modified release injection [1 x 7.5 mg chamber], 1 dual chamber syringe (containered trade product pack)

4.2.5 Packs

A product pack (MPP, CTPP or TPP) always contains components (MPUUs or TPUUs) in a primary container. The primary container is the lowest level (non-ingestible) container which can be physically handled, that immediately surrounds the therapeutic good. Examples of a primary container are: blister pack, bottle, vial, cartridge, and injection device. Some products may also have a secondary container that envelops the components contained within one or more primary containers.

The component(s) within a primary container may:

- have the same active ingredients, strength and form;
- have the same active ingredients, different strengths but similar form; or
- have different active ingredients, different strengths but similar form.

When there are multiple identical representations of the same component(s) within the same type of primary container, the product pack (MPP or CTPP) is said to have subpacks. See Section 4.2.5.1 for further details.

Where there are multiple different components within a secondary container, the product pack is said to be a combination pack. See Section 4.2.5.2 for further details.

4.2.5.1 Subpacks and multipacks

A multipack is a product which contains two or more identical packs, known as subpacks, within a pack.

Subpacks and multipacks are only represented for specific product categories. These categories include, but are not limited to, oral contraceptives and hormone replacement therapy products. They will be added when they are deemed to be required:

- for consistency;
- for clinical reasons; or
- when they are represented as subpacks in the Pharmaceutical Benefits Scheme (PBS).

4.2.5.2 Combination packs

If a product pack contains multiple units of use, with each Unit of Use contained in a separate primary container, then the product pack is deemed to be a combination pack. The individual packs within a combination pack may have different active ingredients, or the same ingredients in different strengths (for example, Actair Initiation Treatment). They may have the same form or have different forms.

A product can also be a combination pack if there is one Unit of Use but with two or more Unit of Use Size values and contained in a separate primary container (for example, Voltaren No Mess Applicator).

Note that when a product has two different units of use and one of these units of use is an inert diluent, the product will be modelled as multi-component and not as a combination.

It should be noted that some individual packs which are described as an MPP or TPP may not actually be available as a TPP, even though the TPP exists within the AMT (that is, an individual pack in a combination pack may only be available as part of the combined CTPP and is not commercially available separately).

Although the individual container types may be different, the CTPP representing the combination pack will have an associated container type of "pack".

See Appendix J Container Types for further detail on containers.

4.3 Medicinal Product (MP)

4.3.1 Medicinal Product definition

A Medicinal Product (MP) is the abstract representation of the intended active ingredients or substances (devoid of strength and form), which when formulated as a therapeutic good, are intended for use in treating or preventing disease in humans. 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 and complementary medicines, as well as prescription medicines.

Excipients will not be modelled in the AMT unless presented with a clear use case that is agreed to by the relevant Australian Digital Health Agency governance body or bodies. A Medicinal Product will only define inactive (inert) ingredients where these are part of multi-component products, or diluents provided for the preparation of the actual administrable form of a product.

The Medicinal Product name is derived from the intended active ingredient, with the following knowledge or rules incorporated:

- the precise ingredient (with modification) is specified, where this is therapeutically necessary or clinically significant (refer to Appendix B);
- the Medicinal Product defines a group of products, which contain substances with the same active entity; and
- where the ingredient is an enantiomer, (that is, an ingredient that exists as two stereoisomers) the specific enantiomer will only be described if it is defined as part of the Australian Approved Name (AAN) or similar. For example the AMT uses tryptophan, and not l-tryptophan.

Within the AMT a "base" is defined as the active moiety of the ingredient name (that is, the segment of the molecule which has an intended therapeutic effect on the body). A "primary modified base" is defined as a base plus an additional entity which is combined with the base (but does not have an intended therapeutic effect on the body). Primary modified bases may include salts, esters or waters of hydration. It may be a modification to the base molecule to assist with stability, solubility, bioavailability, or so on. A "secondary modified base" is a primary modified base which has been further modified in some way (but this modification does not have an intended therapeutic effect on the body). This modification frequently indicates the hydration status of the primary modified base but may also be another modification, such as an ester.

Table 4: Examples of ingredient types

Ingredient type	Ingredient name	base segment	primary modification segment	secondary modification segment
base	atenolol	atenolol	N/A	N/A
primary modified base	ranitidine hydrochloride	ranitidine	hydrochloride	N/A
	amoxicillin trihydrate	amoxicillin	trihydrate	N/A
	betamethasone sodium phosphate	betamethasone	sodium phosphate	N/A
secondary modified base	suxamethonium chloride dihydrate	suxamethonium	chloride	dihydrate
	azithromycin monohydrate hemiethanolate	azithromycin	monohydrate	hemiethanolate

All medicines with the same base active ingredient will be considered to be equivalent within the terminology unless evidence exists to indicate a clinical difference. Refer to Appendix B.1 for full details and examples. A new MP, containing modification details, will be created if new evidence indicating a difference becomes available. Please note that this clinically based criterion might override the following types of analysis:

- physiological/pharmacokinetic/pharmacodynamic equivalence
- bioequivalence
- equivalence within decision support

Where the substance modification is deemed to be clinically important and therefore represented in the MP, this modified substance is also the intended active ingredient. All Medicinal Product concepts will have a relationship to each of their active ingredients, using one or more HAS INTENDED ACTIVE INGREDIENT relationships.

For multi-ingredient products, the associated MP Fully Specified Name will always include all of the individual substances, while the MP Preferred Term will show ingredients according to AMT-MP-PT-3 in Section 4.3.2.4.

The MP of "inert substance" will be created where inactive (inert) ingredients are part of multi-component products or diluents provided for the preparation of the actual administrable form of a product.

Table 5: Examples of Medicinal Product FSNs and PTs

Type of product	Fully Specified Name	Preferred Term
Single ingredient	amoxicillin (medicinal product)	amoxicillin
Single ingredient – primary modified base exception	calcium carbonate (medicinal product)	calcium carbonate
Multi-ingredient	codeine + paracetamol (medicinal product)	paracetamol + codeine

4.3.2 MP descriptions

4.3.2.1 MP Fully Specified Name definition

The Fully Specified Name of a Medicinal Product follows the syntax[4]:

```
MP FSN := MP_Ingredient_Details " (medicinal product)"
```

where the component parts are described as follows:

[4] For an explanation of syntax conventions, refer to Section 2.1.

Table 6: MP description

Description Component	Description
MP_Ingredient_Details	A list of the Fully Specified Names (without the semantic tag) of each of the MP's intended active ingredients, with ingredients of the same MP component separated by a " + " and grouped together. Ingredients are ordered alphanumerically, irrespective of casing. Exception: Where the intended active ingredient is "inert substance", this will always be shown last. If the intended active ingredient name is the same for more than one ingredient in an MP, then the intended active ingredient name is only shown once. If the individual ingredient or set of intended active ingredients is exactly the same for more than one component in a multi-component product, the MP for the component will only be shown once. If the individual ingredient or set of intended active ingredients is exactly the same for more than one product in a combination product, the MP for the product will only be shown once.
(medicinal product)	The semantic tag used in the Fully Specified Name of all MP concepts.

4.3.2.2 MP Fully Specified Name rules

Table 7: MP Fully Specified Name rules

Rule ID	Description
AMT–MP-FSN-1	Capitalisation rules as defined in Appendix A apply.
AMT–MP–FSN-2	The MP Fully Specified Name will be derived from the intended active ingredient of the relevant Substance Fully Specified Name. EXCEPTION The full name of an ingredient, including the modification (that is, the Substance Fully Specified Name without the semantic tag) will be used in the case of discernible therapeutic differences to the base. Where a primary or secondary modified base is not clinically significant but the representation of the modification is required for safety reasons, then the MP will be represented as the primary or secondary modification, as appropriate. See Appendix B for further information.
AMT–MP-FSN-3	The MP Fully Specified Name will include all intended active ingredients for a multi-ingredient preparation. The MP Fully Specified Name will also include the description "inert substance" as the actual ingredient name where inactive (inert) ingredients are part of multi-component products or diluents provided for the preparation of the actual administrable form of a product.
AMT–MP-FSN-4	The MP Fully Specified Name will describe a single component MP concept.

4.3.2.3 MP Preferred Term definition

The Preferred Term of an MP will, by default, follow the syntax:

```
MP PT := Ingredient_Details
```

where the component parts are described as follows:

Table 8: MP Preferred Term description

Description Component	Description
Ingredient_Details	A list (alphanumerical by default) of the Preferred Terms of each of the MP's intended active ingredients, with: • ingredients of the same MP component separated by a " + " and grouped together; • MP components, which contain exactly the same ingredients, only shown once. • If the intended active ingredient name is the same for more than one ingredient in an MP, then the intended active ingredient name is only shown once. • By default the order of this list is alphanumerical, irrespective of casing, however a "Preferred term order" may be assigned. Refer to AMT-MP-PT-4 for further details.

Note that variation to this syntax may occur to meet the requirements of clinical practice as agreed by the appropriate AMT governance body. In particular, the Preferred Term of MPs with more than three active ingredients per component may be manually created (refer to rule AMT-MP-PT-3 in Section 4.3.2.4 for more details, and to Appendix D for exceptions).

4.3.2.4 MP Preferred Term rules

Table 9: Medicinal Product Preferred Term rules

Rule ID	Description
AMT-MP-PT-1	Capitalisation rules as defined in Appendix A apply.
AMT-MP-PT-2	The MP Preferred Term will be derived from the intended active ingredient of the relevant Substance Preferred Term. EXCEPTION The full name of an ingredient, including the modification (that is, the Substance Preferred Term) will be used in the case of discernible therapeutic differences to the base. Where a primary or secondary modified base is not clinically significant but the representation of the modification is required for safety reasons, then the MP will be represented as a primary or secondary modification, as appropriate. See Appendix B for further information.
AMT-MP-PT-3	For Medicinal Products with greater than three intended active ingredients, AMT authors may create a clinically intuitive name based on the review of each individual product. Note that to date, this has only been implemented for influenza vaccines. EXCEPTION The following groups of products will retain all ingredient names in the MP PT: • vaccines (note that due to the length of the intended active ingredient names for vaccine ingredients, these products may have an abbreviated term created regardless of the number of ingredients); and • large volume parenteral injections. The addition of items to the exceptions list will be reviewed on a case-by-case basis. The current exception list is attached as Appendix D. The MP Preferred Term will also include the description "inert substance" as the actual ingredient name where inactive (inert) ingredients are part of multi-component products or diluents provided for the preparation of the actual administrable form of a product.

Rule ID	Description
AMT-MP-PT-4	For multi-ingredient products, the order of the ingredients will be based on the order used by the innovator product in the AMT (that is, the AMT product with the lowest ARTG ID). All subsequent products with the same combination of ingredients will follow the order of the innovator product. Where the innovator product stipulates the ingredients as part of the TP, then the ingredients will follow that order. Example: **MP FSN:** aspirin + clopidogrel (medicinal product) **MP PT:** clopidogrel + aspirin **MP FSN:** clavulanic acid + ticarcillin (medicinal product) **MP PT:** ticarcillin + clavulanic acid
AMT-MP-PT-5	The MP Preferred Term will describe a single component MP concept.

4.4 Medicinal Product Unit of Use (MPUU)

4.4.1 Medicinal Product Unit of Use definition

A Medicinal Product Unit of Use (MPUU) is an abstract concept representing the properties of one or more equivalent Trade Product Units of Use (TPUUs). Equivalent TPUUs are those that have the same intended active ingredient (or the same precise active ingredients, where the modification is therapeutically necessary), as well as the same strength, dose form, and Unit of Use, and where the TPUUs are considered to be quantitatively equivalent. The MPUU will be represented by the associated MP's ingredient name, strength, form and, where appropriate, the Unit of Use. An MPUU will include single dose units of inactive (inert) ingredients (where these are part of 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 available strength of a product. If an existing product has a change of ingredient, such that it does not conform to the ingredient of the original MPUU, then a new MPUU will be created for the new product.

The MPUU may represent the name of a primary or secondary modified base for safety reasons or where this is the Australian Basis of Strength Substance (BoSS) representation of the active ingredient.[5] For example:

- Where the primary or secondary modified base is not clinically significant but is required for reasons of safety. For example, perindopril erbumine and perindopril arginine. In this case, two modified bases exist where the BoSS is the modified base. Although the modified base is not clinically significant, this needs to be represented as it is relevant to decisions concerning the dose.

Example (MPUU PT): perindopril arginine 5 mg tablet

perindopril erbumine 4 mg tablet

[5] The BoSS is the name of the ingredient that the strength of the product is based on. It may be a base, primary modified base or secondary modified base.

- Where the BoSS is less modified than the IAI, the modification details will appear in brackets. For example, where the BoSS is amphotericin B and the IAI is amphotericin B lipid complex, the MPUU Preferred Term would be “amphotericin B (as lipid complex) 100 mg/20 mL injection, vial”.

All MPUU concepts will also have relationships to all of their intended active ingredients, as identified by the HAS INTENDED ACTIVE INGREDIENT and HAS AUSTRALIAN BoSS relationships.

The following table provides examples of MPUU Fully Specified Names and Preferred Terms for all different strength representation rules. Refer to Appendix E for further details.

Table 10: Examples of MPUU Fully Specified Names and Preferred Terms for different strength representation rules

Type of product	Fully Specified Name	Preferred Term
creams and ointments, ear preparations, enemas, gels, eye preparations, intravenous infusions, injections, lotions, mouthwashes, powders, sachets, sunscreens	hydrocortisone 10 mg / 1 g cream (medicinal product unit of use)	hydrocortisone 1% cream
capsules and tablets, inhalations, powders for injection, nasal drops, oral liquids, spray preparations	diclofenac sodium 50 mg enteric tablet (medicinal product unit of use)	diclofenac sodium 50 mg enteric tablet
hormone replacement therapy patch	estradiol 100 microgram / 24 hours patch (medicinal product unit of use)	estradiol 100 microgram/24 hours patch
nicotine replacement therapy patch	nicotine 10 mg / 16 hours patch (medicinal product unit of use)	nicotine 10 mg/16 hours patch
glyceryl trinitrate patch	glyceryl trinitrate 10 mg / 24 hours patch (medicinal product unit of use)	glyceryl trinitrate 10 mg/24 hours patch
analgesic patch	buprenorphine 20 microgram / 1 hour patch (medicinal product unit of use)	buprenorphine 20 microgram/hour patch

4.4.2 MPUU descriptions

4.4.2.1 MPUU Fully Specified Name definition

The Fully Specified Name of an MPUU follows the syntax:

```
MPUU FSN :=    Ingredients_With_Strength “ ” Form
               [“, ” Unit_Of_Use_Details]
               “ (medicinal product unit of use)”
```

where the component parts are described as follows:

Table 11: MPUU description

Description Component	Description
Ingredients_With_Strength	An alphanumerical list of the name and strength (if available) of each of the BoSS ingredients of the MPUU, where: • The name string and strength string (for the same ingredient) are separated by a space. • The name and strength pairs for different ingredients are separated by a " + ". • The ingredient(s) are based on the MPUU's BoSS. This may be a base or a modified substance. • The Strength component is based on the strength of the MPUU's BoSS ingredients. It is a representation of the numerator and denominator Strength components of the BoSS. • If no BoSS ingredient exists, then the substance details from the MP will be used. • If no BoSS strength exists, then the strength representation shown will be the text string from the Other Strength Representation if it exists (for example, bandages and dressings), otherwise no strength will be shown (for example, representing inert substances, non-medicated dressings, diagnostic aids and nutritional supplements).
Form	The manufactured dose form of the MPUU, defined in a non-proprietary way.
Unit_Of_Use_Details	A list of the Unit of Use details, which may include: • Unit of Use Size (UoUS): The size of the Unit of Use. • Unit of Use: The unit dose item that can be physically handled. When these values are shown, the first of these is preceded by a comma followed by a space. Note that the Unit of Use Size (value and units) is not shown when: • it has a value of "1" and a unit that matches the Preferred Term of the MPUU's Form (or one of this Form's parents in the form hierarchy6); OR • when it has a value of "1" and a unit of "each"; OR • when the Unit of Use is either "continuous" or "measure". For any value >= 10,000 a space will be included after every third digit starting from the right. For example: 10 000; 500 000; 1 000 000.
(medicinal product unit of use)	The semantic tag used in the Fully Specified Name of all MPUU concepts.

Note that the Preferred Term of MPUUs with more than three intended active ingredients will be manually created in some cases, using the manually created MP ingredient details (refer to rule AMT-MP-PT-3 in Sections 4.3.2.4, and Appendix D for more details).

[6] Australian concept > Australian qualifier > form.

4.4.2.2 MPUU Fully Specified Name rules

Table 12: MPUU Fully Specified Name rules

Rule ID	Description
AMT-MPUU-FSN-1	Capitalisation rules as defined in Appendix A apply.
AMT-MPUU-FSN-2	The MPUU ingredient will be derived from the intended active ingredient, as defined by its associated BoSS ingredient. Therefore, where a modified base is the BoSS, the MPUU will represent that ingredient name. EXCEPTIONS Where representation of the modified base in the MP is required for safety reasons (refer to Appendix B), the relevant MPUU will also represent the modified base. Where the BoSS is less modified than the IAI, the modification details will appear in brackets. For example, where the BoSS is amphotericin B and the IAI is amphotericin B lipid complex, the MPUU Preferred Term would be “amphotericin B (as lipid complex) 100 mg/20 mL injection, vial”.
AMT-MPUU-FSN–3	Strength expression. The MPUU Fully Specified Name will include strength expression (if available). The strength expression general rules and application to specific medication forms is outlined in Appendix E. EXCEPTIONS See AMT-APP-STR-9 in Appendix E.
AMT-MPUU-FSN–4	Form. The form is derived from the *TGA Approved Terminology for Medicines*, Dosage Forms (Section 8.3) [3]. The form expressed is the parent form (that is, the general form is used in the medicinal concepts, whereas the more specific form is used in the Trade concepts). The form will be expressed as a singular form (for example, tablet, ampoule). For further detail on AMT dose forms refer to Appendix G. EXCEPTION Where the specific form is deemed therapeutically necessary to support clinical decisions at the MPUU level, the form is expressed as the specific form. For example a therapeutically significant form such as “modified release injection” would be included in the MPUU but a non-significant form such as “powder for injection” would appear as the parent form of “injection”.

4.4.2.3 MPUU Preferred Term definition

The Preferred Term of an MPUU, by default, follows the syntax:

```
MPUU PT :=     Ingredients_With_Strength “ ” Form
               [“, ” Unit_Of_Use_Details]
```

where the component parts are described as follows:

Table 13: MPUU Preferred Term description

Description Component	Description
Ingredients_With_Strength	The name and strength (if available) of each of the ingredients of the MPUU, where: • the name string and strength string (for the same ingredient) are separated by a space; AND

Description Component	Description
	• the name and strength pairs for different ingredients are separated by a " + "; AND • the list, by default, is in alphanumerical order of the ingredient names. However, when the "PreferredTermOrder" description of the associated MPUU is populated, this order is used instead. The ingredient(s) are based on the MPUU's BoSS. This may be a base or a modified base substance. If no BoSS ingredient exists, then the substance details from the MP will be used. The Strength component is based on the strength of the MPUU's BoSS ingredient. The Strength component may be one of the following: • A representation of the numerator and denominator strength; OR • A representation of the numerator and denominator strength, followed by the Other Strength Representation; OR • Other Strength Representation; OR • Other Strength Representation followed by a representation of the numerator and denominator strength. If the Strength component includes a representation of the numerator and denominator Strength components of the BoSS and the value of the denominator units is equal to "1", then this value will not be shown. For example, 500 mg/mL, not 500 mg/1 mL. If the Strength component includes a representation of the numerator and denominator Strength components of the BoSS, then the associated strength units (Unit of Measure (UoM)) are plural units if the associated strength value > 1. Exceptions: For the units of measure of "microgram" the Preferred Term is used instead of the plural units. If no BoSS strength exists, then the strength representation shown will be the text string from the Other Strength Representation if it exists (for example, bandages and dressings), otherwise no strength will be shown (for example, inert substances, non-medicated dressings, diagnostic aids and nutritional supplements).
Form	The manufactured dose form of the MPUU, defined in a non-proprietary way.
Unit_Of_Use_Details	A list of the Unit of Use details, which may include: • Unit of Use Size (UoUS): The size of the Unit of Use. • Unit of Use: The unit dose item that can be physically handled. When these values are shown, the first of these is preceded by a comma followed by a space. Note that the Unit of Use Size (value and units) is not shown when: • it has a value of "1" and a unit that matches the Preferred Term of the MPUU's Form (or one of this Form's parents in the form hierarchy); OR • when it has a value of "1" and a unit of "each"; OR • when the Unit of Use is either "continuous" or "measure"; OR • it is the same as the preferred strength denominator (value and units) for all of its ingredients; OR • there is only one ingredient and the strength denominator value does not exist and the strength numerator (value and units) are the same as Unit of Use Size. For any value >= 10,000 a space will be included after every third digit starting from the right. For example: 10 000; 500 000; 1 000 000.

The following table shows the different ingredient types and their respective MPUU representations, with an example of each type of ingredient.

Table 14: Examples of ingredient types and associated MPUU representations

Ingredient Type	BoSS	MP	MPUU
base: abciximab	base abciximab	base abciximab	base abciximab
primary modified base: ranitidine hydrochloride	base ranitidine	base ranitidine	base ranitidine
primary modified base: rabeprazole sodium	primary modified base rabeprazole sodium	base rabeprazole	primary modified base rabeprazole sodium
clinically significant modified base, BoSS = base: erythromycin ethylsuccinate	base erythromycin	primary modified base erythromycin ethylsuccinate	base erythromycin (as ethylsuccinate)

Note that variation to this syntax may occur to meet the requirements of clinical practice as agreed by the appropriate AMT governance body. In particular, the Preferred Term of MPUUs with more than three active ingredients may be manually created (refer to rule AMT-MP-PT-3 in Section 4.3.2.4 for more details).

For example: for a product containing potassium available from multiple sources (for example, Chlorvescent) the MPUU would additionally contain the total amount of potassium (in millimoles) as follows:

Term according to rules: potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg effervescent tablet

Created term: potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) effervescent tablet

4.4.2.4 MPUU Preferred Term rules

Table 15: MPUU Preferred Term rules

Rule ID	Description
AMT-MPUU-PT-1	Capitalisation rules as defined in Appendix A apply.
AMT-MPUU-PT-2	The MPUU ingredient will be derived from the intended active ingredient, as defined by its associated BoSS ingredient. Therefore, where a modified base is the BoSS, the MPUU will represent that ingredient name. EXCEPTIONS Where representation of the modified base in the MP is required for safety reasons (refer to Appendix B), the relevant MPUU will also represent the modified base. Where the BoSS is less modified than the IAI, the modification details will appear in brackets. For example, where the BoSS is amphotericin B and the IAI is amphotericin B lipid complex, the MPUU Preferred Term would be “amphotericin B (as lipid complex) 100 mg/20 mL injection, vial”.

Rule ID	Description
AMT-MPUU-PT-3	Strength expression. The MPUU Preferred Term will include strength expression (if available). The strength expression general rules and application to specific medication forms is outlined in Appendix E. EXCEPTION See AMT-APP-STR-9 in Appendix E. Strength expression may include an alternative strength representation different to the typical numerator/denominator strength expression. It may include a dual strength representation. Refer to Appendix E.2.
AMT-MPUU-PT-4	Form. The form is derived from the TGA Approved Terminology for Medicines, Dosage Forms. The form expressed is the parent form (that is, the general form is used in the medicinal concepts, whereas the more specific form is used in the Trade concepts). The form will be expressed as a singular form (for example, tablet, ampoule). EXCEPTION Where the specific form is deemed therapeutically necessary to support clinical decisions at the MPUU level, the form is expressed as the specific form. For example a therapeutically significant form such as “modified release injection” would be included in the MPUU but a non-significant form such as “powder for injection” would appear as the parent form of “injection”.

4.5 Medicinal Product Pack (MPP)

4.5.1 Medicinal Product Pack definition

A Medicinal Product Pack (MPP) is an abstract concept representing the properties of one or more quantitatively equivalent Trade Product Packs (TPPs). Quantitatively equivalent TPPs are those that have the same base active ingredient (or the same precise active ingredients, where the modified base is therapeutically necessary, for example, where the active ingredient is discernibly therapeutically different to the base – refer to Appendix B.1), as well as the same strength, dose form and pack size.

Note that every MPP will have one or more corresponding TPPs associated with it.

4.5.2 MPP descriptions

4.5.2.1 MPP Fully Specified Name definition

The Fully Specified Name of an MPP follows the syntax:

```
MPP FSN :=    MPUU_Details {“ (&) ” MPUU_Details} “, ”
              Total_Quantity_Size_Details “ (medicinal product pack)”
```

where the component parts are described as follows:

Table 16: MPP Fully Specified Name description

Description Component	Description
MPUU_Details	The details about an individual MPUU that is contained within the MPP, including: • the list of ingredients and strengths (formatted as per MPUU Fully Specified Name's Ingredients_With_Strength component) contained in the given MPUU component (where "MPP has MPUU"). This list is ordered alphanumerically based on the BoSS, followed (if necessary) by descending strength order based on the BoSS; and • the dose form of the MPUU, for prescribing, dispensing or administration, as defined for the corresponding MPUU; and • for multi-component products only, the quantity and size of this MPUU in the given MPP is represented inside square brackets. This detail is defined by the Unit of Use quantity value followed by " x ", followed by the Unit of Use Size value and units (separated by a space), followed by a space and the Unit of Use quantity unit. For example: [1 x 250 mg vial]. The Unit of Use Size value and units will not be shown when it is equal to "1 each". If the Unit of Use quantity value is greater than "1" then plural units are used for the associated quantity units (for example, tablets, capsules, vials) with the exception of "microgram".

Description Component	Description
Total_Quantity_Size_Details	A list of the Total Quantity Size details, which may include: • Unit of Use quantity value: The quantity of the Unit of Use. • Unit of Use quantity unit: The quantity of the unit dose item(s) that can be physically handled. • This component usually includes the Unit of Use quantity value and units, separated by a space (for example, 25 tablets). If the value field is greater than "1" then plural units are used for the associated quantity units (for example, tablets, capsules, vials) with the exception of "microgram". • If the MPP represents a single component product, then Total_Quantity_Size_Details is represented by the Unit of Use quantity value, followed by " x ", followed by the Unit of Use Size value followed by a space, then the Unit of Use Size unit followed by a space, and the Unit of Use quantity unit. (for example, 5 x 2 mL vials). • If the MPP has an associated subpack concept, then Total_Quantity_Size_Details is represented by the Subpack_Details. The Subpack_Details is represented by the MPP.Subpack quantity value (for example, 4), " × ", and then the result of the sum of the individual Unit of Use quantity values of all of the components (for example, 112) divided by the MPP.Subpack quantity value, followed by a space, and then the Unit of Use quantity units (for example, tablets). For example: 4 x 28 tablets • If the MPP represents a multi-component product which does not have an associated subpack and is not itself a subpack, and the units of use all share the same dose form, then Total_Quantity_Size_Details is represented by the total of the Unit of Use quantity values for all of the components, followed by a space, and the Unit of Use quantity units. Note that the Unit of Use quantity units will always be plural. For example: the Total_Quantity_Size_Details is represented by "24 tablets" in the following MPP Fully Specified Name - codeine phosphate hemihydrate 6 mg + paracetamol 500 mg + pseudoephedrine hydrochloride 30 mg tablet [16 tablets] (&) paracetamol 500 mg + pseudoephedrine hydrochloride 30 mg + triprolidine hydrochloride 1.25 mg tablet [8 tablets], 24 tablets (medicinal product pack) • If the MPP represents a multi-component product which does not have an associated subpack and is not itself a subpack, and the units of use do not share the same dose form, then Total_Quantity_Size_Details is represented by the text "1 pack". • If the MPP represents a multi-component product and one or more of the components is a subpack concept, then Total_Quantity_Size_Details is represented by the text "1 pack". • If the MPP represents a dual chamber product, which may or may not have an associated subpack, then Total_Quantity_Size_Details is represented by the number of actual dual chambered entities within that pack size (for example, 1 dual chamber syringe). Note that the Total_Quantity_Size_Details for a subpack will always be plural (for example, 5 dual chamber syringes). • If the MPP represents a combination product then Total_Quantity_Size_Details is represented by the text "1 pack". For any value >= 10,000 a space will be included after every third digit starting from the right. For example: 10 000; 500 000; 1 000 000.
(medicinal product pack)	The semantic tag used in the Fully Specified Name of all MPP concepts.

4.5.2.2 MPP Fully Specified Name rules

Table 17: MPP Fully Specified Name rules

Rule ID	Description
AMT-MPP-FSN-1	Capitalisation rules as defined in Appendix A apply.
AMT-MPP-FSN-2	The MPP ingredient will be derived from the intended active ingredient, as defined by its associated BoSS ingredient. Therefore, where a modified base is the BoSS, the MPP will represent that ingredient name, otherwise the MPP will represent the ingredient name as defined by the MP (that is, a modified base will only be displayed if it is the BoSS). EXCEPTION Where representation of the modified base in the MP is required for safety reasons (refer to Appendix B), the relevant MPP will also represent the modified base. The MPP Fully Specified Name will also include the description “inert substance” as the actual ingredient name where inactive (inert) ingredients are part of multi-component products or diluents provided for the preparation of the actual administrable form of a product. For example: inert substance diluent [1 x 4 mL ampoule] (&) valproate sodium 400 mg injection [1 x 400 mg vial], 1 pack (medicinal product pack)
AMT-MPP-FSN-3	Strength expression All MPP Fully Specified Name will include a strength expression when available. The strength expression general rules and application to specific medication forms are outlined in Appendix E. EXCEPTION There are occasions when this is not applicable. Examples of this include aqueous cream (when used as a substance and not as a product), water for irrigation, water for injection. **Note:** The addition to the exceptions list will be reviewed on a case-by-case basis. Refer to Appendix E.
AMT-MPP-FSN-4	Form. The form is derived from the TGA Approved Terminology for Medicines, Dosage Forms. The form expressed is the parent form (that is, the general form is used in the medicinal concepts, whereas the more specific form is used in the Trade concepts). The form will be expressed as a singular form (for example, tablet, ampoule). EXCEPTION Where the specific form is deemed therapeutically necessary to support clinical decisions at the MPUU level, the form is expressed as the specific form. For example a therapeutically significant form such as “modified release injection” would be included in the MPUU but a non-significant form such as “powder for injection” would appear as the parent form of “injection”.

4.5.2.3 MPP Preferred Term definition

The Preferred Term of an MPP, by default, follows the syntax:

```
MPP PT :=    MPUU_Details {“ (&) ” MPUU_Details} “, ”
             Total_Quantity_Size_Details
```

where the component parts are described as follows:

Table 18: MPP Preferred Term description

Description Component	Description
MPUU_Details	The following apply to all MPP product types: The details about an individual MPUU that is contained within the MPP, including: • the list of ingredients and strengths (formatted as per MPUU Preferred Term's Ingredients_With_Strength component) contained in the given MPUU component (where MPP HAS MPUU); • the dose form of the MPUU, for prescribing, dispensing or administration, as defined for the corresponding MPUU; and • the quantity Unit of Measure is only used when it is different from the form of the MPUU (or one of the form's parents in the *form* hierarchy). For example, if the quantity Unit of Measure is tablet and the dose form is either tablet or enteric tablet, then the quantity Unit of Measure is not shown (e.g. "pantoprazole 20 mg enteric tablet, 20" and not "pantoprazole 20 mg enteric tablet, 20 tablets"). For those MPUU components with manually created Preferred Terms (for example, those containing more than three ingredients where an MP has been created manually), the MPUU's Preferred Term will be used. For example, if the MPUU Preferred Term is "influenza virus vaccine 2009 injection, 0.5 mL syringe", then the MPP Preferred Term will be "influenza virus vaccine 2009 injection, 0.5 mL syringe". The following apply to multi-component products only: For each component, the component quantity details will be enclosed in square brackets and immediately follow the form. The component quantity details are represented by: UoU quantity value " x " UoU size value and units (separated by a space) then a space and then the UoU quantity units For example: [2 x 10 mL vials] • The order of the components will be based on the order used by the innovator product in the AMT. All subsequent products with the same combination of components will follow the order of the innovator product. • Where the intended active ingredient for a component is "inert substance", this component will always be shown last. • If the Unit of Use quantity value is greater than "1" then plural units are used for the associated unit of measure (for example, tablets, capsules, vials) with the exception of "microgram" • If the Unit of Use Size value and units is "1 each" then do not show " x Unit of Use Size value and units" • If the Unit of Use Size value and units equals the BoSS numerator value and units then do not show " x Unit of Use Size value and units". For example, "docetaxel 20 mg injection [1 x 20 mg vial]", then show "docetaxel 20 mg injection [1 vial]" • If the component quantity value has a value of "1" and Unit of Use size value and units does not equal the BoSS numerator value and units, then do not show "1 x". For example, "docetaxel 20 mg/0.5 mL injection [1 x 0.5 mL vial]", then show "docetaxel 20 mg/0.5 mL injection [0.5 mL vial]" • If the form is "diluent" then show " x Unit of Use Size value and units" unless the Unit of Use Size value and units is "1 each". • If the form is "diluent" and the Unit of Use quantity value is equal to 1, then do not show "1 x ".

Total_Quantity_Size_Details	A list of the Total Quantity Size details, which may include: • Unit of Use quantity value: The quantity of the Unit of Use. • Unit of Use quantity unit: The quantity of the unit dose item(s) that can be physically handled. • This component usually includes the Unit of Use quantity value and units (for example, 25 tablets). If the Unit of Use quantity units is the same as the dose form, then the Unit of Use quantity units is not shown. For example, paracetamol 500 mg tablet, 25 (as opposed to paracetamol 500 mg tablet, 25 tablets). • In all instances, if the value is greater than “1” then plural units are used for the associated quantity units, for example, tablets, capsules, vials; with the exception of “microgram”. • If the MPP represents a single component product, then Total_Quantity_Size_Details is represented by the Unit of Use quantity value, “ x ”, then the Unit of Use Size value and units (separated by a space), and the Unit of Use quantity units. (for example, 5 x 2 mL vials). • If the MPP represents a single component product, then the Unit of Use Size value and units is not shown when Unit of Use Size value and units equals the BoSS numerator value and units. For example, “desferrioxamine mesilate 2 g injection, 1 x 2 g vial”, then show “desferrioxamine mesilate 2 g injection, 1 vial” • If the MPP represents a single component product, and if the Unit of Use quantity value has a value of “1” and Unit of Use size value and units does not equal the BoSS numerator value and units, then do not show “1 x”. For example, "naloxone hydrochloride 2 mg/5 mL injection, 1 x 5 mL syringe”, then show "naloxone hydrochloride 2 mg/5 mL injection, 5 mL syringe" • If the MPP has an associated subpack concept, then Total_Quantity_Size_Details is represented by the Subpack_Details. The Subpack_Details is represented by the MPP.Subpack quantity value (for example, 4), “ × ”, and then the result of the calculation of the Total_Subpack_Quantity_Value (for example, 112) divided by the MPP.Subpack quantity value (for example, 4), followed by a space, and then the Total_Subpack_Quantity_Units (for example, tablets). The Total_Subpack_Quantity_Value is the sum of the individual Unit of Use quantity values of all of the components. For example: 4 x 28 (Note that the total subpack quantity units is “tablets” and this is not shown because it matches the dose form). • If the MPP represents a multi-component product which does not have an associated subpack and is not itself a subpack, and the units of use all share the same dose form, then Total_Quantity_Size_Details is represented by the total of the Unit of Use quantity values for all of the components, followed by a space, and the Unit of Use quantity units. Note that the Unit of Use quantity units (where shown) will always be plural. • If the MPP represents a multi-component product which does not have an associated subpack and is not itself a subpack, and the units of use do not share the same dose form, then Total_Quantity_Size_Details is represented by the text “1 pack”. • If the MPP represents a multi-component product and one or more of the components is a subpack concept, then Total_Quantity_Size_Details is represented by the text “1 pack”. • If the MPP represents a dual chamber product, which may or may not have an associated subpack, then Total_Quantity_Size_Details is represented by the number of actual dual chambered entities within that pack size (for example, 1 dual chamber syringe). Note that the Total_Quantity_Size_Details for a subpack will always be plural (for example, 5 dual chamber syringes).

Description Component	Description
	• If the MPP represents a combination product then Total_Quantity_Size_Details is represented by the text “1 pack”. For any value >= 10,000 a space will be included after every third digit starting from the right. For example: 10 000; 500 000; 1 000 000.

4.5.2.4 MPP Preferred Term rules

Table 19: MPP Preferred Term rules

Rule ID	Description
AMT-MPP-PT-1	Capitalisation rules as defined in Appendix A apply.
AMT-MPP-PT-2	The MPP ingredient will be derived from the intended active ingredient, as defined by its associated BoSS ingredient. Therefore, where a modified base is the BoSS, the MPP will represent that ingredient name, otherwise the MPP will represent the ingredient name as defined by the MP (that is, a modified base will only be displayed if it is the BoSS). EXCEPTION Where representation of the modified base in the MP is required for safety reasons (refer to Appendix B), the relevant MPP will also represent the modified base. The MPP Preferred Term will also include the description “inert substance” as the actual ingredient name where inactive (inert) ingredients are part of multi-component products or diluents provided for the preparation of the actual administrable form of a product.
AMT-MPP-PT-3	Strength expression All MPP Preferred Term will include a strength expression when available. The strength expression general rules and application to specific medication forms are outlined in Appendix E. EXCEPTION There are occasions when this is not applicable. Examples of this include Calamine lotion, Vitamin B compound tablets, Aqueous cream. **Note:** The addition to the exceptions list will be reviewed on a case-by-case basis. Refer to Appendix E. Strength expression may include an alternative strength representation different to the typical numerator/denominator strength expression. It may include a dual strength representation. Refer to Appendices E.2.1 and E.2.2.
AMT-MPP-PT-4	Form. The form is derived from the TGA Approved Terminology for Medicines, Dosage Forms. The form expressed is the parent form (that is, the general form is used in the medicinal concepts, whereas the more specific form is used in the Trade concepts). The form will be expressed as a singular form (for example, tablet, ampoule). EXCEPTION Where the specific form is deemed therapeutically necessary to support clinical decisions at the MPUU level, the form is expressed as the specific form. For example a therapeutically significant form such as “modified release injection” would be included in the MPUU but a non-significant form such as “powder for injection” would appear as the parent form of “injection”.

4.5.2.5 MPP “Preferred component order”

Definition

The MPP Preferred component order is used to define a component order other than alphanumerical for the MPP Preferred Term only. The MPP Fully Specified Name will always show

components in alphanumerical order, unless the intended active ingredient for a component is “inert substance”, in which case this component will always be shown last.

Note that this is an additional description type which is not released in the terminology release files.

4.6 Trade Product (TP)

4.6.1 Trade Product definition

The Trade Product (TP) represents the product brand name, for either single component products, or components of multi-component products regardless of ingredients. The TP may also include any additional detail necessary for identification. For example: strength representation for multi-ingredient products (where this is necessary for differentiation); proprietary form, delivery device or container; an alternative name which has market recognisability. Where a product has a generic name (that is, the name of the product is a substance name or an indication for treatment) the sponsor, manufacturer or house brand details will also be included as part of the TP.

Table 20: Examples of TP Fully Specified Names and Preferred Terms

Type of product	Fully Specified Name	Preferred Term
Single ingredient	Amoxil (trade product)	Amoxil
Single ingredient (generic)	Morphine Sulfate (Hospira) (trade product)	Morphine Sulfate (Hospira)
Single ingredient	Canesten Clotrimazole (trade product)	Canesten Clotrimazole
Single ingredient	Canesten Bifonazole (trade product)	Canesten Bifonazole
Multi-ingredient	Panadeine Forte (trade product)	Panadeine Forte
Multi-ingredient (generic)	Cold and Flu (Chemmart) (trade product)	Cold and Flu (Chemmart)
Combination product	Triphasil (trade product)	Triphasil
Combination pack	• Nexium Hp7 (trade product) • Nexium (trade product) • Klacid (trade product) • Amoxil (trade product)	• Nexium Hp7 • Nexium • Klacid • Amoxil

4.6.2 TP details

The TP will contain detail necessary for unambiguous identification of the product at this level of the model.

The following additional information (where it forms part of the product name in the sponsor information such as the label, PI or CMI PI = "product information", CMI = "consumer medicine information".) will be included in the TP name for both the Fully Specified Name and the Preferred Term as indicated below.

Table 21: TP description

Additional Information	Include in Trade Product name	Preferred Term Example
Alternative name which is well recognised in the market.	yes	Compound Sodium Lactate (Hartmann's) (Baxter)

Additional Information	Include in Trade Product name	Preferred Term Example
Strength representation for single ingredient items	no	Not applicable.
Numerals	No, unless a numeral appears at the end of a TP, and a strength immediately follows (in the TPUU, TPP and CTPP), a hyphen will be added between the brand name and the number.	Rani-2
Strength representation for multi-ingredient items.	yes (only as per AMT-TP-FSN-2)	Accuretic 20/12.5 Micardis Plus 40/12.5
	Where strength is included, the units will only be included if they form part of the product name in the sponsor information such as the PI or CMI. Where the strength units are included, they will be separated from the strength value by a space.	Dilart HCT 160/12.5 mg Olmetec Plus 20/12.5 Jardiamet 12.5 mg/500 mg
	Where strength units are included, they will be represented as they would appear within a strength field. For example "microgram" would be used, not "mcg" or "µg".	Adronat Plus 70 mg/140 microgram
	For any value >= 10,000 a space will be included after every third digit starting from the right. For example: 10 000; 500 000; 1 000 000.	Ubistesin Forte 4% / 1 in 100 000
	Where there is "%" displayed in the strength for a multi-ingredient product, a space will be inserted between the numerator and "/" and the denominator to assist with readability. Where there is no "%", or Unit of Measure, displayed in the trade name, the TP will omit any spaces between the numerator, "/", and denominator.	Genteal Gel 0.3% / 0.2% Medijel 0.05% / 0.66%
	If the product name in the PI or CMI does not have a strength representation and there is more than one strength available, then a strength value (but not units) will be added. The order of the strength values will correspond to the Preferred Term ingredient order.	Moduretic (Note that there is no strength included as it does not form part of the product name in the sponsor information.)

Additional Information	Include in Trade Product name	Preferred Term Example
Strength representation for multi-component items.	Strength values will be included for the parent TP only if they form part of the product name in the sponsor information such as the PI or CMI.	Xylocaine 1% with Adrenaline 1 in 100 000 Citanest 3% with Adrenaline 1 in 300 000 Dental
	Where a ratio strength appears in the TP, the ":" will be replaced by the word "in" if the ratio represents a dilution of the active ingredient.	
	Where the ratio sign ":" represents a comparison in proportion between two ingredients, the ratio sign ":" will be retained in the TP.	Ketovie 3:1 THC5:CBD20 (Tilray)
Form	No, unless the form is required to differentiate two (or more) TPs which have different MPs.	Genteal Eye Drops (MP is hypromellose) Genteal Gel 0.3% / 0.2% (MP is hypromellose + carbomer-980)
Form where detail is equivalent or partially equivalent to the AMT form.	No, unless it is required to create a meaningful TP description.	Worming Tablet (Chemmart) Microshield Angel Antimicrobial Hand Gel (Note that the AMT dose form assigned to this product is "gel" and hence it would not normally be included in the TP, however the TP is nonsensical if this form is omitted.)
Form where detail is not equivalent to the AMT form.	yes	Aerius Syrup (Note that the TGA form for this product is "oral liquid: solution".) Nurofen Liquid Capsule
Proprietary form (Refer to Appendix H.1)	yes	Risperdal Quicklet
	May be either singular or plural in the TP, according to the documentation related to the product.	Ventolin Nebules
Proprietary delivery device	yes	Bricanyl Turbuhaler Enbrel Auto-Injector
	May be either singular or plural in the TP, according to the documentation related to the product.	*(no current example available)*
Proprietary container (Refer to Appendix H.2)	yes	Atrovent UDV Tropicamide Minims (Bausch & Lomb)
	May be either singular or plural in the TP, according to the documentation related to the product.	*(no current example available)*
Information that denotes a route or method of administration and the dose form of the associated product does not infer the route or method of administration.	yes	Metoprolol IV (Mylan) (Note that the name for this product in the PI/CMI is "Metoprolol IV Mylan" and the AMT dose form is "injection: solution".)

Additional Information	Include in Trade Product name	Preferred Term Example
Information that denotes a route or method of administration and the dose form of the associated product infers the route of administration.	no	Not applicable (no current example available)
Indication	yes	Aciclovir Cold Sore (Your Pharmacy) Clofeme Thrush Treatment Comfeel Plus Pressure Relieving
	Where there is an abbreviated medical diagnosis for a nutritional supplement, the abbreviation will form the first part of the TP.	MSUD Lophlex HCU Anamix Junior PKU Lophlex LQ
	Where a product includes a specific population group as part of their trade name, this will not form the first part of the TP.	Panadol Children's Claratyne Children's Ibuprofen Children's (Chemmart) Nurofen for Children Baby 3+ Months
Information that denotes a manufacturer's product code that is relevant at the Unit of Use or pack levels.	yes (for bandages and dressings only)	Aquacel (177902) Hydrocoll (900939/1) Tielle (MTL101E)
Sponsor details	No, except where a product has a generic name (that is, the name of the product is a substance name or an indication for treatment) the sponsor, manufacturer, house brand or combination pack details will also be included as part of the TP. Any extra detail such as country affiliation, PTY LTD status will be omitted from the TP.	Amlodipine (Terry White Chemists) Ibuprofen (Herron) Krill Oil (Nature's Own) Acid and Heartburn Relief (GenRx) Cold Sore Fighter (Bioglan) Magmin (no sponsor is included as this is not a generic name) Evicel Thrombin
Substance modification or hydration details (for generic products)	No, except: The TP for a generic product will only include modifications (including hydration status) where it forms part of the product name in the sponsor information such as the PI or CMI. (no current example available)	Morphine (Juno) (While the actual substance used to formulate this product and the BoSS are both morphine hydrochloride trihydrate, the hydrochloride trihydrate is not included in the Trade Product as it does not form part of the product name in the PI or CMI.)

Additional Information	Include in Trade Product name	Preferred Term Example
Information that denotes a particular monograph (for example, APF, BP) on which the product formulation is based. The standard will only be included in marketed products if it is necessary to include it in order to differentiate between two products. The year of the monograph will not be included. Note that for non-commercially marketed products, the sponsor name will be "extemporaneous".	No, except where the product is a non-commercially marketed product	Emulsifying Ointment (David Craig) Aqueous Cream (David Craig) Podophyllin Compound BP (extemporaneous) Thymol Compound APF (extemporaneous)
Information that denotes a release or pharmacokinetic characteristic of the product.	yes	Ritalin LA Asasantin SR Seroquel XR
Textual description that is logically part of the brand name, or which is necessary to distinguish between items in a product range.	yes	Abbocillin VK Accu-Chek Advantage II Pegatron Combination Therapy
	Commas and full stops will be used where appropriate, as represented on the product label and in the supporting documentation.	Sinutab Sinus, Allergy and Pain Relief Zinc, Starch and Talc Dusting Powder APF (extemporaneous) B.I.P. Paste O.R.S. (Aspen)
	Where the conjunction “&” or “+” appear in the trade name, the ampersand character “&” shall be converted to “and”, and “+” shall be converted to “plus”.	Lemsip Max Cold and Flu Dimetapp PE Day plus Night Cough Cold plus Flu
	Where the symbol cannot be substituted with the word, the symbol will be retained in the TP.	Sunsense Ultra SPF 30+ Centrum Advance 50+
	Where a symbol (For example: *; ~) is present, the product name will be reviewed on a case by case basis.	BGstar

4.6.3 TP descriptions

4.6.3.1 TP Fully Specified Name definition

The Fully Specified Name of a TP follows the syntax:

TP FSN :=	TF_Name " (trade product)"

where the component parts are described as follows:

Table 22: TP Fully Specified Name description

Description Component	Description
TF_Name	The product brand name, for either single component products, or components of multi-component products, and including any necessary additional information as defined in Section 4.6.1. Examples include: a textual description that is necessary to distinguish between items in a product range; a strength representation for multi-ingredient products (where required for differentiation); or a proprietary form, delivery device or container.
(trade product)	The semantic tag used in the Fully Specified Name of all TP concepts.

4.6.3.2 TP Fully Specified Name rules

Table 23: TP Fully Specified Name rules

Rule ID	Description
AMT-TP-FSN-1	Capitalisation rules as defined in Appendix A apply.
AMT-TP-FSN-2	The TF_Name will be derived from the product brand name and any additional detail that is necessary to define the product, as defined in Section 4.6.1. Examples include: a textual description that is necessary to distinguish between items in a product range; a strength representation for multi-ingredient products (where required for differentiation); or a proprietary form, delivery device or container. Each TF_Name will consist of products with the same Medicinal Product (for example, Canesten Clotrimazole (which has a related MP of clotrimazole) and Canesten Bifonazole (which has a related MP of bifonazole) will be created as two TF_Names). The TF_Name may differentiate between different available strengths (for example, Panadeine and Panadeine Forte). For multi-ingredient products with multiple strengths available, then to avoid ambiguity, the TF_Name will include a representation of the strength (for example, Caduet 10/10 and Caduet 5/20). Strength representation in the TF_Name may be omitted for multi-ingredient products when only one strength is currently marketed in Australia (for example, Moduretic tablets), except where the strength forms part of any of the following: the label, PI or CMI (for example Qtern 5/10).
AMT-TP-FSN-3	A generic product is one in which the name of the product is a substance name or an indication for treatment. For generic products, the TF_Name will be populated with the generic name, followed by a " " and the sponsor/manufacturer/house brand name surrounded by "(" and ")". For example: • Simvastatin (GenRx) • Methotrexate (Ebewe) Where a generic product name includes an abbreviation for a sponsor/manufacturer/house brand name as a hyphenated suffix, the TF_Name will be populated with generic name followed by a " " and the abbreviation for the sponsor/manufacturer/house brand name surrounded by "(" and ")". For example: Meloxicam (GA). Where a modified base is included as part of the TF_Name, the first letter of the modification will be uppercased. **Note:** This rule also applies to products that consist of a standard formulation, for example, Calamine Lotion.
AMT-TP-FSN-4	For products where the name consists of a housebrand name and a brand name, the TF_Name will consist of the brand name only. The sponsor will not be included. For example: Magmin, not Magmin (Blackmores).

Note that variation to this syntax may occur to meet the requirements of clinical practice as agreed by the appropriate AMT governance body.
Where disambiguation is required for two or more products, each of the ingredients will be

included in the TF_Name. The ingredients shall appear in the same order in which they are referred to in the TF_Name, and shall be enclosed within a single bracket, with each of the ingredients separated by a "/" with no spacing around it. Each ingredient shall be represented as the BoSS without hydration.
For example, "Coveram 5 mg/10 mg tablet, 30" is ambiguous as it is not possible to distinguish it from Coveram 10 mg/5 mg tablet, 30. Disambiguation as described above results in the creation of the following unambiguous descriptions:

Term according to rules:	Coveram 5 mg/10 mg
Created term:	Coveram 5 mg/10 mg (perindopril arginine/amlodipine)
Term according to rules:	Coveram 10 mg/5 mg
Created term:	Coveram 10 mg/5 mg (perindopril arginine/amlodipine)

4.6.3.3 TP Preferred Term definition

The Preferred Term of a TP, by default, follows the syntax:

TP PT := TF_Name

where the component parts are described as follows:

Table 24: TP Preferred Term description

Description Component	Description
TF_Name	The product brand name, for either single component products, or components of multi-component products regardless of ingredients, and including any necessary additional information as defined in Section 4.6.1. Examples include: a textual description that is necessary to distinguish between items in a product range; a strength representation for multi-ingredient products (where required for differentiation); or a proprietary form, delivery device or container.

4.6.3.4 TP Preferred Term rules

Table 25: TP Preferred Term rules

Rule ID	Description
AMT-TP-PT-1	Capitalisation rules as defined in Appendix A apply.
AMT-TP-PT-2	The TF_Name will be derived from the product brand name and any additional detail that is necessary to define the product, as defined in Section 4.6.1. Examples include: a textual description that is necessary to distinguish between items in a product range; a strength representation for multi-ingredient products (where required for differentiation); or a proprietary form, delivery device or container. Each TF_Name will consist of products with the same Medicinal Product (for example, Canesten Clotrimazole (which has a related MP of clotrimazole) and Canesten Bifonazole (which has a related MP of bifonazole) will be created as two TF_Names). The TF_Name may differentiate between different available strengths (for example, Panadeine and Panadeine Forte). For multi-ingredient products with multiple strengths available, then to avoid ambiguity, the TF_Name will include a representation of the strength (for example, Caduet 10/10 and Caduet 5/20). Strength representation in the TF_Name may be omitted for multi-ingredient products when only one strength is currently marketed in Australia (for example, Moduretic tablets).

Rule ID	Description
AMT-TP-PT-3	A generic product is one in which the name of the product is a substance name or an indication for treatment. For generic products, the TF_Name will be populated with the generic name, followed by a space and the sponsor/manufacturer/house brand name surrounded by "(" and ")". For example: • Simvastatin (GenRx) • Methotrexate (Ebewe) Where a generic product name includes an abbreviation for a sponsor/manufacturer/house brand name as a hyphenated suffix, the TF_Name will be populated with generic name followed by a space and the abbreviation for the sponsor/manufacturer/house brand name surrounded by "(" and ")". For example: Meloxicam (GA). Where a modified base is included as part of the TF_Name, the first letter of the modification will be uppercased. **Note:** This rule also applies to products that consist of a standard formulation, for example, Calamine Lotion.

4.7 Trade Product Unit of Use (TPUU)

4.7.1 Trade Product Unit of Use definition

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, for example, 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 multi-component products or diluents provided for the preparation of the actual administrable form of a product. This is the medicinal object or unit that is able to be physically handled for example, tablet, capsule, vial, ampoule, patch, etc.

4.7.1.1 Exceptions to TPUU Preferred Term descriptions

Note that a small number of TPUUs will show additional detail in the Preferred Term. Where included, this additional detail will consist of the BoSS substance and strength enclosed by curved brackets, as represented in the Fully Specified Name. This is to avoid:

- duplicate or identical Preferred Terms (which may have different conceptIds); or
- misleading terms which would be created for those units of use containing "inert substance" as the ingredient.

4.7.1.2 Exceptions for products with "inert substance" ingredients

For products in which one of the components has an intended active ingredient of "inert substance" the ingredients should be included in every component.

Example 1: Brevinor

For the TPP Preferred Term "Brevinor 28 Day (21 x 500 microgram/35 microgram tablets, 7 x inert tablets), 4 x 28".

TPUU FSN:	Brevinor 28 Day (ethinylestradiol 35 microgram + norethisterone 500 microgram) tablet (trade product unit of use)
TPUU PT:	Brevinor 28 Day (norethisterone 500 microgram + ethinylestradiol 35 microgram) tablet

TPUU FSN:	Brevinor 28 Day (inert substance) tablet (trade product unit of use)
TPUU PT:	Brevinor 28 Day (inert substance) tablet

Note that without the ingredient detail, they would share a common TPUU Preferred Term of "Brevinor 28 day tablet".

4.7.1.3 Exceptions for multi-component products where one or more of the components is multi-ingredient

For multi-component products where one or more of the components is multi-ingredient, the ingredients should be included in every component.

Example 1: Triphasil

For the TPP Preferred Term "Triphasil (6 x 50 microgram/30 microgram tablets, 5 x 75 microgram/40 microgram tablets, 10 x 125 microgram/30 microgram tablets, 7 x inert tablets), 4 x 28":

TPUU FSN:	Triphasil (ethinylestradiol 30 microgram + levonorgestrel 125 microgram) tablet (trade product unit of use)
TPUU PT:	Triphasil (ethinylestradiol 30 microgram + levonorgestrel 125 microgram) tablet

TPUU FSN:	Triphasil (ethinylestradiol 30 microgram + levonorgestrel 50 microgram) tablet (trade product unit of use)
TPUU PT:	Triphasil (ethinylestradiol 30 microgram + levonorgestrel 50 microgram) tablet

TPUU FSN:	Triphasil (ethinylestradiol 40 microgram + levonorgestrel 75 microgram) tablet (trade product unit of use)
TPUU PT:	Triphasil (ethinylestradiol 40 microgram + levonorgestrel 75 microgram) tablet

TPUU FSN:	Triphasil (inert substance) tablet (trade product unit of use)
TPUU PT:	Triphasil (inert substance) tablet

Note that without the ingredient detail, they would share a common TPUU Preferred Term of "Triphasil tablet".

Example 2: Trisequens

For the TPP Preferred Term of "Trisequens, 28 tablets":

TPUU FSN:	Trisequens (estradiol 1 mg) tablet (trade product unit of use)
TPUU PT:	Trisequens (estradiol 1 mg) tablet

TPUU FSN:	Trisequens (estradiol 2 mg) tablet (trade product unit of use)
TPUU PT:	Trisequens (estradiol 2 mg) tablet

TPUU FSN:	Trisequens (estradiol 2 mg + norethisterone acetate 1 mg) tablet (trade product unit of use)
TPUU PT:	Trisequens (norethisterone acetate 1 mg + estradiol 2 mg) tablet

Note that without the ingredient detail, there would be the potential for ambiguity between the three TPUU descriptions, particularly with the multi-ingredient TPUU which would not display a strength, and when seen in isolation, it may not be clear which TPUU it is describing.

4.7.2 TPUU descriptions

4.7.2.1 TPUU Fully Specified Name definition

The Fully Specified Name of a TPUU follows the syntax:

```
TPUU FSN :=  TF_Name [" " Other_Identifying_Information] [" (" Ingredient_Strength {" + "
             Ingredient_Strength} ")"] " " Form [", " Unit_Of_Use_Details] " (trade product unit of use)"
```

where the component parts are described as follows:

Table 26: TPUU Fully Specified Name description

Description Component	Description
TF_Name	The product brand name, for either single component products, or components of multi-component products regardless of ingredients, and including any necessary additional information as defined in Section 4.6.1. Examples include: a textual description that is necessary to distinguish between items in a product range; a strength representation for multi-ingredient products (where required for differentiation); a proprietary form, delivery device or container.
Other_Identifying_Information	Additional details that are required to avoid ambiguity or duplication in the constructed description, within a given product range. This information should be descriptive information that is specific to the Trade concept (for example, "Sugar Free", "Refill", "Strawberry"). Capitalisation rules as defined in Appendix A will apply.
Ingredient_Strength	An alphanumerical list of the name and strength (if available) of each of the active ingredients in the TPUU, derived from the associated MPUU Fully Specified Name.
Form	This is a child form where appropriate, otherwise it is the Preferred Term of the Form concept that is the destination of the MPUU HAS MANUFACTURED DOSE FORM relationship. Note that where a proprietary dose form is included as part of the TF_Name, then the associated dose form (as indicated in Appendix H.1) will be included here.
Unit_Of_Use_Details	The Unit_Of_Use_Details are derived exactly from the associated MPUU Fully Specified Name.
(trade product unit of use)	The semantic tag used in the Fully Specified Name of all Trade Product Unit of Use concepts.

4.7.2.2 TPUU Fully Specified Name rules

Table 27: TPUU Fully Specified Name rules

Rule ID	Description
AMT-TPUU-FSN-1	Capitalisation rules as defined in Appendix A apply.

Rule ID	Description
AMT-TPUU-FSN–2	Strength expression. The strength expression general rules and application to specific medication forms is outlined in Appendix E. For multi-ingredient products when the constructed description does not include a representation of strength (either trade product or strength expression), then the missing details will be added to the TP according to TP rules to prevent ambiguity.
AMT-TPUU-FSN–3	Form The form expressed in the TPUU is the specific form (that is, the specific form is used in the Trade concepts, whereas the more general form is used in the medicinal concepts). Refer to Appendix G for further detail. The form will be expressed as a singular form (for example, tablet, ampoule). Where the TF_Name includes a proprietary form, the corresponding form, as shown in Appendix H.1 must be used.
AMT-TPUU-FSN–4	No additional name segments will be added to the constructed description. EXCEPTION: Other Identifying Information In instances where the constructed description may result in ambiguity or duplication, within a given product range, additional details may be added in Other_Identifying_Information (for example, Sugar Free, Refill, a given flavour). For example: • Lemsip Max Cold and Flu Blackcurrant 1 g powder for oral liquid, 1 sachet (trade product unit of use) • Dimetapp 12 Hour Refill 500 microgram / 1 mL nasal spray (trade product unit of use) Capitalisation rules as defined in Appendix A will apply.

4.7.2.3 TPUU Preferred Term definition

The Preferred Term of a TPUU, by default, follows the syntax:

TPUU PT := TF_Name [" " Other_Identifying_Information] [" (" Ingredient_Strength ")"] [" " Form] [", " Unit_Of_Use_Details]

where the component parts are described as follows:

Table 28: TPUU Preferred Term description

Description Component	Description
TF_Name	The product brand name, for either single component products, or components of multi-component products regardless of ingredients, and including any necessary additional information as defined in Section 4.6.1. Examples include: a textual description that is necessary to distinguish between items in a product range; a strength representation for multi-ingredient products (where required for differentiation); a proprietary form, delivery device or container.
Other_Identifying_Information	Additional details that are required to avoid ambiguity or duplication in the constructed description, within a given product range. This information should be descriptive information that is specific to the Trade concept (for example, "Sugar Free", "Refill", "Strawberry"). Capitalisation rules as defined in Appendix A will apply.

Description Component	Description
Ingredient_Strength	For single ingredient products, ingredient strength (but not ingredient name) is displayed. For multi-ingredient products, neither ingredient strength nor ingredient name are displayed. EXCEPTIONS: There are a small number of exceptions to inclusion of ingredient name and strength. Refer to Section 4.7.1.
Form	This is a child form where appropriate, otherwise it is the Preferred Term of the Form concept that is the destination of the MPUU HAS MANUFACTURED DOSE FORM relationship. Note that where a proprietary dose form is included as part of the TF_Name, then the associated dose form (as indicated in Appendix H.1) should be included here. If the associated dose form results in duplicated dose forms adjacent in the descriptions, the second form will be suppressed and not displayed in the Preferred Term descriptions of the TPUU. For example, "QV Cream cream" will be displayed as "QV Cream".
Unit_Of_Use_Details	The Unit_Of_Use_Details are derived exactly from the associated MPUU Fully Specified Name.

Note that variation to this syntax may occur to meet the requirements of clinical practice as agreed by the appropriate AMT governance body. Refer to exceptions in Section 4.7.1.

4.7.2.4 TPUU Preferred Term rules

Table 29: TPUU Preferred Term rules

Rule ID	Description
AMT-TPUU-PT–1	Capitalisation rules as defined in Appendix A apply.
AMT-TPUU-PT-2	Strength expression. The TPUU Preferred Term will include strength expression (if available) for single ingredient products only. The strength expression general rules and application to specific medication forms is outlined in Appendix E. EXCEPTIONS See AMT-APP-STR-9 in Appendix E. Strength expression may include an alternative strength representation different to the typical numerator/denominator strength expression. Refer to Appendix E.1. Alternatively it may include a dual strength representation. Refer to Appendix E.2.
AMT-TPUU-PT–3	Form The form is derived from the TGA Approved Terminology for Medicines, Dosage Forms. The form expressed in the TPUU is the specific form (that is, the specific form is used in the Trade concepts, whereas the more general form is used in the medicinal concepts). The form will be expressed as a singular form (for example, tablet, ampoule). Where the TF_Name includes a proprietary form, the corresponding form, as shown in Appendix H.1 must be used. If the associated dose form results in duplicated dose forms adjacent in the descriptions, the second form will be suppressed and not displayed in the Preferred Term descriptions of the TPUU. For example, "QV Cream cream" will be displayed as "QV Cream".

Rule ID	Description
AMT-TPUU-PT-4	No additional name segments will be added to the constructed description. EXCEPTION: Other Identifying Information In instances where the constructed description may result in ambiguity or duplication, within a given product range, additional details may be added in Other Identifying Information (for example, Sugar Free, Refill, a given flavour). For example: • Lemsip Max Cold and Flu Blackcurrant 1 g powder for oral liquid, 1 sachet • Dimetapp 12 Hour Refill 0.05% nasal spray Capitalisation rules as defined in Appendix A will apply.
AMT-TPUU-PT-5	Products of the same Trade Product name with different formulations For products where two different formulations exist with the same Trade Product name, the duplicated Preferred Term of the existing (older) product will be differentiated with the term 'Old Formulation', in title casing, followed by the year that the old formulation was superseded. The information pertaining to the date that the old formulation was superseded will be confirmed via manufacturer data or TGA. The term and date will be applied to the end of the Preferred Term of the Trade Product Unit of Use, Trade Product Pack and Containered Trade Product Pack, contained within brackets. The method to apply this change is to create a new Preferred Term that contains the differentiating information, then retire the old Preferred Term to avoid ambiguity. The new formulation will not have any additional text applied. For example: Trade Product Unit of Use Preferred Term: Elevit tablet (Old Formulation 2017)

4.7.2.5 TPUU "Other identifying information" definition and rules

Definition

The TPUU "Other identifying information" allows optional descriptive information about the TPUU to be displayed (for example, Sugar Free, Refill, a given flavour). This information is required to avoid ambiguity or duplication in the constructed descriptions for TPUU. This will be sourced from TGA data, Sponsor's Product Information or Consumer Medicine Information.
Note that this is an additional description type which is not released in the terminology release files.

Table 30: TPUU "Other identifying information" rules

Rule ID	Rule
AMT-TPUU-OII-1	Capitalisation rules as defined in Appendix A will apply.
AMT-TPUU-OII-2	A TPUU may not have more than one Other_Identifying_Information descriptor.
AMT-TPUU-OII-3	Population of this field is optional.

4.8 Trade Product Pack (TPP)

4.8.1 TPP definition

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. This information is included in the CTPP. It may, however, imply a container type, when this information is included in the Total Quantity Size Details.

4.8.2 TPP descriptions

4.8.2.1 TPP Fully Specified Name definition

The Fully Specified Name of a TPP follows the syntax:

TPP FSN := TF_Name [" " Other_Identifying_Information] " [“ TP_Details “] (" Ingredient_Strength {" _" Ingredient_Strength} ") " Form ["[" Component_Quantity_Details "]"] {" (&)" " [“ TP_Details “] (" Ingredient_Strength {" " Ingredient_Strength} ") " Form ["[" Component_Quantity_Details "]"]} ", " Total_Quantity_Size_Details (trade product pack)

where the component parts are described as follows:

Table 31: TPP Fully Specified Name description

Description Component	Description
TF_Name	The product brand name, for either single component products, or components of multi-component products regardless of ingredients, and including any necessary additional information as defined in Section 4.6.1. Examples include: a textual description that is necessary to distinguish between items in a product range; a strength representation for multi-ingredient products (where required for differentiation); or a proprietary form, delivery device or container.
Other_Identifying_Information	Additional details that are required to avoid ambiguity or duplication in the constructed description, within a given product range. This information should be descriptive information that is specific to the Trade concept (for example, "Sugar Free", "Refill", "Strawberry"). Capitalisation rules as defined in Appendix A will apply.
TP_Details	TP_Details represent the TF_Name for the given TP. Note that TP_Details will only be included if it is required to differentiate two otherwise identical multi-component or combination pack products. Where there is at least one component TP_Details that is required to differentiate two otherwise identical multi-component or combination pack products, then the TP_Details will be included for each component. Esomeprazole Hp7 (Sandoz) (Amoxycillin (Sandoz) (amoxicillin) 500 mg) capsule [28 capsules] (&) (Clarithromycin (Sandoz) (clarithromycin) 500 mg) film-coated tablet [14 tablets] (&) (Esomeprazole (SZ) (esomeprazole) 20 mg) enteric tablet [14 tablets], 1 pack (trade product pack) Esomeprazole Hp7 (Sandoz) (Amoxycillin (Sandoz) (amoxicillin) 500 mg) capsule [28 capsules] (&) (Clarithromycin (Sandoz) (clarithromycin) 500 mg) film-coated tablet [14 tablets] (&) (Esomeprazole (Sandoz) (esomeprazole) 20 mg) enteric tablet [14 tablets], 1 pack (trade product pack) Note that the two Esomeprazole Hp7 (Sandoz) presentations contain two different TP_Details for components (Esomeprazole (Sandoz) (esomeprazole) 20 mg) enteric tablet [14 tablets]and (Esomeprazole (SZ) (esomeprazole) 20 mg) enteric tablet [14 tablets], and thus all components express TP_Details.
Ingredient_Strength	An alphanumerical list of the name and strength (if available) of each of the active ingredients in the TPUU, derived from the associated MPUU Fully Specified Name. For multi-component products, this list of components will be ordered alphanumerically, followed by descending strength order based on the BoSS.

Description Component	Description
Form	This is the form as derived from the component TPUU Fully Specified Name. If the associated dose form results in duplicated dose forms adjacent in the descriptions, the second form will be suppressed and not displayed in the Preferred Term descriptions of the TPP. For example, "QV Cream cream, 100 g" will be displayed as "QV Cream, 100 g".
Component_Quantity_Details	Component_Quantity_Details is represented for each TPUU in the TPP, and is only populated for multi-component or combination pack products. The quantity and size of this TPUU in the given TPP is represented inside square brackets. This detail is defined by the Unit of Use quantity value followed by " x ", followed by the Unit of Use Size value and units (separated by a space), followed by a space and the Unit of Use quantity units. For example: [1 x 250 mg vial]. The Unit of Use Size value and units will not be shown when it is equal to "1 each". If the Unit of Use quantity value is greater than "1" then plural units are used for the associated quantity units (for example, tablets, capsules, vials) with the exception of "microgram".
Total_Quantity_Size_Details	This is derived from the Total_Quantity_Size_Details of the related MPP Fully Specified Name. For any value >= 10,000 a space will be included after every third digit starting from the right. For example: 10 000; 500 000; 1 000 000.
(trade product pack)	The semantic tag used in the Fully Specified Name of all TPP concepts.

4.8.2.2 TPP Fully Specified Name rules

Table 32: TPP Fully Specified Name rules

Rule ID	Description
AMT-TPP-FSN-1	Capitalisation rules as defined in Appendix A apply.
AMT-TPP-FSN-2	FORM This is the form as derived from the component TPUU Fully Specified Name.

4.8.2.2.1 TPP Preferred Term brief definition – single component and multipack TPP

The Preferred Term of a single component or multipack TPP, by default, follows the syntax:

TPP PT := TF_Name [" " Other_Identifying_Information] " " [Ingredient_Strength] " " Form ", " Total_Quantity_Size_Details

where the component parts are described as follows:

Table 33: TPP Preferred Term description

Description Component	Description
TF_Name	The product brand name, for either single component products, or components of multi-component products regardless of ingredients, and including any necessary additional information as defined in Section 4.6.1. The TF_Name will always be shown and is represented exactly as shown in the parent TP Preferred Term description. Examples include: a textual description that is necessary to distinguish between items in a product range; a strength representation for multi-ingredient products (where required for differentiation); or a proprietary form, delivery device or container.
Other_Identifying_Information	Additional details that are required to avoid ambiguity or duplication in the constructed description, within a given product range. This information should be descriptive information that is specific to the TPUU (for example, "Sugar Free", "Refill", "Strawberry").
Ingredient_Strength	This is derived from the strength as represented by Ingredients_With_Strength in the MPUU Preferred Term. For single ingredient products, ingredient strength (but not ingredient name) is displayed. For multi-ingredient products, neither ingredient strength nor ingredient name are displayed. EXCEPTIONS: There are a small number of exceptions to inclusion of ingredient name and strength. Refer to Section 4.7.1.
Form	This is the form as derived from the TPUU Preferred Term.
Total_Quantity_Size_Details	This is derived from the Total_Quantity_Size_Details of the related MPP Preferred Term.

4.8.2.2.2 TPP Preferred Term brief definition – multi-component TPP

The Preferred Term of a multi-component TPP, by default, follows the syntax:

TPP PT := TF_Name [" " Other_Identifying_Information] " (" Component_Details "), " Total_Quantity_Size_Details

where the component parts are described as follows:

Table 34: TPP Preferred Term description

Description Component	Description
TF_Name	The product brand name, for either single component products, or components of multi-component products regardless of ingredients, and including any necessary additional information as defined in Section 4.6.1. The TF_Name will always be shown and is represented exactly as shown in the parent TP Preferred Term description. Examples include: a textual description that is necessary to distinguish between items in a product range; a strength representation for multi-ingredient products (where required for differentiation); or a proprietary form, delivery device or container.
Other_Identifying_Information	Additional details that are required to avoid ambiguity or duplication in the constructed description, within a given product range. This information should be descriptive information that is specific to the Trade Product Unit of Use (for example, "Sugar Free", "Refill", "Strawberry").

Description Component	Description
Component_Details GENERAL	GENERAL COMMENT Component_Details will vary depending on the type of product. Please refer to each of the available options below. One Component_Details must be shown for every different Unit of Use within a product. The details for each component will be separated by ", " and will be represented in the component order derived from the MPP Preferred Term.
Component_Details IAI is an active therapeutic moiety	Where the IAI is an active therapeutic moiety, the Component_Details will consist of: <UoU.quantity.value> <"x"> <TP_Details> <UoU.size.value> <UoU.size.unit> <strength> <"vaccine"> <UoU.quantity.unit(s)>
Component_Details IAI = inert substance	Where the IAI = inert substance, the Component_Details will consist of: <UoU.quantity.value> <"x"> <TP_Details> <UoU.size.value> <UoU.size.unit> <"inert"> <trade.dose.form> <UoU.quantity.unit(s)>
Component_Details UoU.quantity units is not a descriptive unit of measure	Where the UoU.quantity units is not a descriptive Unit of Measure (refer to Appendix F.5), the Component_Details will consist of: <UoU.quantity.value> <"x"> <TP_Details> <strength> <UoU.quantity.value.units> <medicinal.dose.form>
Component_Details a component of a multi-component product is a multpack	Where a component of a multi-component product is a multipack, then Component_Details will consist of <Total_Quantity_Size_Details> <"x"> <TP_Details> <UoU.quantity.units (plural)>
UoU.quantity.value	The Unit of Use quantity value followed by " x " is always shown. If the component represents a subpack, then UoU.quantity.value is replaced by subpack.quantity x single.pack.UoU.quantity.value where subpack.quantity is equal to the number of subpacks within the parent pack, and single.pack.UoU.quantity.value is equal to the total number of units of use within the single pack.

Description Component	Description
TP_Details	TP_Details consists of the TF_Name and the Other_Identifying_Information for the given TP. Note that Other_Identifying_Information will only be included in the component details if it is required to differentiate two otherwise identical multi-component products. This may mean that in some instances it appears in the TPUU but not in the component details. For example the parent TPP Preferred Term of "Colonprep Kit A (1 x Colonlytely sachet, 2 x Picolax sachets), 1 pack" has component TPPs of "Colonlytely Original Flavour powder for oral liquid, 68.58 g sachet" and "Picolax powder for oral liquid, 2 x 20 g sachets". Note that the OII of "Original Flavour" appears in the component description for Picolax, but does not appear in the parent pack component details, as there is not another parent pack which uses another flavour of Colonlytely. If the complete TP_Details for every component is exactly the same as the complete TF_Name for the parent pack, then TP_Details are not shown for any component. If the TF_Name and every TP_Details contains exactly the same sponsor information in brackets, then this sponsor information will not be shown in the TP_Details for any component. If there is a common text string across the TF_Name and every TP_Details then the common part will be removed from all of the component TP_Details, otherwise include the full TP_Details for every component. However, do not remove the common text string from any of the product TP_Details if it would completely remove the TP_Details from one or more components, but not all of the components. If there is no text string in common across the TF_Name and the TP_Details for every component, then show complete TP_Details for every component. Remove all brackets from the component TP_Details unless they enclose sponsor details.
UoU.size.value and UoU.size.unit	This represents the size value and units of the Unit of Use for the particular component. UoU.size.value and UoU.size.unit may only be shown if TP_Details are not shown. However, they will be shown with TP_Details if necessary to differentiate two otherwise identical products. UoU.size.value and UoU.size.unit will not be shown if they equal "1 each". UoU.size.value and UoU.size.unit will not be shown if the value is equal to "1" and the units exactly matches the Unit of Use quantity units.
strength	This may only be shown when there are no TP_Details shown for a particular component, or if the related TPUU is available with a different strength in another multi-component product (to avoid duplication of the TPP Preferred Term). Do not show strength if it exactly matches the UoU.size.value and UoU.size.units. This represents the strength value and units for the particular component, as derived from the MPUU Preferred Term. Where the MPUU Preferred Term shows dual strength, this will also be shown in the component details. For multi-ingredient units of use, the strength of each BoSS is shown, separated by a forward slash. The order of the strengths will be derived from the ingredient order in the related MPUU Preferred Term. The need to include more than two ingredient strengths will be determined on a case-by-case basis, bearing in mind the need to avoid any duplication of Preferred Term descriptions.

Description Component	Description
UoU.quantity.value.units	This represents the Unit of Use quantity value followed by a space and then the Unit of Use quantity units. This will only be shown if the related TPUU is available with a different value or units in another multi-component product (to avoid duplication of the TPP Preferred Term).
vaccine	The text "vaccine" will only be included if the product is intended for use as a vaccine.
inert	The text "inert" will only be included if the IAI for the component is equal to "inert substance".
medicinal.dose.form	The form shown will be derived from the form used in the MPUU Preferred Term.
trade.dose.form	This will only be shown where the IAI for the component is equal to "inert substance". The form shown will be derived from the form used in the TPUU Preferred Term. This will not be shown where it exactly matches the UoU.quantity.unit.
UoU.quantity.unit(s)	This represents the units used to describe the actual units of use within a product. The Unit of Use describes the smallest possible constituent which can be handled. Where the UoU.quantity.value is greater than "1" then the plural form of the UoU.quantity.unit will be used.
Total_Quantity_Size_Details	This is derived from the Total_Quantity_Size_Details of the related MPP Preferred Term.

4.8.2.3 TPP Preferred Term rules

Table 35: TPP Preferred Term rules

Rule ID	Description
AMT-TPP-PT-1	Capitalisation rules as defined in Appendix A apply.
AMT-TPP-PT-2	FORM If the Multi-component pack contains multiple forms then form will not be included.
AMT-TPP-PT-3	Products of the same Trade Product name with different formulations For products where two different formulations exist with the same Trade Product name, the duplicated Preferred Term of the existing (older) product will be differentiated with the term 'Old Formulation', in title casing, followed by the year that the old formulation was superseded. The information pertaining to the date that the old formulation was superseded will be confirmed via manufacturer data or TGA. The term and date will be applied to the end of the Preferred Term of the Trade Product Unit of Use, Trade Product Pack and Containered Trade Product Pack, contained within brackets. The method to apply this change is to create a new Preferred Term that contains the differentiating information, then retire the old Preferred Term to avoid ambiguity. The new formulation will not have any additional text applied. For example: Trade Product Pack Preferred Term: Elevit tablet, 30 (Old Formulation 2017)

4.9 Containered Trade Product Pack (CTPP)

4.9.1 CTPP definition

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

4.9.2 CTPP descriptions

4.9.2.1 CTPP Fully Specified Name definition

The Fully Specified Name of a CTPP follows the syntax:

CTPP FSN := TPP_FSN_Details ", " Container " (containered trade product pack)"

where the component parts are described as follows:

Table 36: CTPP Fully Specified Name description

Description Component	Description
TPP_FSN_Details	The details included in the Fully Specified Name of the associated TPP, but without the semantic tag (that is, without "(trade product pack)").
Container	The Preferred Term of the container type of the CTPP, as defined by the relationship CTPP HAS CONTAINER TYPE. If the container type duplicates the preceding text from the TPP, then the container type will be suppressed and not displayed in the Fully Specified Name description of the CTPP. Where the CTPP has a subpack, then the container type (where shown) will be pluralised.
(containered trade product pack)	The semantic tag used in the Fully Specified Name of all CTPP concepts.

4.9.2.2 CTPP Fully Specified Name rules

Table 37: CTPP Fully Specified Name rules

Rule ID	Description
AMT-CTPP-FSN-1	Capitalisation rules as defined in Appendix A apply.
AMT-CTPP-FSN-2	Container Type Container type will be populated, as defined by the TGA. See Appendix J. If the container type duplicates the preceding text from the TPP, then the container type will be suppressed and not displayed in he Fully Specified Name description of the CTPP.

4.9.2.3 Containered Trade Product Pack Preferred Term definition

The Preferred Term of a CTPP, by default, follows the syntax:

CTPP PT := TPP_PT_Details [", " Container]

where the component parts are described as follows:

Table 38: CTPP Preferred Term description

Description Component	Description
TPP_PT_Details	The details included in the Preferred Term of the associated TPP.
Container	The Preferred Term of the container type of the CTPP, as defined by the relationship CTPP HAS CONTAINER TYPE. If the container type duplicates the preceding text from the TPP, then the container type will be suppressed and not displayed in the Preferred Term description of the CTPP. Where the CTPP has a subpack, then the container type (where shown) will be pluralised.

4.9.2.4 CTPP Preferred Term rules

Table 39: CTPP PT rules

Rule ID	Description
AMT-CTPP-PT-1	Capitalisation rules as defined in Appendix A apply.
AMT-CTPP-PT-2	Container Type Container type will be populated, as defined by the TGA, or approved for inclusion as per Appendix J. If the container type duplicates the preceding text from the TPP, then the container type will be suppressed and not displayed in the Preferred Term description of the CTPP.
AMT-CTPP-PT-3	Products of the same Trade Product name with different formulations For products where two different formulations exist with the same Trade Product name, the duplicated Preferred Term of the existing (older) product will be differentiated with the term 'Old Formulation', in title casing, followed by the year that the old formulation was superseded. The information pertaining to the date that the old formulation was superseded will be confirmed by sponsor information. The term and date will be applied to the end of the Preferred Term of the Trade Product Unit of Use, Trade Product Pack and Containered Trade Product Pack, contained within brackets. The method to apply this change is to create a new Preferred Term that contains the differentiating information, then retire the old Preferred Term to avoid ambiguity. The new formulation will not have any additional text applied. For example: Containered Trade Product Pack Preferred Term: Elevit tablet, 30, blister pack (Old Formulation 2017)

5 Substance concepts

These concepts represent the ingredients within products.

5.1 Substance (SUB)

5.1.1 Substance definition

These are concepts that represent the chemical entities that may act as ingredients of therapeutic goods, as follows:

- Complete substances that act as actual active ingredients of therapeutic goods, for example, heparin sodium, perindopril arginine and dexamethasone sodium phosphate. This class of substance may or may not be a modified base or other type of derivative.
- BoSS concepts that may or may not be available as actual ingredients, for example, perindopril or dexamethasone.
- Inert substances are included in the AMT as an ingredient only when they are provided by the manufacturer as part of a pack, and are designed to be used to reconstitute (for example, Flolan) or dilute (for example, Jevtana) the accompanying product component containing the active ingredient(s), prior to use.
- Excipients are not included in the AMT as ingredients.

An IS MODIFICATION OF relationship exists to link a modified base ingredient to its related base ingredient within the *Substance* hierarchy (for example, acamprosate calcium is a modification of acamprosate).

5.2 Substance descriptions

5.2.1 Substance FSN definition

The FSN of a Substance follows the syntax:

```
SUB FSN := Ingredient_Name “ (AU substance)”
```

where the component parts are described as follows:

Table 40: Substance FSN description

Description Component	Description
Ingredient_Name	The name of the Substance.
(AU substance)	The semantic tag used in the FSN of all Ingredient concepts.

5.2.2 Substance FSN rules

Table 41: Substance FSN rules

Rule ID	Description
AMT-SUB-FSN-1	Capitalisation rules as defined in Appendix A apply.
AMT-SUB-FSN-2	The Substance FSN will be derived from the Australian Approved Name (AAN) or similar (for example, ABN or AHN), as specified in the *TGA Approved Terminology for Medicines* [3]. The base form of the Substance as well as the modification will be represented. EXCEPTION This may, however, differ to allow for other approved or clinically intuitive names, or natural language word order. Current exceptions are listed in Appendix C and will be added to on a case-by-case basis.
AMT-SUB-FSN-3	No additional name segments will be added to the Substance FSN. EXCEPTION In instances where the name may lead to ambiguity, additional details may be added, for example, animal origin, plant part and plant preparation. Current exceptions: • bovine • equine • fruit • human • human-bovine • husk • leaf • porcine • root Additions to the exceptions list will be reviewed on a case-by-case basis.
AMT-SUB-FSN-4	Where a Substance name includes digits as part of the name, the digits will be preceded by a hyphen, with no spaces on either side of the hyphen. For example: macrogol-3350, peginterferon alfa-2a.

5.2.3 Substance PT definition

The Preferred Term of a Substance follows the syntax:

```
SUB PT := Ingredient_Name
```

where the component parts are described as follows:

Table 42: Substance PT description

Description Component	Description
Ingredient_Name	The name of the Substance.

5.2.4 Substance PT rules

Table 43: Substance PT rules

Rule ID	Description
AMT-SUB-PT-1	Capitalisation rules as defined in Appendix A apply.
AMT-SUB-PT-2	The Substance PT will be derived from the AAN[7] or similar (for example, ABN, AHN), as specified in the Australian Register of Therapeutic Goods. The base form of the Substance as well as the modification will be represented. EXCEPTION This may, however, differ to allow for other approved or clinically intuitive names, or natural language word order. Current exceptions are listed in Appendix C and will be added to on a case-by-case basis.
AMT-SUB-PT-3	No additional name segments will be added to the Substance PT. EXCEPTION In instances where the name may lead to ambiguity, additional details may be added, for example, animal origin, plant part and plant preparation. Current exceptions: • bovine • equine • fruit • human • human-bovine • husk • leaf • porcine • root Additions to the exceptions list will be reviewed on a case-by-case basis.
AMT-SUB-PT-4	Where a Substance name includes digits as part of the name, the digits will be preceded by a hyphen, with no spaces on either side of the hyphen. For example: macrogol-3350, peginterferon alfa-2a.

Table 44: Examples of Substance FSNs and PTs

Fully Specified Name	Preferred Term
amoxicillin (AU substance)	amoxicillin
morphine (AU substance)	morphine
calcium carbonate (AU substance)	calcium carbonate

[7] See *Basic Terminology of Stereochemistry (IUPAC Recommendations 1996)*. [10]

6 Australian Qualifier concepts

6.1 Australian Qualifier definition

These are concepts used to qualify other concepts. These concepts will be used in the AMT to provide atomic data used to construct the name of the product and provide additional information about an AMT product concept.

Table 45: Australian Qualifier concepts

Concept Name	Definition
Container Type (CT)	This qualifier concept defines the type of containers that immediately cover the medicine, and can be physically handled. It does not include an article intended for ingestion. Examples include ampoule, bottle, blister pack, vial and so on.
Form (F)	This qualifier concept describes the dose formulation, for example, tablet, capsules or eye drops. The form may also be described in the terminology as a dose form. The dose form is the form in which the product is manufactured and transported (that is, the dose form created by the manufacturer, for example, powder for reconstitution as suspension). It should be noted that this does not necessarily represent the administered dose form. (The administered dose form is the form of the product when it is administered to a patient, for example, oral liquid , which is reconstituted from the manufactured dose form of powder for reconstitution.) 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.
Unit of Measure (UoM)	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: • Strength numerator units • Strength denominator units • Proportion units (see Appendix F.4) • Unit of Use quantity units • Unit of Use Size units
Unit of Use (UoU)	The Unit of Use describes a discrete unit dose form (for example, tablet, capsule) or a continuous substance where a consistent physically measurable unit or sub-unit cannot be identified (for example, cream, eye drops).

6.2 Australian Qualifier descriptions

6.2.1 Australian Qualifier FSN definition and rules

6.2.1.1 Definition

The FSN of an Australian Qualifier follows the syntax:

```
Australian Qualifier FSN :=      Qualifier_Name " (AU qualifier)"
```

where the component parts are described as follows:

Table 46: Australian Qualifier FSN description

Description Component	Description
Qualifier_Name	The term used to describe the specific qualifier concept.
(AU qualifier)	The semantic tag used in the FSN of all Australian Qualifier concepts.

6.2.1.2 Rules

None applicable

6.2.2 Australian Qualifier PT definition and rules

6.2.2.1 Definition

The Preferred Term of an Australian Qualifier follows the syntax:

```
Australian Qualifier PT := Qualifier_Name
```

where the component parts are described as follows:

Table 47: Australian Qualifier PT description

Description Component	Description
Qualifier_Name	The term used to describe the specific qualifier concept.

Table 48: Australian Qualifier PT rules

Rule ID	Description
AMT-AQ-PT-1	The Form PT will be the same as the Form FSN without the word "dose form" and the semantic tag of "(AU qualifier)". For example, where the FSN is "injection: solution dose form (AU qualifier)", the PT will be "injection: solution". See Appendix G for Preferred Term Forms.

Table 49: Examples of Australian Qualifier concepts

Concept Name	Fully Specified Name	Preferred Term
Container Type (CT)	vial (AU qualifier)	vial
Form (F)	enteric tablet dose form (AU qualifier)	enteric tablet
Unit of Measure (UoM)	microgram unit (AU qualifier)	microgram
Unit of Use	measure Unit of Use (AU qualifier)	measure

6.3 Plural name description

6.3.1 Definition

The plural name used when the value of the Unit of Measure is greater than one. Refer to Appendix I for more information.

Note that this is an additional description type which is not released in the terminology release files.

Appendix A Capitalisation

Table 50: Capitalisation rules

Rule ID	Description
AMT-APP-CAP-1	The first character of a description (FSN, PT, synonym or Australian Additional description) will either be lower case or an integer, except where specified below in AMT-APP-CAP-2 to AMT-APP-CAP-10 inclusive.
AMT-APP-CAP-2	Trade Product names and Other Identifying Information will have each word in the name expressed as title case, including the form, where it appears as part of the TF_Name (for example, Dimetapp Chesty Cough Elixir). Individual words which appear as all upper or all lower cased will be title cased (for example, Ganfort not GANFORT, Elevit not elevit). Each word in a hyphenated name will be expressed as title case (for example, Duro-Tuss, Anti-Inflammatory). EXCEPTIONS Unique brand specific casing will be maintained only if it assists with readability. This also applies to concatenated terms (for example, DaktaGold not DaktaGOLD, GlucoOz). Articles such as “the” will be in lower case. Conjunctions such as “and” and prepositions such as “with” will be in lower case. Certain words, such as “plus” may be either in title case or lower case, depending on their use. Where “plus” is used as a conjunction it will be “plus” (for example, Day plus Night) and when it is used as a noun it will be “Plus” (for example, Coversyl Plus). Where an abbreviation which is included in the TP is an abbreviation for a substance name, then this abbreviation will be upper cased. For example: where the letters “hct” or “hctz” are used to indicate “hydrochlorothiazide” then they will be shown as “HCT” or “HCTZ”; where the letters “rbv” are used to represent “ribavirin”, then they will be shown as “RBV”. Where an acronym is included in the TP then this acronym will be upper cased. For example: “SR” as an acronym for sustained release; “LD” as an acronym for low dose; ZSC; Restore O.R.S. Where a TP contains a series of letters which do not form a word, these letters will be upper cased. For example, Aridon APN.
AMT-APP-CAP-3	Proper nouns will always be expressed in title case (for example, Bacillus Calmette and Guerin, Brisbane).
AMT-APP-CAP-4	Roman numerals will always be expressed in upper case (for example, factor XIII, antithrombin III).
AMT-APP-CAP-5	Chemical element symbols will be expressed in upper case (for a single letter) or in a mixture of upper and lower case (for more than one letter) according to International Union of Pure and Applied Chemistry (IUPAC) convention (for example, carbon (C), chromium (51Cr) edetate, cyanocobalamin (57Co)).[8]

[8] See *Basic Terminology of Stereochemistry (IUPAC Recommendations 1996)* [10]

Rule ID	Description
AMT-APP-CAP-6	Single letters preceding or following a substance name will be expressed in upper case (for example, B/Malaysia/2506/2004-like strain (B/Malaysia/2506/2004) haemagglutinin, vitamin C, amphotericin B).
AMT-APP-CAP-7	Binomial names used to describe an organism or plant will be expressed in full, using title case for the first word of the name, according to convention (for example, Haemophilus influenzae, Vaccinium macrocarpon).
AMT-APP-CAP-8	Organic chemical names. Each name will be expressed in lower case and will have any digits or single letters preceded or followed (as appropriate) immediately by a hyphen with no space (for example, methyl-2-methoxy-3-pyrazine). Chemical ring position will always be expressed in lower case (for example, ortho-dichlorobenzene, para-dichlorobenzene). Casing which is related to the stereochemistry of a molecule will follow IUPAC conventions (for example, dl-alpha-tocopheryl).[9] Isomeric names which have the full expression of the isomer embedded in the name will be entirely in lower case (for example, dextromethorphan, levodopa, cisatracurium).
AMT-APP-CAP-9	Sponsor names, manufacturers and house brands which are expressed in full or abbreviated will have each word in the name expressed as title case. (for example, Aspen, Novartis, Apo) Sponsor names, manufacturers and house brands which are acronyms will be upper cased. (For example, AFT, CSL, DRLA.) Where sponsor names appear with mixed casing in the associated documentation (for example, PI, CMI, product label, sponsor website, etc.) this mixed casing will be represented in the AMT. For example: DRx, GenRx.
AMT-APP-CAP-10	Where an accent forms part of a word in a registered product name, Sponsor name, manufacturer or house brand, the accent will not be represented. (For example, Alfare not Alfaré; Nestle not Nestlé.)
AMT-APP-CAP-11	Greek letters will be expressed as the actual English spelling of the word rather than using the traditional Greek symbol (for example, “alpha” and not “α“).

[9] See *Basic Terminology of Stereochemistry (IUPAC Recommendations 1996)* [10]

Appendix B Exception examples for MP and MPUU

As previously described in Section 4.3.1 (Medicinal Product Definition), the Medicinal Product will be represented free of chemical modifications to a base unless one or more of the following exceptions apply, in which case the name will be represented by the full name including the modification.

Note: Where it is considered that the physiological modified form does not materially affect the use of that compound, the name will be represented by the base. For the purpose of this document, the definition of a base incorporates the following entities:

The base of a modified base, for example:

modified base	**base**
calcium gluconate	calcium
clodronate sodium	clodronate

The abstract representation of an active moiety of a compound, for example:

compound	**base (or active moiety)**
perindopril arginine	perindopril
antazoline hydrochloride	antazoline

Addition of compounds to this list will be made according to the clinical impact of the compound, in consultation with external stakeholders and other appropriate expert bodies to ensure that only clinically significant representations are utilised in the AMT.

B.1 Discernible therapeutic differences to the base (clinically significant modifications)

A discernible therapeutic difference is defined as a modification to the base that materially changes the therapeutic potency of the base, the duration of action of the base, the onset of action of the base, the pharmacological target of the base or the adverse reaction profile of the base, such that prescribing and administration decisions should, in the opinion of an appropriate expert body, be made at the level of the modification to the base. The MP name will consist of the base name with modification, where there is clear scientific evidence to show it to be discernibly therapeutically different from the base. This MP will also be represented as the IAI.

Where different modified forms of a specific base active ingredient result in significant variations in the content of base active ingredient, and where dosage is calculated on the base active ingredient amount, the modified base will be displayed in full in the MP. Examples of bases where this applies are: caffeine, lithium and quinine.

Modifications to a base will also include the following:

- where both the base and modification exert a therapeutic effect (for example, methenamine hippurate, silver sulphadiazine);

- where both the base and modification exert a different therapeutic effect resulting in the substance having more than one therapeutic purpose (for example, calcium carbonate in calcium supplements (due to calcium content) versus calcium carbonate in antacids (due to carbonate content)); and
- where the type of modification results in a distinct use of the active ingredient (for example, topical use of selenium sulfide).

For example, the following modifications are considered therapeutically different to the base and will be represented in the MP and IAI:

- hyoscine butylbromide
- hyoscine hydrobromide
- zuclopenthixol acetate
- zuclopenthixol decanoate

Modifications which may be made to a base include:

- albumin bound formulations
- lipid formulations
- liposomal formulations

For items that include discernible therapeutic differences to the base, the modification will follow the name of the substance. Where multiple modifications are present, the order will be determined on a case-by-case basis.

For example:

doxorubicin hydrochloride (as pegylated liposomal)

Appendix C Ingredient naming conventions

Ingredient names will be derived from the TGA Australian Approved Names for Therapeutic Substances with the following exceptions.

C.1 Ingredients ending in "-ate" or "-ic acid"

In some instances, ingredients that end in "-ate" when available as a modified base, shall be changed so that the base is represented by ending in "-ic acid" where appropriate, based on decisions made by an expert panel. The current edition of *Martindale: The Complete Drug Reference* [4] will be the reference source. The relevant base ingredients will always be displayed as follows:

- acetate
- alendronate
- alginate
- amidotrizoic acid
- aminolevulinic acid
- ascorbic acid
- azelaic acid
- benzoic acid
- boric acid
- citric acid
- clavulanic acid
- clodronate
- cromoglycate
- edetic acid
- etidronate
- etacrynic acid
- folic acid
- folinic acid
- fusidate
- gadobenic acid
- gadopentetic acid
- gadoteric acid
- gadoxetic acid
- hyaluronic acid
- ibandronate

- iotroxic acid
- lactate
- mefenamic acid
- mycophenolate
- nicotinic acid
- pamidronate
- polylactic acid
- risedronate
- salicylic acid
- tartaric acid
- tiaprofenic acid
- tiludronate
- tranexamic acid
- ursodeoxycholic acid
- valproate
- zoledronic acid

C.2 Ingredient minus base name

In some instances, the "IngredientMinusBase" has been changed in order for the expression to make more sense in the context in which it is used. This represents the "(as modification)" portion of the name where this detail appears. In these cases, IngredientMinusBase does not equal the modification component of the name minus the base component of the name, and is represented by a more intuitive name.

As an example, this means that when the ingredient is "ferrous fumarate", where the base is "iron" (and not "ferrous") the MPUU ingredient details would potentially show "iron (as ferrous fumarate)".

Note: The following table contains examples only and is not exhaustive.

Table 51: Examples of clinically significant portions of ingredient names

Ingredient Name	Base	IngredientMinusBase
ferric pyrophosphate	iron	ferric pyrophosphate
ferrous fumarate	iron	ferrous fumarate

C.3 Waters of hydration

Waters of hydration shall only be expressed for each ingredient in the FSN where hydration is present and the modification is deemed to be clinically significant (according to Appendix B). Where an ingredient is found to be anhydrous or dried, this shall not be expressed.

Note that waters of hydration shall only be expressed in the Preferred Term if they are part of the proprietary name. For example:

MP FSN: atropine sulfate monohydrate (medicinal product)

MP PT: atropine sulfate monohydrate

MPUU FSN: atropine sulfate monohydrate 600 microgram tablet (medicinal product unit of use)

MPUU PT: atropine sulfate monohydrate 600 microgram tablet

C.4 Insulins

The TGA name for insulins will be modified to show the type of insulin as follows:

- insulin aspart
- insulin aspart protamine
- insulin detemir
- insulin glargine
- insulin glulisine
- insulin lispro
- insulin lispro protamine
- insulin isophane bovine
- insulin isophane human
- insulin neutral bovine
- insulin neutral human

C.5 Intuitive ingredient names

Certain set combinations of ingredients have been assigned an intuitive name in order to enhance product recognition. The following list shows all such names in use in the AMT. These names are used only in the PT and where used, the relevant strength (where it would normally be present) is omitted.

Table 52: List of FSN MP descriptions and their related intuitive MP descriptions

FSN MP	Intuitive MP
A/New Caledonia/20/99 (H1N1)-like strain (A/New Caledonia/20/99 (IVR-116)) haemagglutinin + A/Wisconsin/67/2005 (H3N2)-like strain (A/Wisconsin/67/2005 (NYMCX-161B)) haemagglutinin + B/Malaysia/2506/2004-like strain (B/Malaysia/2506/2004) haemagglutinin (medicinal product)	influenza virus vaccine 2007
A/Brisbane/10/2007 (H3N2)-like strain (A/Brisbane/10/2007 IVR-147) haemagglutinin + A/Solomon Islands/3/2006 (H1N1)-like strain (A/Solomon Islands/3/2006 IVR-145) haemagglutinin + B/Florida/4/2006-like strain (B/Brisbane/3/2007) haemagglutinin (medicinal product)	influenza virus vaccine 2008
A/Brisbane/10/2007 (H3N2) - like strain (A/Brisbane/10/2007 (H3N2) (IVR-147)) + A/Brisbane/59/2007 (H1N1) - like strain (A/Brisbane/59/2007 (H1N1) (IVR-148)) + B/Florida/4/2006 - like strain (B/Florida /4/2006) (medicinal product)	influenza virus vaccine 2009

FSN MP	Intuitive MP
A/California/7/2009 (H1N1) - like strain (A/California/7/2009 (NYMC X-181)) + A/Perth/16/2009 (H3N2) - like strain (A/Wisconsin/15/2009 (NYMC X-183)) + B/Brisbane/60/2008 - like strain (B/Brisbane/60/2008) (medicinal product)	influenza virus vaccine 2010
A/California/7/2009 (H1N1) - like strain (A/California/7/2009 (NYMC X-181)) + A/Perth/16/2009 (H3N2) - like strain (A/Victoria/210/2009 (NYMC X-187)) + B/Brisbane/60/2008 - like strain (B/Brisbane/60/2008) (medicinal product)	influenza virus vaccine 2011-2012
A/California/7/2009 (H1N1) - like strain (A/California/7/2009 (NYMC X-181)) + A/Victoria/361/2009 (H3N2) - like strain (A/Victoria/361/2011 (IVR-165)) + B/Wisconsin/1/2010 - like strain (B/Hubei-Wujiagang/158/2009 (NYMC BX-39)) (medicinal product)	influenza virus vaccine 2013
A/California/7/2009 (H1N1) (NYMC X-179A) (A/California/7/2009 (H1N1)pdm09-like) inactivated vaccine + A/Texas/50/2012 (NYMC X-223A) (A/Texas/50/2012 (H3N2)-like) inactivated vaccine + B/Massachusetts/2/2012 (NYMC BX-51B) (B/Massachusetts/2/2012-like) inactivated vaccine (medicinal product)	influenza virus vaccine 2014
A/California/7/2009 (H1N1) - like virus + A/Switzerland/9715293/2013 (H3N2) - like virus + B/Phuket/3073/2013 - like virus (medicinal product)	influenza virus trivalent vaccine 2015
A/California/7/2009 (H1N1) - like virus + A/Switzerland/9715293/2013 (H3N2) - like virus + B/Brisbane/60/2008 - like virus + B/Phuket/3073/2013 - like virus (medicinal product)	influenza virus quadrivalent vaccine 2015
A/California/07/2009 (H1N1) pdm09 - like virus + A/Hong Kong/4801/2014 (H3N2) - like virus + B/Brisbane/60/2008 - like virus + B/Phuket/3073/2013 - like virus (medicinal product)	influenza virus quadrivalent vaccine 2016
brown snake (Pseudonaja textilis) antivenom + death adder (Acanthophis antarcticus) antivenom + king brown snake (Pseudechis australis) antivenom + taipan snake (Oxyuranus scutellatus) antivenom + tiger snake (Notechis scutatus) antivenom (medicinal product)	polyvalent Australian snake antivenom

C.5.1.1 Example: vaccine injection

MPUU FSN	A/California/7/2009 (H1N1) (NYMC X-179A) (A/California/7/2009 (H1N1)pdm09-like) inactivated vaccine 15 microgram + A/Texas/50/2012 (NYMC X-223A) (A/Texas/50/2012 (H3N2)-like) inactivated vaccine 15 microgram + B/Massachusetts/2/2012 (NYMC BX-51B) (B/Massachusetts/2/2012-like) inactivated vaccine 15 microgram injection, 0.5 mL syringe (medicinal product unit of use)
MPUU PT	A/California/7/2009 (H1N1) (NYMC X-179A) (A/California/7/2009 (H1N1)pdm09-like) inactivated vaccine 15 microgram + A/Texas/50/2012 (NYMC X-223A) (A/Texas/50/2012 (H3N2)-like) inactivated vaccine 15 microgram + B/Massachusetts/2/2012 (NYMC BX-51B) (B/Massachusetts/2/2012-like) inactivated vaccine 15 microgram injection, 0.5 mL syringe
MPUU PT using intuitive ingredient name	influenza trivalent adult vaccine 2014 injection, 0.5 mL syringe

C.5.1.2 Example: antivenom injection

MPUU FSN	brown snake (Pseudonaja textilis) antivenom 1000 units + death adder (Acanthophis antarcticus) antivenom 6000 units + king brown snake (Pseudechis australis) antivenom 18000 units + taipan snake (Oxyuranus scutellatus) antivenom 12000 units + tiger snake (Notechis scutatus) antivenom 3000 units injection, vial (medicinal product unit of use)
MPUU PT	brown snake (Pseudonaja textilis) antivenom 1000 units + death adder (Acanthophis antarcticus) antivenom 6000 units + king brown snake (Pseudechis australis) antivenom 18000 units + taipan snake (Oxyuranus scutellatus) antivenom 12000 units + tiger snake (Notechis scutatus) antivenom 3000 units injection, vial
MPUU PT using intuitive ingredient name	polyvalent Australian snake antivenom injection, vial

C.5.1.3 Example: oral vaccine

FSN	poliovirus serotype 1 live antigen 1000000 CCID50 units + poliovirus serotype 2 live antigen 100000 CCID50 units + poliovirus serotype 3 live antigen 600000 CCID50 units oral liquid, 1 vial (medicinal product unit of use)
PT	poliovirus serotype 1 live antigen 1000000 CCID50 units + poliovirus serotype 2 live antigen 100000 CCID50 units + poliovirus serotype 3 live antigen 600000 CCID50 units oral liquid, 1 vial
PT using intuitive ingredient name	polio trivalent live vaccine oral liquid, 1 vial

Appendix D Examples of products with more than three ingredients

This list is not exhaustive and is provided to illustrate examples of products where more than three ingredients will be specified as part of the Medicinal Product PT.

This list currently contains specific examples, but may contain product groups (for example, vaccines and parenteral nutrition solutions).

For reasons of clinical safety, any products containing paracetamol or pseudoephedrine as an active ingredient will always show this ingredient as one of the three listed ingredients.

Table 53: Examples of products with more than three ingredients

Exception Examples	Trade Product
diphtheria + hepatitis B + pertussis, acellular + poliomyelitis + tetanus vaccine	Infanrix Penta
diphtheria + pertussis, acellular + poliomyelitis + tetanus vaccine	Boostrix-IPV, Infanrix IPV, Quadracel
diphtheria + Haemophilus influenzae type b + hepatitis B + pertussis, acellular + poliomyelitis + tetanus vaccine	Infanrix Hexa
amino acids + fat + glucose + minerals + vitamins	(enteral nutrition solutions)
cobicistat + elvitegravir + emtricitabine + tenofovir disoproxil fumarate	Stribild

Appendix E General strength formats

The rules described in this section pertain to strength details as represented in the description text of AMT concepts, and should not be confused with strength details as represented in the *Strength reference set*. For further information on the *Strength reference set*, refer to the *AMT v3 Technical Implementation Guide*. [2]

Table 54: General strength format rules

Rule ID	Description
AMT-APP-STR-1	Strength is to be expressed in accordance with the requirements stipulated by the *General requirements for labels for medicines*. [5]
AMT-APP-STR-2	The strength units will be consistent with the *Unit of Measure*.
AMT-APP-STR-3	Note that any overage contained in the product to allow the formulated amount to be administered is not specified.

Rule ID	Description
AMT-APP-STR-4	In general, the strength of an active ingredient should be expressed by a number between 1 and 999 metric units, and where required, to a maximum of 3 decimal places. If the number of units is less than 1, the next lower unit level should be used (for example, 500 micrograms should be used in preference to 0.5 mg). If the number of units is equal to or greater than 1000, the next higher unit level should be used (for example, 2 g should be used in preference to 2000 mg). This means that the units of strength may vary across a range of products. For example ceftriaxone may have powder for injection strengths of 500 mg, 1 g and 2 g. Where the Trade name of a product implies a strength unit, this will be disregarded in the strength expression of the product, and the above rules will apply (for example, Naprosyn SR 1000 (naproxen 1 g) modified release tablet, 1 tablet (trade product unit of use)). EXCEPTIONS Safety considerations will be taken into account when converting units. If dose titration is likely to occur across a range of products, then strength units for the product group will be reviewed on an individual basis, especially if titration involves use of more than one strength unit. Current exceptions (listed at the base level) are: • fentanyl will always be expressed as micrograms, for example, fentanyl 1600 microgram lozenge. • dexmedetomidine will always be expressed as micrograms, for example, dexmedetomidine 1000 microgram/10 mL injection. • vitamin A and vitamin A derivatives will always be expressed as microgram RE, for example, retinol palmitate 1050 microgram RE. Strengths of ingredients less than 1 microgram will be reviewed on a case-by-case basis to ensure that the represented strength conforms to current clinical practice, for example, calcitriol 0.25 microgram capsule (not 250 nanograms). Where the value for volume is less than 1 millilitre it will not be converted (that is, to conform to current clinical practice these volumes will not be expressed as microlitres), for example, dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, syringe. Where the molar value is less than 1 micromole it will not be converted (that is, to conform to current clinical practice these values will not be expressed as nanomoles), for example, no examples currently exist in the AMT. Where the Unit of Measure is an index of reactivity (IR) with a value of less than 1, it will not be converted, as there is no appropriate unit to convert it to (for example, it will continue to exist as 0.5 IR). For example: for example, house dust mite American + European 0.1 IR/mL injection, vial.
AMT-APP-STR-5	A space will be inserted between the strength value and strength Unit of Measure. This space must be a non-breaking space to ensure that the strength value and strength unit expressions are always kept together. For any value >= 10,000 a space will be included after every third digit starting from the right. For example: 10 000; 500 000; 1 000 000. For any value >= one million, the value will be expressed as a digit to state the number of millions (or part thereof) followed by the text "million". For example, the numerical value of 1 000 000 would be represented as "1 million", the numerical value of 1 500 000 would be represented as "1.5 million".
AMT-APP-STR-6	Strength units of measure will be expressed as singular if the value is less than or equal to "1", and will be expressed as plural if the value is greater than "1". This rule applies to full descriptions only – it does not apply to abbreviations. EXCEPTION: The strength units of measure of "microgram" will always be singular.
AMT-APP-STR-7	The full term "units" will be used rather than the abbreviated "U".
AMT-APP-STR-8	The percentage strength will not be qualified with the appropriate w/w or w/v unless required to avoid duplication of descriptions which only show an Other Strength Representation. For example, "coal tar prepared 1% w/w lotion" and "coal tar prepared 1% w/v lotion".

Rule ID	Description
AMT-APP-STR-9	A strength expression is mandatory unless defined as an exception as follows: Where a product is an allergen extract, the strength expression general rules will apply, except that no ingredient strength denominator will be expressed. The denominator value will be assumed from the unit dose form details. Examples: • Where a product is a vaccine. Refer to K.1.11 • Where a product is an antivenom. Refer to K.2.3 • Where an ingredient is inert in its own right and a strength expression would not be appropriate, then no strength is expressed. Examples: ○ water ○ water purified ○ water for injections ○ water for irrigation ○ inert substance diluent • Where a group of ingredients forms a compound where the inclusion of strength is meaningless at either the ingredient level or the product level. Examples: ○ aqueous cream ○ calamine lotion ○ vitamin B compound
AMT-APP-STR-10	Where the strength or volume of a product is not a set single value but may vary within a given range, the strength or volume will be expressed as the range, with the lower numerical value, followed by the word "to" and then the upper numerical and the relevant units.
AMT-APP-STR-11	Where the strength or volume of a product is expressed with a lower limit or an approximate (that is, contains not less than, contains equal to or greater than, more than, or approximately) the strength or volume will be expressed as a specific value without any other descriptors. This rule is mostly encountered with medicines containing biological components where an exact strength cannot be stated. For example: • factor II • factor X • von Willebrand factor
AMT-APP-STR-12	The percentage strength of a product, where included as defined in Appendix E.1 will not be shown when this value is equal to 100%.

E.1 Strength expression rules for specific medication forms

The following table sets out rules for display of strengths for various forms. For safety reasons, some items will have an alternative representation of the strength or dual representation of strength. This will be used for ingredients such as lignocaine and adrenaline. In these cases, strength can be expressed as biological activity, in units, or as ratios/percentages as well as in terms of milligrams or micrograms.

Table 55: Examples of exceptions and associated rules for strength expressions

Medication Form	Rules	Example
Solid unit dose forms e.g. tablets, capsules, pessaries, suppositories, lozenge, pastille, chewing gum	Strength is to be expressed as the amount per unit dose form.	amoxicillin 500 mg capsule fentanyl 400 microgram lozenge
Liquid unit dose forms e.g. single dose injections	The strength of liquid single dose injections is to be expressed as the amount of drug present in the unit dose volume.	gentamicin 80 mg/2 mL injection
	EXCEPTION Water for injection will not have a specified strength. This will also apply to other products that do not have an associated specific strength.	water for injection 10 mL injection
Liquid unit dose forms e.g. multidose injections	Strength is to be expressed as the amount of active ingredient per mL. This method will be used for insulins and other identified multidose injections where the intention is that only a proportion of the total quantity will be administered at any one time.	insulin aspart 100 units/mL injection
Liquid unit dose forms – others e.g. sachets of liquid	Strength is to be expressed as the amount of drug per mL.	chlorhexidine gluconate 1.2 mg/mL sachet
Continuous solid unit doses e.g. granules, powder	Strength is to be expressed as the weight of the active ingredient.	sodium bicarbonate 1.76 g sachet
Continuous semi-solid preparations e.g. creams, gels, ointments	If a product is applied locally and is intended to have a local effect then a single strength as % should be displayed.	hydrocortisone 1% cream
	If a product is applied locally and is intended to have a systemic effect then a single strength as mg (or similar) should be displayed. If the product documentation also represents the strength in a different form (such as %), then dual strength as % followed by mg (or similar) in brackets should be displayed.	testosterone 1% (12.5 mg/actuation) gel, actuation
Continuous liquid preparations, other than for ingestion e.g. mouthwash, paints, eye drops, ear drops, nasal drops, etc.	Strength is to be expressed as weight or volume per gram or mL (or other weight or volume of the product as appropriate).	
	If a product is applied locally and is intended to have a local effect then a single strength as % should be displayed.	chlorhexidine gluconate 0.2% mouthwash

Medication Form	Rules	Example
	If a product is applied locally and is intended to have a systemic effect then a single strength as mg (or similar) should be displayed. If the product documentation also represents the strength in a different form (such as %), then dual strength as % followed by mg (or similar) in brackets should be displayed.	*(no current example available)*
Continuous liquid preparations for ingestion e.g. oral solutions, oral suspensions, oral emulsions, oral liquids	Strength will be expressed as the amount of active ingredient in a stated volume, as is represented on the package label.	erythromycin 200 mg/5 mL oral liquid ciclosporin 100 mg/mL oral liquid
	Note: where a powder for oral suspension is labelled in terms of the reconstituted form, the strength will be represented as the amount of active ingredient in the reconstituted dose volume.	amoxicillin 250 mg/5 mL powder for oral liquid
Continuous solid preparations e.g. granules, powders	Strength will usually be expressed as weight per weight or weight per volume.	psyllium husk powder 535 mg/g powder for oral liquid
Patches	Strength will be expressed as the amount of active drug released over a stated time.	estradiol 25 microgram/24 hours patch
Inhalers and sprays e.g. inhalers and sprays, pressurised inhalers, dry powder inhalers, nasal spray, sublingual spray	Metered dose inhalers: The strength is expressed as the amount (weight) per actuation. Other inhalers: The strength is expressed as per mL or per mg, whichever is appropriate to the form of the inhaler.	beclomethasone 50 microgram/actuation powder for inhalation
Implants	The strength is expressed either as the amount per implant or device.	estradiol 20 mg implant
Dry powder injections	The strength is expressed as the amount per vial (usually as a weight).	amoxicillin 500 mg powder for injection

E.2 Dual strength representation

Dual strength representation of a substance may be included where relevant to meet clinical requirements, including:

- potential safety concerns for dosing and administration purposes
- when product documentation expresses the strength of the substance(s) in multiple ways
- oral preparations containing elements (excluding multivitamins, electrolyte replacement and nutritional products), if stated in the product information
- the number of mmol for potassium only (as per E.2.1)

Examples of items where this may be used include:

- adrenaline and noradrenaline for parenteral use. For example, adrenaline 1 in 1000 (1 mg/mL) injection, ampoules.

- calcium supplement for osteoporosis. For example, calcium carbonate 1.5 g (calcium 600 mg) tablet.
- hormone replacement products. For example, testosterone 1% (25 mg/2.5 g) gel, sachet.

Note: This list is not exhaustive and additional examples will be added as determined by clinical practice.

E.2.1 Strength representation for products containing potassium

The mmol strength of potassium will always be displayed in descriptions for:

- parenteral products,
- oral products which contain at least 7.5 mmol/unit dose, or if the maximum daily dose provides at least 15 mmol of potassium.

This excludes products for topical/external use (e.g. cream, irrigation solution) and nutritional supplements.

Note:

- If this information is not readily available in the product documentation, the mmol strength will need to be calculated (and rounded up to 1 decimal place) to ensure it is within range.
- If no maximum daily dose is available in the product information, then the mmol strength will only be included if it contains at least 7.5 mmol/unit dose
- The % strength will be dropped off for the potassium component in parenteral products as no more than two strengths should be displayed. For example, potassium chloride 2.98 g (potassium 40 mmol)/L + sodium chloride 0.584% (5.84 g/L) injection, bag

The mmol strength will follow the numerator/denominator strength of the substance. For example:

- single source of potassium - monobasic potassium phosphate 1.361 g (potassium 10 mmol)/10 mL injection, ampoule
- multiple sources of potassium - potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) effervescent tablet

E.2.2 Acceptable synonyms

When a product is expressed with both a single strength and a strength range, an acceptable synonym displaying the alternate strength may be added to the MPUU, MPP, TPUU, TPP and CTPP concepts.

For example:

Oncotice BCG

- Product label states a strength of 5 x 10^8 CFU
- Prescribed, and PI states a strength of 2-8x10^8 CFU

MPUU: Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Tice strain 500 million CFU injection, vial

Synonym: Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Tice strain 200 million to 800 million CFU injection, vial

Note: This rule does not apply to vaccine products. See Appendix K.1 for the use of synonyms in vaccines.

E.3 Strength expression rules for specific substances

The following table shows substances which have specific strength representation requirements. This strength representation should be shown for all instances of these substances in all products within the AMT.

Table 56: Substances with specific strength representation requirements

Substance	Strength Representation
alpha tocopherol	mg with units in (...)
dl-alpha-tocopheryl acetate	mg with units in (...)
anti-D rho immunoglobulin, human	units only
antithrombin III	units only
bacitracin zinc	units only
bleomycin sulfate	units only
colecalciferol	mg with units in (...)
d-alpha-tocopherol	mg with units in (...)
d-alpha-tocopheryl acetate	mg with units in (...)
d-alpha-tocopheryl acid succinate	mg with units in (...)
epoetin alfa	units only
epoetin beta	units only
epoetin lambda	units only
factor II	units only
factor IX	units only
factor VIII	units only
factor XIII	units only
felypressin	units only
follitropin alfa	units with mg in (...)
follitropin beta	units with mg in (...)
gonadotrophin - chorionic human	units only
gonadotrophin-menopausal human	units only
heparin sodium	units only
hyaluronidase	units only
interferon alfa-2a	units with mg in (...)
interferon alfa-2b	units with mg in (...)

Substance	Strength Representation
interferon beta-1a	units with mg in (...)
interferon beta-1b	units with mg in (...)
interferon gamma-1b	units with mg in (...)
lenograstim	units with mg in (...)
lutropin alfa	units only
moroctocog alfa	units only
nonacog alfa	units only
nystatin	units only
octocog alfa	units only
ornipressin	units only
oxytocin	units only
pancreatic extract	units only
protein C	units only
calcitonin salmon (salcatonin)	units only
somatropin	mg only
streptokinase	units only
tenecteplase	mg only
vitamin A and vitamin A derivatives	microgram RE

Appendix F Units of Measure

F.1 Rules

Units of Measure are used in several places within the AMT. They are used to quantify the value of strength of active ingredient and excipient (if necessary) at MPUU and TPUU level respectively and at the MPP and TPP level to indicate the amount of MP within a container, for example, Quantity = 28, Unit of Measure = tablet.

Table 57: Units of Measure rules

Rule ID	Rule
AMT-APP-UOM-1	International System of Units (SI units) will be used where appropriate at MPUU and TPUU level, descriptive terms as listed below will be used at MPP and TPP level.
AMT-APP-UOM-2	In general, the Units of Measure should be expressed by a number between 1 and 999 metric units. If the number of units is less than 1, the next lower unit level should be used. If the number of units is equal to or greater than 1000, the next higher unit level should be used. For example: • If the value is equal to or greater than 1000 milligram (mg), convert to and display as gram (g). • If the value is less than one milligram (mg) convert to and display as microgram. • If the value is equal to or greater than 1000 millilitre (mL), convert to and display as litre (L). EXCEPTIONS • If the value is less than one millilitre do not convert. • If the value is less than one micromole do not convert. • If the value is equal to or greater than 1000 microgram RE, do not convert.
AMT-APP-UOM-3	For any value >= 10,000 a space will be included after every third digit starting from the right. For example: 10 000; 500 000; 1 000 000. For any value >= one million, the value will be expressed as a digit to state the number of millions (or part thereof) followed by the text “million”. For example, the numerical value of 1 000 00 would be represented as “1 million”, the numerical value of 1 500 000 would be represented as “1.5 million”.
AMT-APP-UOM-4	All FSN descriptions will always contain the word “unit” immediately prior to the semantic tag, unless the descriptor itself ends with the word “unit” (this is to avoid duplication). For example: gram unit (AU qualifier), millilitre unit (AU qualifier), ELISA unit (AU qualifier), (not ELISA unit unit (AU qualifier)).
AMT-APP-UOM-5	All FSN descriptions for composite units of measure will have the word “unit” at the end of both the numerator descriptor and the denominator descriptor. As described in AMT-APP-UOM-4, duplication of the term unit will not occur. For example: milligram unit per each unit, gram unit per litre unit, Kyowa unit per each unit (not Kyowa unit unit per each unit).

Rule ID	Rule
AMT-APP-UOM-6	The Unit of Measure PT will not show the word “unit” or the semantic tag of “(AU qualifier)”. For example, where the FSN is “ampoule unit (AU qualifier)”, the PT will be “ampoule”.

F.2 Preferred Terms

AMT Preferred Term descriptions will not state the descriptor for units of measure where the measure is “international units”, “anti-Xa international units” or “mouse lethal dose 50 units”. These are expressed in the PT as “units”, unless the descriptor is required to avoid ambiguity.

Where there is only one type of unit for a particular ingredient, then “unit” is sufficient detail in the PT strength expression. Where there are two or more types of units, then the full detail of all of the units must be specified in the PT strength expression.

For example, bleomycin products will retain the descriptor of international to avoid ambiguity between different products which have their strength defined by either international units or USP units.

Note that the Unit of Measure PT description will still contain the word “international”, only the descriptions constructed using this Unit of Measure will be affected.

Table 58: Examples of Preferred Terms

Fully Specified Name	Preferred Term (for Unit of Measure qualifier)	Term used in generated PT descriptions
international unit (AU qualifier)	international unit	unit
million international units (AU qualifier)	million international units	million units
anti-Xa international unit (AU qualifier)	anti-Xa international unit	anti-Xa unit
mouse lethal dose 50% unit (AU qualifier)	mouse LD50 unit	unit

F.3 Units of Measure

The following Units of Measure lists are derived from TGA Units of Proportion, located in the Code Tables at www.ebs.tga.gov.au.[10]

Note: This list contains examples only and is not definitive.

Table 59: Area

Description	Abbreviation
square centimetre unit	square cm

[10] In the sidebar, select **Public TGA Information > Code Tables**.

Table 60: Biological units

Description	Abbreviation
anti-Xa international unit	anti-Xa international unit
antigen unit	antigen unit
D antigen unit	D antigen unit
Enzyme-Linked ImmunoSorbent Assay unit	ELISA unit
index of reactivity unit	IR
kallikrein inactivator unit	KI unit
Kyowa unit	Kyowa unit
lipase unit	LipU
thousand acid lactase unit	thousand ALU
thousand alpha-amylase dextrinising unit	thousand DUAA
thousand cellulase unit	thousand CU
thousand haemoglobin units on the tyrosine basis	thousand HUT
trillion vector genomes unit	trillion vector genomes
unit	unit

Table 61: Mass

Description	Abbreviation
gram unit	g
kilogram unit	kg
microgram unit	microgram
milligram unit	mg

Table 62: Microbiological cultures

Description	Abbreviation
billion organisms unit	billion organisms
billion vibrios unit	billion vibrios
billion viral particles unit	billion viral particles
cell culture infectious dose 50% unit	CCID50 unit
million cell culture infectious dose 50% unit	million CCID50 unit
million colony forming unit	million colony forming units
million organisms unit	million organisms
mouse lethal dose 50% unit	mouse LD50 unit

Description	Abbreviation
plaque forming unit	PFU
tissue culture infectious dose 50% unit	TCID50 unit
tuberculin unit	tuberculin unit

Table 63: Time

Description	Abbreviation
hour unit	hour

Table 64: Type of International Units

Description	Abbreviation
international unit	international unit
million international unit	million international unit

Table 65: Type of Pharmacopoeial Units

Description	Abbreviation
British Pharmacopoeial unit	BP unit

Table 66: Volume

Description	Abbreviation
litre unit	L
millilitre unit	mL

Table 67: Radiation Activity Units

Description	Abbreviation
kilobecquerel unit	kilobecquerel unit

Table 68: Miscellaneous Units

Description	Abbreviation
each unit	each
microgram Retinol Equivalent unit	microgram RE
percentage unit	%

F.4 Proportions

The following Units of Measure list is derived from TGA Units of Proportion, located in the Code Tables at www.ebs.tga.gov.au [11]

Table 69: Proportions

Description	Unit/Proportion
anti-Xa international unit per millilitre unit	anti-Xa international unit/mL
antigen unit per millilitre unit	antigen unit/mL
billion organisms per each unit	billion organisms/each
billion vibrios per each unit	billion vibrios/each
billion viral particles unit per millilitre unit	billion viral particles/mL
British Pharmacopoeial unit per each unit	BP unit/each
cell culture infectious dose 50% unit per each unit	CCID50 unit/each
D antigen unit per each unit	D antigen unit/each
Enzyme-Linked ImmunoSorbent Assay unit per each unit	ELISA unit/each
Enzyme-Linked ImmunoSorbent Assay unit per millilitre unit	ELISA unit/mL
gram unit per application unit	g/application
gram per each unit	g/each
gram per millilitre unit	g/mL
index of reactivity per millilitre unit	IR/mL
international unit per each unit	international unit/each
international unit per gram unit	international unit/g
international unit per millilitre unit	international unit/mL
kallikrein inactivator unit per millilitre unit	KI unit/mL
kilobecquerel per each unit	kilobecquerel/each
Kyowa unit per each unit	Kyowa unit/each
microgram per 16 hour unit	microgram/16 h
microgram per 24 hour unit	microgram/24 h
microgram per actuation unit	microgram/actuation
microgram per each unit	microgram/each
microgram per gram unit	microgram/g
microgram per hour unit	microgram/hour

[11] In the sidebar, select **Public TGA Information > Code Tables**.

Description	Unit/Proportion
microgram per millilitre unit	microgram/mL
microgram per square centimetre unit	microgram/cm
microgram unit per 16 hours unit	microgram/16 h
milligram per 24 hours unit	mg/24 h
milligram per actuation unit	mg/actuation
milligram per each unit	mg/each
milligram per gram unit	mg/g
milligram per milligram unit	mg/mg
milligram per millilitre unit	mg/mL
milligram per square unit	mg/square
millilitre per each unit	mL/each
millilitre per gram unit	mL/g
millilitre per millilitre unit	mL/mL
million cell culture infectious dose 50% unit per millilitre unit	million CCID50 units/mL
million colony forming units per each unit	million CFU/each
million international units per millilitre unit	million international units/mL
million organisms per each unit	million organisms/each
million organisms unit per millilitre unit	million organisms/mL
mouse lethal dose 50% unit per each unit	MLD 50 unit/each
percentage per each unit	%/each
plaque forming unit per each unit	PFU/each
tissue culture infectious dose 50% unit per each unit	TCID50 unit/each
trillion vector genomes unit per millilitre unit	trillion vector genomes/mL
tuberculin unit per millilitre unit	tuberculin unit/mL
unit per each unit	unit/each
unit per millilitre unit	unit/mL

F.5 Descriptive units of measure

Descriptive units of measure may be defined as those units which are not SI units.

Descriptive units of measure will be represented in the singular where the related value is equal to unity. For all other values, the descriptive Unit of Measure will be represented as a plural.

For example:

- 1 ampoule, 5 ampoules
- 1 metered dose, 120 metered doses

F.5.1 Valid descriptive units of measure

Note: This list contains examples only and is not definitive.

- actuation
- aerosol can
- ampoule
- application
- bag
- bandage
- bar
- bead
- blister
- bottle
- can
- capsule
- cartridge
- diagnostic strip
- diagnostic tablet
- dressing
- drop
- drug delivery system
- enema
- film
- foam dressing
- glove
- gum
- implant
- jar
- lozenge
- pack
- pad
- pastille
- patch
- pessary
- ribbon
- ring
- roll
- rope
- sachet
- sheet
- square
- stick
- strip
- suppository
- syringe
- system
- tablet
- tube
- unit dose
- vial
- wafer

Appendix G Form

The form will be derived from TGA Dosage Forms, located in the Code Tables at www.ebs.tga.gov.au,[12] but may include additional forms created where necessary.

Where there is more than one subtype of a dosage form (for example, capsule), the general description is shown in capitals at the start of the relevant entries. It should be noted that there is no Preferred Term for these general descriptions. The definitions of the subtypes should be read in the context of this general description.

Certain products are intended for administration via one specific route and have been especially formulated with this route in mind. These products should have the most specific form applied to them, to assist with ensuring safety in their administration. Such specific forms include (but are not limited to) intraocular injection and intrathecal injection.

If a product has several modes of ingestion these products should have the less specific form applied to them. For example: when a tablet can be crushed, chewed, dispersed or swallowed whole, the dose form will revert to the less specific dose form of "tablet".

Note: Additional forms have been added to provide further defining information, for example, intrathecal injection.

Table 70: Form definitions

Preferred Term	Description	Medicinal dose form	Trade dose form
bandage	A strip or roll of cloth or other material that may be wound around a part of the body in a variety of ways to secure a dressing, maintain pressure over a compress, or immobilise a limb or other part of the body.	bandage	bandage
four layer bandage	A bandage made up of four layers.	four layer bandage	four layer bandage
high stretch bandage	A bandage which has a high degree of stretch.	high stretch bandage	high stretch bandage

[12] In the sidebar, select **Public TGA Information > Code Tables**.

Preferred Term	Description	Medicinal dose form	Trade dose form
large D/E size bandage	A bandage available in a large D/E size.	large D/E size bandage	large D/E size bandage
large limb size bandage	A bandage available in a large limb size.	large limb size bandage	large limb size bandage
large size bandage	A bandage available in a large size.	large size bandage	large size bandage
lightweight bandage	A bandage available in a light weight.	lightweight bandage	lightweight bandage
medium C/D size bandage	A bandage available in a medium C/D size.	medium C/D size bandage	medium C/D size bandage
medium limb size bandage	A bandage available in a medium limb size.	medium limb size bandage	medium limb size bandage
medium size bandage	A bandage available in a medium size.	medium size bandage	medium size bandage
short stretch bandage	A bandage which has a short degree of stretch.	short stretch bandage	short stretch bandage
small B/C size bandage	A bandage available in a small B/C size.	small B/C size bandage	small B/C size bandage
small limb size bandage	A bandage available in a small limb size.	small limb size bandage	small limb size bandage
small size bandage	A bandage available in a small size.	small size bandage	small size bandage
straight bandage	A bandage available in a straight length.	straight bandage	straight bandage
triangular bandage	A square of cloth folded or cut in the shape of a triangle. It may be used as a sling, a cover, or a thick pad to control bleeding.	triangular bandage	triangular bandage
two layer bandage	A bandage made up of two layers.	two layer bandage	two layer bandage
XX/large size bandage	A bandage available in an XX/large size.	XX/large size bandage	XX/large size bandage
bar	A solid dose form that is shaped into a bar.	bar	bar
soap bar	A bar that contains a detergent.	soap bar	soap bar

Preferred Term	Description	Medicinal dose form	Trade dose form
block	A solid dose form that is generally scored to denote individual units of use.	block	block
bud	The immature part of a plant that has been dried and prepared for consumption.	bud	bud
capsule	A solid dose form consisting of a shell and a filling.	capsule	capsule
enteric capsule	A capsule that is intended to resist the action of gastric fluid and release the active ingredient(s) into the intestinal fluid.	enteric capsule	enteric capsule
modified release capsule	A capsule in which the rate or place of release of at least one of the active ingredient(s) in the gastrointestinal tract has been modified.	modified release capsule	modified release capsule

Preferred Term	Description	Medicinal dose form	Trade dose form
collodion	A liquid dose form for application to the skin. When allowed to dry, a flexible film is formed at the site of application.	collodion	collodion

Preferred Term	Description	Medicinal dose form	Trade dose form
conditioner	A liquid dose form that is applied to condition the hair, head or scalp areas.	conditioner	conditioner
cream	A semi-solid dose form that is generally an emulsion in aqueous base.	cream	cream

Preferred Term	Description	Medicinal dose form	Trade dose form
diluent	A dose form that is intended to be mixed with active ingredient(s) before administration.	diluent	diluent
dressing	A clean or sterile covering applied directly to a wound or diseased tissue.	dressing	dressing
hydroactive dressing	A dressing for wounds with medium to high exudate, generally multi-layered highly absorbent polymer, with a surface adhesive and a waterproof outer layer. Exudate fluid is trapped within the dressing to maintain a moist environment.	hydroactive dressing	hydroactive dressing
island dressing	A dressing with a non-adherent wound pad, which absorbs wound exudates without sticking to the wound, surrounded by an adhesive area extending on all sides of the pad.	island dressing	island dressing

Preferred Term	Description	Medicinal dose form	Trade dose form
medicated dressing	A dressing containing one or more active ingredients.	medicated dressing	medicated dressing
sacral dressing	A dressing intended to be applied directly to the sacral area.	sacral dressing	sacral dressing
tulle dressing	A dressing composed of a soft fine weave or net which is generally non-adherent.	tulle dressing	tulle dressing
drug delivery system	A dose form contained within a medium or carrier that allows for the uniform release or targeting of active ingredient(s).	drug delivery system	drug delivery system
intrauterine drug delivery system	A drug delivery system intended for use in the uterus.	intrauterine drug delivery system	intrauterine drug delivery system
vaginal drug delivery system	A drug delivery system intended for use in the vagina.	vaginal drug delivery system	vaginal drug delivery system
ear drops	A liquid dose form intended for instillation into the aural canal using a dropper.	ear drops	ear drops
enema	A dose form intended for rectal administration.	enema	enema
eye and ear drops	A liquid dose form intended for instillation into the conjunctival sac or aural canal using a dropper.	eye/ear drops	eye/ear drops
eye drops	A liquid dose form intended for instillation into the conjunctival sac using a dropper.	eye drops	eye drops
eye gel	A gel intended for administration into the eye.	eye gel	eye gel
eye ointment	An ointment intended for administration into the eye.	eye ointment	eye ointment
eye pad	A pad used specifically for the eye area.	eye pad	eye pad
eye strip	A strip impregnated with active ingredient(s) that is intended for use on the conjunctiva.	eye strip	eye strip

Preferred Term	Description	Medicinal dose form	Trade dose form
film	A thin, flat, flexible solid preparation intended to disintegrate or dissolve rapidly in contact with body fluids.	film	film
sublingual film	A film intended for sublingual administration.	sublingual film	sublingual film
foam	A dispersion of gas in a liquid or solid creating a semi-solid substance.	foam	foam
foam dressing	A soft, open cell hydrophobic and hydrophilic dressing for exuding wounds that is absorbent and non-adherent and can take the shape of the wound cavity and which may consist of single or multiple layers.	foam dressing	foam dressing
medicinal gas	A gas for therapeutic use.	gas	medicinal gas
gel	A semi-solid dose form containing a gelling agent.	gel	gel
intestinal gel	A gel intended for direct administration to the gastrointestinal tract.	intestinal gel	intestinal gel
glove	A sterile or clean fitted covering for the hands, usually with a separate sheath for each finger and thumb.	glove	glove
large glove	A sterile or clean fitted covering for the hands, usually with a separate sheath for each finger and thumb, available in a large size.	large glove	large glove
medium glove	A sterile or clean fitted covering for the hands, usually with a separate sheath for each finger and thumb, available in a medium size.	medium glove	medium glove
small glove	A sterile or clean fitted covering for the hands, usually with a separate sheath for each finger and thumb, available in a small size.	small glove	small glove

Preferred Term	Description	Medicinal dose form	Trade dose form
granules	A solid dose form consisting of dry aggregates of powder particles that are intended for oral use.	granules	granules
effervescent granules	Granules that effervesce when dissolved or dispersed in water.	effervescent granules	effervescent granules
enteric coated granules	Granules that are intended to resist the action of gastric fluid and release the active ingredient(s) into the intestinal fluid.	enteric coated granules	enteric coated granules
modified release granules	Granules in which the rate or place of release of at least one of the active ingredient(s) in the gastrointestinal tract has been modified.	modified release granules	modified release granules
chewing gum	A gum that is intended to be to be chewed to release the active ingredient(s) into the oral cavity and is subsequently discarded.	gum	chewing gum
haemodialysis solution	A solution for use in dialysis via a haemodialysis machine.	haemodialysis solution	haemodialysis solution
implant	A drug delivery system intended for implantation in the body.	implant	implant
inhalation	A dose form that is intended for inhalation.	inhalation	inhalation
powder for inhalation	A powder intended for inhalation.	powder for inhalation	powder for inhalation
inhalation solution	An inhalation that is a solution.	inhalation solution	inhalation solution
injection	A sterile liquid that is intended to be administered parenterally.	injection	injection
intraocular injection	An injection intended to be administered intraocularly.	intraocular injection	intraocular injection
intrathecal injection	An injection intended to be administered intrathecally.	intrathecal injection	intrathecal injection
modified release injection	An injection in which the rate of diffusion of at least one of the active ingredient(s) into the systemic circulation has been modified.	modified release injection	modified release injection

Preferred Term	Description	Medicinal dose form	Trade dose form
powder for injection	A powder for reconstitution with a suitable liquid to be used as an injection.	injection	powder for injection
intratracheal suspension	A suspension intended for intratracheal administration.	intratracheal suspension	intratracheal suspension
liniment	A liquid or semi-solid dose form intended for application to skin with friction.	liniment	liniment
liquid	A dose form that has the consistency of a liquid.	liquid	liquid
lotion	A viscous, liquid dose form intended for application to the skin.	lotion	lotion
lozenge	A hard, solid dose form intended to dissolve or disintegrate slowly in the mouth.	lozenge	lozenge
mouthwash	A liquid dose form for oral use but not ingestion. Generally used for its deodorant, refreshing, or antiseptic effect.	mouthwash	mouthwash
powder for mouthwash	A powder for reconstitution with a suitable liquid intended for use as a mouthwash.	powder for mouthwash	powder for mouthwash
nasal drops	A liquid dose form intended to be instilled into the nose using a dropper.	nasal drops	nasal drops
nasal spray	A spray intended for nasal administration.	nasal spray	nasal spray
oil	A liquid or easily liquefiable dose form that is insoluble in water.	oil	oil
bath oil	An oil intended for topical application in a bath or shower or may be applied directly to the skin.	bath oil	bath oil
oral oil	An oil intended for oral administration.	oral oil	oral oil
ointment	A semi-solid dose form that is generally a solution or dispersion in a non-aqueous base.	ointment	ointment

Preferred Term	Description	Medicinal dose form	Trade dose form
oral liquid	A liquid dose form intended for oral administration.	oral liquid	oral liquid
powder for oral liquid	A powder for reconstitution with a suitable liquid intended for oral administration.	powder for oral liquid	powder for oral liquid
oral semi-solid	A firm, semi-solid dose form intended for oral administration.	oral semi-solid	oral semi-solid
pad	A mass of soft material used to cushion shock, prevent wear or absorb moisture.	pad	pad
waterproof pad	A pad that has a waterproof surface.	waterproof pad	waterproof pad
paint	A liquid dose form that when allowed to dry, leaves a thin coating at the site of application.	paint	paint
paste	A semi-solid dose form containing a large proportion of solids uniformly dispersed in a suitable vehicle.	paste	paste
pastille	A soft, solid dose form intended to dissolve or disintegrate slowly in the mouth.	pastille	pastille
patch	A drug delivery system with an adhesive backing that is applied to the skin.	patch	patch
pessary	A solid dose form intended for intra-vaginal use.	pessary	pessary
modified release pessary	A pessary in which the rate of release of at least one of the active ingredients has been modified.	modified release pessary	modified release pessary
powder	A solid dose form of finely divided ingredients.	powder	powder
ribbon	A dressing available in a flattened ribbon intended for packing a wound.	ribbon	ribbon
roll	A long tightly wound strip of material.	roll	roll

Preferred Term	Description	Medicinal dose form	Trade dose form
wrapped pack roll	A roll available in a wrapped pack.	wrapped pack roll	wrapped pack roll
rope	A dressing available in a cylindrical rope intended for packing a wound.	rope	rope
shampoo	A liquid dose form containing a surfactant that is applied to the hair, head or scalp areas.	shampoo	shampoo
sheet	A dressing available in a flat sheet.	sheet	sheet
solution	A liquid dose form of dissolved active ingredient(s).	solution	solution
irrigation solution	A solution intended for washing, irrigation and rinsing purposes.	solution	irrigation solution
peritoneal dialysis solution	A solution for use in dialysis via the peritoneal cavity.	peritoneal dialysis solution	peritoneal dialysis solution
powder for intraocular irrigation solution	A powder for reconstitution with a suitable liquid intended for intraocular irrigation.	intraocular irrigation solution	powder for intraocular irrigation solution
powder for irrigation solution	A powder for reconstitution with a suitable liquid intended for irrigation.	solution	powder for irrigation solution
sponge	A porous, absorbent mass that may be used to absorb fluids.	sponge	sponge
spray	A liquid dose form intended for application after dispersion via a spray device.	spray	spray
pressurised spray	A spray in which the active ingredient(s) is held under pressure and delivered by the actuation of a valve.	spray	pressurised spray
stick	A solid dose form that is generally a long, cylindrical shape.	stick	stick
lip stick	A stick intended for application to the lips.	lip stick	lip stick
diagnostic strip	A strip containing reagents or dyes or involving other means, intended to be used for diagnosis.	diagnostic strip	diagnostic strip

Preferred Term	Description	Medicinal dose form	Trade dose form
suppository	A solid dose form intended for rectal administration.	suppository	suppository
suspension	A liquid dose form containing suspended solid particles.	suspension	suspension
tablet	A solid dose form prepared by moulding or compression.	tablet	tablet
chewable tablet	A tablet with a palatable formulation intended to be chewed.	chewable tablet	chewable tablet
compound diagnostic tablet	A tablet intended to be used in vitro for diagnosis. It is not intended for oral human use.	compound diagnostic tablet	compound diagnostic tablet
dispersible tablet	A tablet which rapidly produces a uniform dispersion in water and is intended to be dispersed prior to administration.	dispersible tablet	dispersible tablet
effervescent tablet	A tablet that effervesces when dissolved or dispersed in water.	effervescent tablet	effervescent tablet
enteric tablet	A tablet that is intended to resist the action of gastric fluid and release the active ingredient(s) into the intestinal fluid.	enteric tablet	enteric tablet
modified release tablet	A tablet in which the rate or place of release of at least one of the active ingredient(s) in the gastrointestinal tract has been modified.	modified release tablet	modified release tablet
orally disintegrating tablet	A tablet that rapidly disintegrates in the oral cavity.	orally disintegrating tablet	orally disintegrating tablet
soluble tablet	A tablet that is intended to be dissolved in water prior to administration.	soluble tablet	soluble tablet
sublingual tablet	A tablet intended for sublingual administration.	sublingual tablet	sublingual tablet
tape	Strips of material, used to secure bandages.	tape	tape

Preferred Term	Description	Medicinal dose form	Trade dose form
tincture	A liquid dose form diluted with alcohol.	tincture	tincture
toothpaste	A paste intended to be used for cleaning and polishing the teeth.	toothpaste	toothpaste
vaginal cream	A cream intended for intra-vaginal use.	vaginal cream	vaginal cream
vaginal gel	A gel intended for intra-vaginal use.	vaginal gel	vaginal gel
wafer	A solid dose form intended to disintegrate or dissolve when placed in the oral cavity.	wafer	wafer
sublingual wafer	A wafer intended for sublingual administration.	sublingual wafer	sublingual wafer

Appendix H Proprietary descriptions and equivalents

H.1 Dose form and associated proprietary form

Some manufacturers have dosage forms with names that are specific to their products. This appendix lists these proprietary forms and the AMT dosage form that must be used whenever the proprietary form appears in the Trade Product description.

Note: This list is not exhaustive and may be added to as new proprietary forms become available.

Table 71: Examples of proprietary forms (by PT)

Preferred Term	Associated Proprietary Form(s)
capsule	Pulvule, Sprinkle
modified release capsule	Spansule
capsule	Sleepgel
eye drops	Minims
gel	Emulgel
inhalation	Autohaler
inhalation solution	Nebule, Respule, Sterineb
powder for inhalation	Accuhaler, Rotacap, Spincap, Turbuhaler
pessary	Ovula
patch	Invisipatch
tablet	Caplet, Tabsule
chewable tablet	Infatab
tablet	Filmtab
modified release tablet	Durule, Repetab, Timespan
orally disintegrating tablet	Fastab, Quicklet, Reditab, Soltab, Zapid
wafer	Zydis

The following table displays similar information, presented with an emphasis on proprietary forms.

Table 72: Examples of proprietary forms (by proprietary form)

Proprietary Form	Associated Preferred Term
Accuhaler	powder for inhalation
Autohaler	inhalation
Caplet	tablet
Capseal	tablet
Durule	modified release tablet
Emulgel	gel
Fastab	orally disintegrating tablet
Filmtab	tablet
Infatab	chewable tablet
Invisipatch	patch
Mini Cap	tablet
Minims	eye drops
Nebule	inhalation solution
Ovula	pessary
Pulvule	capsule
Quicklet	orally disintegrating tablet
Reditab	orally disintegrating tablet
Repetab	modified release tablet
Respule	inhalation solution
Rotacap	powder for inhalation
Sleepgel	capsule
Soltab	orally disintegrating tablet
Spansule	modified release capsule
Spincap	powder for inhalation

Proprietary Form	Associated Preferred Term
Sprinkle	capsule
Sterineb	inhalation solution
Tabsule	tablet
Timespan	modified release tablet
Turbuhaler	powder for inhalation
Zapid	orally disintegrating tablet
Zydis	wafer

H.2 Container types and associated proprietary container

Some manufacturers have container types with a name that is specific to their product(s). This appendix lists these proprietary containers and the AMT container type that must be used whenever the proprietary container appears in the Trade Product description.

Note: This list is not exhaustive and may be added to as new proprietary container types become available.

Table 73: Examples of proprietary container types (by PT)

Preferred Term	Associated Proprietary Container type(s)
aerosol can	Quickmist, MDI, Rapihaler
ampoule	Cipule, Nasule, UDV, Uni-Dose
blister pack	Breezehaler, Rotadisk
cartridge	Inhalator, Innolet, Penfill, Respimat
dry powder inhaler	Genuair
dual chamber composite pack	Act-O-Vial, Clearclick, Redipen
pen device	Auto-Injector, Solostar
syringe	Min-I-Jet, Novolet, PFS, Sureclick
tube	Minims

The following table displays similar information, presented with an emphasis on proprietary containers.

Table 74: Examples of proprietary container types (by proprietary container)

Proprietary container type	Associated Preferred Term
Act-O-Vial	dual chamber composite pack
Auto-Injector	pen device
Breezehaler	blister pack
Cipule	ampoule
Clearclick	dual chamber composite pack
Genuair	dry powder inhaler
Inhalator	cartridge
Innolet	cartridge
MDI	aerosol can
Min-I-Jet	syringe
Minims	tube
Nasule	ampoule
Novolet	syringe
Penfill	cartridge
PFS	syringe
Quickmist	aerosol can
Rapihaler	aerosol can
Redipen	dual chamber composite pack
Respimat	cartridge
Rotadisk	blister pack
Solostar	pen device
Sureclick	syringe
UDV	ampoule
Uni-Dose	ampoule

Appendix I Pack Quantity Unit of Measure

Each pack quantity Unit of Measure has an associated unit dose form indicator, which indicates if the pack quantity Unit of Measure is continuous or discrete. In some instances, the unit does form indicator may vary between products. A discrete dose form is a form that is available as distinct or individual parts (for example, tablet or suppository). A continuous dose form is a form that is available as a given quantity of which only a portion of this is used at one time (for example, cream, oral liquid). In some instances, the unit dose form indicator may vary between products (for example, granules in a single dose sachet would be discrete, but granules in a bulk container would be continuous).

Note: For mass and volume, units may vary according to the pack size, for example, g or kg, mL or L.

Table 75: Examples of Pack Quantity Units of Measure

Dose Form Preferred Term	Associated Pack Quantity Unit of Measure (Singular)	Associated Pack Quantity Unit of Measure (Plural)
bandage	bandage	bandages
four layer bandage	bandage	bandages
high stretch bandage	bandage	bandages
large D/E size bandage	bandage	bandages
large limb size bandage	bandage	bandages
large size bandage	bandage	bandages
lightweight bandage	bandage	bandages
medium C/D size bandage	bandage	bandages
medium limb size bandage	bandage	bandages
medium size bandage	bandage	bandages
short stretch bandage	bandage	bandages
small B/C size bandage	bandage	bandages
small limb size bandage	bandage	bandages

Dose Form Preferred Term	Associated Pack Quantity Unit of Measure (Singular)	Associated Pack Quantity Unit of Measure (Plural)
small size bandage	bandage	bandages
straight bandage	bandage	bandages
triangular bandage	bandage	bandages
two layer bandage	bandage	bandages
XX/large size bandage	bandage	bandages
bar	bar	bars
soap bar	soap bar	soap bars
block	block	blocks
capsule	capsule	capsules
enteric capsule	capsule	capsules
modified release capsule	capsule	capsules
collodion	mL	mL
conditioner	mL	mL
cream	g	g
diluent	ampoule, vial (dependent on container type)	ampoules, vials (dependent on container type)
dressing	dressing	dressings
hydroactive dressing	dressing	dressings
island dressing	dressing	dressings
medicated dressing	dressing	dressings
sacral dressing	dressing	dressings
tulle dressing	dressing	dressings
drug delivery system	drug delivery system	drug delivery systems
intrauterine drug delivery system	intrauterine drug delivery system	intrauterine drug delivery systems
vaginal drug delivery system	vaginal drug delivery system	vaginal drug delivery systems
ear drops	mL	mL
enema	mL	mL

Dose Form Preferred Term	Associated Pack Quantity Unit of Measure (Singular)	Associated Pack Quantity Unit of Measure (Plural)
eye and ear	g or mL (dependent on form)	g or mL (dependent on form)
eye and ear drops	mL	mL
eye drops	mL	mL
eye gel	g	g
eye ointment	g	g
eye pad	pad	pads
eye strip	strip	strips
film	film	films
sublingual film	film	films
foam	g	g
foam dressing	dressing	dressings
medicinal gas	L	L
gel	g	g
intestinal gel	g	g
glove	glove	gloves
large glove	glove	gloves
medium glove	glove	gloves
small glove	glove	gloves
granules[13]	g or sachet	g or sachets
effervescent granules (see note 13)	g or sachet	g or sachets
enteric coated granules (see note 13)	g or sachet	g or sachets

[13] If the Unit Dose Form Indicator is “continuous”, the Pack Unit Measure is “g”; if it is “discrete”, the Pack Unit measure is “sachets”.

Dose Form Preferred Term	Associated Pack Quantity Unit of Measure (Singular)	Associated Pack Quantity Unit of Measure (Plural)
modified release granules (see note 13)	g or sachet	g or sachets
chewing gum	piece	pieces
implant	implant	implants
inhalation	mL	mL
powder for inhalation	capsule, dose unit (dependent on container type)	capsules, dose units (dependent on container type)
inhalation solution	ampoule, vial (dependent on container type)	ampoules, vials (dependent on container type)
injection	ampoule, syringe, vial (dependent on container type)	ampoules, syringes, vials (dependent on container type)
intraocular injection	ampoule, syringe, vial (dependent on container type)	ampoules, syringes, vials (dependent on container type)
intrathecal injection	ampoule, syringe, vial (dependent on container type)	ampoules, syringes, vials (dependent on container type)
modified release injection	ampoule, syringe, vial (dependent on container type)	ampoules, syringes, vials (dependent on container type)
powder for injection	ampoule, syringe, vial (dependent on container type)	ampoules, syringes, vials (dependent on container type)
liniment	mL	mL
liquid	mL	mL
lotion	mL	mL
lozenge	lozenge	lozenges
mouthwash	mL	mL
powder for mouthwash	g	g
nasal drops	mL	mL
nasal spray	mL	mL
oil	mL	mL
bath oil	mL	mL
oral oil	mL	mL

Dose Form Preferred Term	Associated Pack Quantity Unit of Measure (Singular)	Associated Pack Quantity Unit of Measure (Plural)
ointment	g	g
oral liquid	mL	mL
powder for oral liquid	mL	mL
pad	pad	pads
waterproof pad	pad	pads
paint	mL	mL
paste	g	g
pastille	pastille	pastilles
patch	patch	patches
pessary	pessary	pessaries
modified release pessary	pessary	pessaries
powder	g	g
ribbon	ribbon	ribbons
roll	roll	rolls
wrapped pack roll	roll	rolls
rope	rope	ropes
shampoo	mL	mL
sheet	sheet	sheets
solution	mL	mL
irrigation solution	mL	mL
peritoneal dialysis solution	mL	mL
powder for intraocular irrigation solution	mL	mL
spray	mL	mL
pressurised spray	mL	mL
stick	tube, stick (dependent on container type)	tubes, sticks (dependent on container type)

Dose Form Preferred Term	Associated Pack Quantity Unit of Measure (Singular)	Associated Pack Quantity Unit of Measure (Plural)
lip stick	tube	tubes
diagnostic strip	strip	strips
suppository	suppository	suppositories
suspension	mL	mL
tablet	tablet	tablets
chewable tablet	tablet	tablets
compound diagnostic tablet	tablet	tablets
dispersible tablet	tablet	tablets
effervescent tablet	tablet	tablets
enteric tablet	tablet	tablets
modified release tablet	tablet	tablets
orally disintegrating tablet	tablet	tablets
soluble tablet	tablet	tablets
sublingual tablet	tablet	tablets
tape	tape	tapes
tincture	mL	mL
toothpaste	g	g
vaginal cream	g	g
vaginal gel	g	g
wafer	wafer	wafers
sublingual wafer	wafer	wafers

Appendix J Container Types

Container Types will be derived from TGA Container Codes located in the Code Tables at www.ebs.tga.gov.au.[14] Additional container types will be added if required.

Table 76: Examples of Container Types

Container Type Preferred Term	Description
aerosol can	A container that requires manual activation of an installed valve to release therapeutic goods held under pressure in aerosol form. The doses may or may not be metered.
ampoule	A container sealed by fusion after filling.
applicator	A container that acts as a device for the application of a drug dosage form to a particular site.
bag	A flexible, sealed container that holds a dosage form, usually liquid.
blister pack	A container in which the dosage unit(s) are enclosed in a pre-formed tray or individual pockets.
bottle	A container with a narrow neck, sealed with a stopper or screw closure.
dispensing bottle	A bottle which is used to supply extemporaneously prepared or decanted liquid medicines.
poison bottle	An amber coloured bottle with vertical ridges that run the height of the container, displaying the embossed term "Poison" or "Not to be taken" (or similar).
can	A cylindrical container usually made of metal that has an appropriate closure.
carton	A cardboard (or similar) container that is normally closed.
cartridge	A container that is placed in a dedicated holder prior to use.
compact	A wide flat container with a clip closure.

[14] In the sidebar, select **Public TGA Information > Code Tables**.

Container Type Preferred Term	Description
pack	A container for all combination products, and for those multi-component products where the components have different dose forms. Note that "composite pack" is still in use in some CTPP descriptions, however this will be edited to "pack".
dial dispenser pack	A circular container in which an individual dosage unit is dispensed by rotating the lid to an appropriate position.
dropper container	A container holding a liquid which is to be delivered via a dropper device.
dual chamber bag	A bag in which ingredients or diluent are located in two individual chambers.
dual chamber cartridge	A cartridge in which ingredients or diluent are located in two individual chambers.
dual chamber pen device	A drug-device combination in which the ingredients or diluent are located in individual chambers. The device is supplied pre-loaded and is not replaceable once empty.
dual chamber syringe	A syringe in which ingredients or diluent are located in two individual chambers.
dual chamber vial	A vial in which ingredients or diluent are located in two individual chambers.
gas cylinder	A gas-tight container designed to hold a gas under pressure.
dry powder inhaler	A container holding a powder in a sealed drug reservoir. A metered dose is withdrawn from the reservoir under the force of the patient's inhalation.
jar	A container with a wide neck, usually made of glass or plastic, sealed with an appropriate closure.
multi chamber bag	A bag in which ingredients or diluent are located in two or more individual chambers.
screw cap jar	A jar sealed with a screw closure.
pen device	A drug-device combination that is supplied pre-loaded for injection, and is not replaceable once empty.
pouch	A container holding a semi-solid or liquid preparation between two layers of flexible material, and may have a mouthpiece.
puffer pack	A flexible container from which the liquid or powder contents may be ejected by squeezing.

Container Type Preferred Term	Description
pump pack	A container that requires manual activation of an installed pump to release therapeutic goods. The doses may or may not be metered.
sachet	A container where a single dosage unit is located between two layers of flexible material.
strip pack	A container in which dosage units are enclosed individually in a continuous flexible strip.
syringe	A device used to inject, infuse, or orally administer medications, consisting of a barrel and a plunger.
tub	A wide open mouthed container, with a flat base.
tube	An elongated hollow container made from rigid or flexible material.
vial	A container sealed with a stopper which can be penetrated with a needle.
wrapping	A thin flexible material folded around the product.

Appendix K Special classes of products

The following classes of products have been deemed to be extraordinary in some way and hence some AMT product concepts representing these classes have been modelled outside the typical AMT format.

K.1 Vaccines

The rules governing the vaccines class of products have been created in consultation with the Australian Technical Advisory Group on Immunisations (ATAGI). Any further developments in this area will be done in collaboration with ATAGI to ensure that all technical and safety aspects are considered.

K.1.1 Substances

Vaccine substances will follow the existing editorial rules outlined in 5.2 Substance Descriptions. The name will be derived from the biological name of the component utilised in the vaccine to create the immune response.

A synonym will be included, which matches the Fully Specified Name without the semantic tag. Where the Preferred Term includes an abbreviation or acronym, it will be structured in accordance with SNOMED CT-AU editorial rules, which state that 'Where abbreviations are required in any other type of description then they should ordinarily be fully expanded in the same text string'.

For example:

- Fully Specified Name: Haemophilus influenzae serotype b conjugate (polyribosylribitol phosphate to tetanus toxoid) antigen (AU substance)
- Preferred Term: Haemophilus influenzae type b conjugate (PRP-T) antigen
- Synonym: Haemophilus influenzae serotype b conjugate (polyribosylribitol phosphate to tetanus toxoid) antigen

K.1.2 Fully Specified Names of Notable Concepts

The Fully Specified Name will follow existing editorial rules, whereby each of the intended active ingredients are listed, with multiple ingredients separated by a "+" and ordered alphanumerically.

For example:

- hepatitis A virus antigen (medicinal product)
- measles virus live antigen + mumps virus live antigen + rubella virus live antigen (medicinal product)

K.1.3 Preferred Terms of Medicinal Concepts

The Preferred Term will be derived from the common name for the disease or group of diseases caused by an infective agent that are preventable by the vaccine.

The common name(s) will be listed, separated by a "+" with the word "vaccine" stated at the end. Where a characteristic technology must be stated (see K.1.5), it should be stated prior to the word "vaccine".

For example:

- hepatitis A vaccine
- measles + mumps + rubella live vaccine

The text descriptors "disease" and "infection" do not usually provide any additional identifying information and will be omitted by default. For example the term will be "meningococcal vaccine" rather than "meningococcal disease vaccine".

Where a specific organism may produce more than one clinical syndrome, the vaccine name will be derived from the causative agent.

For example:

- *Haemophilus influenzae* type b infection may cause either pneumonia or meningitis, thus would be "Haemophilus influenzae type b vaccine" and not "pneumonia vaccine" or "meningitis vaccine".
- *Neiserria meningitides* (meningococci) may cause septicaemia, meningitis or more rarely arthritis or pneumonia; these manifestations may be collectively referred to as 'meningococcal disease', and the vaccine designed for prevention of it would be named "meningococcal vaccine".
- The Human papillomavirus may cause either cervical cancer or genital warts, thus would be called "Human papillomavirus vaccine" and not "cervical cancer vaccine".

Special case: the Bacillus Calmette and Guerin (BCG) vaccine

The marketed indications of Bacillus Calmette and Guerin (BCG) include use as a vaccine for prevention against human tuberculosis disease, as well as for the treatment of bladder carcinoma.

As such, the tuberculosis vaccine will be named:

- MP FSN: "Mycobacterium bovis (Bacillus Calmette and Guerin) live antigen (medicinal product)"
- MP PT: "Mycobacterium bovis (BCG) live vaccine"

Note that this example is a special case, where by in relation to vaccines, the "BCG" is understood and accepted as an acronym. "Tuberculosis live vaccine" and "Mycobacterium bovis live vaccine" will be allowed as acceptable synonyms.

K.1.4 **Valency**

Valency refers to the number of variants of the same target antigen or antigen site contained in the vaccine for prevention of a single disease. The variants may be defined as variations in their type depending on the microbial classification relevant to the microorganism. For example, serotype, serogroup and genotype.

Where vaccines are monovalent, this will be implied rather than explicitly stated. Where vaccines are multivalent, while the Fully Specified Name will list out the individual variants, the Preferred Term will indicate the valency. Valency will also be spelt out up to hexavalent. That is:

- bivalent
- trivalent
- quadrivalent
- pentavalent
- hexavalent

Beyond hexavalent, the numeral will be utilised to indicate how many valencies exists in the vaccine.

For example:

- 13 valent
- 23 valent

An exception exists, whereby valency will not be displayed when modelling a multi-component product, where both components contain an active ingredient.

For example:

- Menveo component 1 Medicinal Product Preferred Term: meningococcal C + meningococcal W135 + meningococcal Y conjugate vaccine
- Menveo component 2 Medicinal Product Preferred Term: meningococcal A conjugate vaccine

Influenza vaccine may be considered a modification of this rule, in that the valency refers to the total number of subtypes and/or lineages of Influenza A and Influenza B. The year acts as the identifier for the specific antigens contained in the formulation for the year (refer to “Year of issue” section below). If several products exist which have the same valency but consist of different variant types or serotypes or serogroups, then both the valency and the types, serotypes, or serogroups will be expressed. (See section K.1.7)

For example, the following three subtypes of influenza A and B, in the 2016 influenza vaccine, form the “influenza *trivalent* vaccine 2016”:

- A/California/7/2009 (H1N1) pdm09-like virus
- A/Hong Kong/4801/2014 (H3N2)-like virus

- B/Brisbane/60/2008-like virus.

K.1.5 Classification of technology

These are the characteristic technologies used to formulate vaccines that will always be included in the Fully Specified Name and Preferred Term:

- live
- conjugate
- conjugate (PRP-T)
- conjugate (PRP-OMP)

Live vaccines may be contraindicated for certain patient groups, hence are of clinical significance, and will be always included in the Fully Specified Name and Preferred Term with text descriptor "live vaccine".

A polysaccharide protein conjugate vaccine consists of an oligosaccharide or polysaccharide attached to a protein carrier. Polysaccharide vaccines also exist without conjugation. As such, for polysaccharide protein conjugate vaccines, the description "conjugate" will always be included in the Fully Specified Name and Preferred Term, to distinguish them from non-conjugate polysaccharide vaccines.

The Haemophilus influenzae type b vaccine exists in two forms, one with polyribosylribitol phosphate to tetanus toxoid conjugation, and the other with polyribosylribitol phosphate to outer membrane protein conjugation. Given that the variations have significantly different clinical implications, the terms "conjugate (PRP-T)" and "conjugate (PRP-OMP)" will always be included in the Fully Specified Name and Preferred Term.

The following are the characteristic technologies used to formulate vaccines that will only be included in the Fully Specified Name and Preferred Term if they are essential for distinguishing between different vaccines which are designed for prevention of the same disease, as they may have significantly different clinical implications:

- inactivated
- recombinant
- polysaccharide
- adjuvanted
- toxoid
- acellular
- whole cell
- cell based
- key components*

*Please note, in this context, the term “component” does not refer to the AMT definition of “single component” or “multi-component”. Rather, components of vaccines refers to the key description of the target antigen, or the number of antigen sites that the vaccine targets. If key components are to be identified for differentiation, the number of key components should be listed.

For example:

- Bexsero Medicinal Product Unit of Use: meningococcal B 4 component vaccine injection, 0.5 mL syringe

Bexsero contains four major protein antigens, however the key description of these target antigens is not the number of antigen sites. It is captured as “meningococcal B 4 component vaccine”.

K.1.6 Strength

Strength will be represented as part of the Fully Specified Name. Where the strength of a vaccine is registered as a range, the Fully Specified Name will only show the minimum value of the range. Where the strength is specified as a minimum or maximum antigen concentration, the Fully Specified Name will show the strength without the minimum or maximum descriptors.

Strength will not be included in the Preferred Term of vaccines. Strength will be added back to the Preferred Term, as an exception, where duplicated Preferred Terms exist in order to clearly differentiate between products.

For example:

- Engerix-B Adult Medicinal Product Unit of Use: hepatitis B adult vaccine *20 microgram/1 mL* injection, syringe
- H-B-Vax II Medicinal Product Unit of Use: hepatitis B adult vaccine *10 microgram/1 mL* injection, syringe

In the event that a duplicated Preferred Term indicates the valency of the vaccine, the Preferred Term will reflect the antigens and strengths that are contained in the vaccine.

For example:

- Differentiated Medicinal Product Unit of Use Preferred Terms:
    - Menactra: meningococcal A 4 microgram/0.5 mL + meningococcal C 4 microgram/0.5 mL + meningococcal W135 4 microgram/0.5 mL + meningococcal Y 4 microgram/0.5 mL conjugate vaccine injection, vial
    - Nimenrix: meningococcal A 5 microgram + meningococcal C 5 microgram + meningococcal W135 5 microgram + meningococcal Y 5 microgram conjugate vaccine injection, vial

Instances will occur where two products exist with different amounts of antigen intended for different clinical indications or populations. These differences may have implications affecting dosing schedules. In this circumstance, a generic term describing the population for which the formulation is intended will be included. If a population descriptor is included, it will precede the

technology (if required) and term “vaccine”. The following terms have no set definition or age ranges assigned to them, and are intended only for differentiation.

For example:

- adult
- adolescent
- child
- adolescent/adult
- dialysis

K.1.7 Year and season-specific formulations

This rule is only applicable to vaccines in which components of the target antigens may vary from one specific season to another season, e.g. influenza vaccines. The year will be specified in the vaccine name.

For example, the following Medicinal Product Preferred Terms:

- influenza trivalent vaccine 2015
- influenza quadrivalent vaccine 2015

This rule can be extended to incorporate the season, as defined by the World Health Organization, as the descriptor if and when for any reason both the Northern-hemisphere and Southern-hemisphere formulations of influenza vaccines for a year are supplied in Australia.

For example, the following Medicinal Product Preferred Terms:

- influenza quadrivalent vaccine southern hemisphere 2015
- influenza quadrivalent vaccine northern hemisphere 2015-2016

In cases where vaccines are developed in response to a specific pandemic being declared, the word “pandemic” can be used to signify the season for which the vaccine is designed.

For example, the following Medicinal Product Preferred Terms:

- influenza vaccine pandemic 2009

Medicinal concepts will include annotation of all years that the formulation was utilised. If the same formulation is released in 2011 and 2012, both years will be included in medicinal concepts, separated by a dash.

For example, the following Medicinal Product Preferred Terms:

- influenza trivalent vaccine 2011-2012

K.1.8 Multi-ingredient vaccines

Multi-ingredient vaccines refer to pre-formulated combination vaccines that are designed to be delivered in a single administration, for the prevention of more than one disease (in distinction to

a multivalent vaccine for the prevention of one particular disease only, caused by multiple variants of the same organism). Preferred Terms for multi-ingredient vaccines will follow the multi-ingredient editorial rules. Ingredients will always appear in the order stipulated by the *Australian Immunisation Handbook.* [6]

For example, the following Medicinal Product Preferred Terms:

- measles + mumps + rubella live vaccine
- diphtheria + tetanus vaccine

Note: In the context of AMT, "multi-ingredient vaccines" refers to what clinicians and *The Australian Immunisation Handbook* [6] consider to be "combination vaccines".

K.1.9 Vaccine preparations for other uses

Names for vaccines should clearly distinguish between vaccines and other products that contain the same or similar components, but are used for therapeutic or diagnostic purposes rather than vaccination.

The specific indication, such as "skin test", of the preparation will be included from the Medicinal Product level where required.

For example:

- Medicinal Product Preferred Term: Q fever skin test
- Medicinal Product Unit of Use Preferred Term: Q fever skin test injection, 0.5 mL vial

The term "non-vaccine" will be included at the end of the name of such medicines to distinguish these from vaccines containing the same or a similar active ingredient.

For example Immucyst will be described as:

- Medicinal Product Unit of Use Preferred Term: Mycobacterium bovis (BCG) live non-vaccine injection, vial

K.1.10 Synonyms

Acceptable Synonyms

For each Medicinal Product, Medicinal Product Unit of Use and Medicinal Product Pack vaccine concept, an acceptable synonym will be included which contains the antigens to aid searching for users. It is not intended for display in clinical systems.

For example:

- Fully Specified Name: rotavirus serotype G1P1A(8) live antigen 1 million CCID50 units / 1.5 mL oral liquid, 1.5 mL syringe (medicinal product unit of use)
- Acceptable synonym: rotavirus type G1P1A(8) live antigen 1 million CCID50 units/1.5 mL oral liquid, syringe

Acronyms

Where the use of an acronym is common clinical practice, the creation of an acceptable synonym that reflects this acronym will be considered. The inclusion of common acronyms as synonyms will enable clinician to search using recognised abbreviations. Acronyms will be included at the Medicinal Product, Medicinal Product Unit of Use and Medicinal Product Pack level. The reference source for common acronyms will be the current version of the *Australian Immunisation Handbook.*

The acronym will be accompanied by the full expansion of the abbreviation, and the strength retained (as per the Preferred Term) if required for differentiation. The acronym should be followed by a space inserted directly prior to the expanded form in parentheses.

For example:

- Medicinal Product Acceptable Synonym: MMR (measles + mumps + rubella) live vaccine
- Medicinal Product Unit of Use Acceptable Synonym: MMR (measles + mumps + rubella) live vaccine injection, vial
- Medicinal Product Pack Acceptable Synonym: MMR (measles + mumps + rubella) live vaccine injection, 10 vials

K.1.11 Additional information – preservatives, adjuvants, production media, microbial strains

Details of preservatives, production media, and microbial strains used in manufacture or protein carriers will not be represented in either Fully Specified Names or Preferred Terms.

K.2 Antivenoms

K.2.1 Fully Specified Name

Antivenom FSNs will include the common name and species name in brackets of the antivenom they contain, followed by the text "antivenom", for example, tiger snake (Notechis scutatus) antivenom.

K.2.2 Preferred Term

Antivenom Preferred Terms will include the common name of the main species they are active against, followed by the text "antivenom", for example, tiger snake antivenom.

K.2.3 Strength

Strength will be expressed as units of antivenom per Unit of Use (for example, per vial). Volume of vials or ampoules may vary but in all cases a complete unit (that is, vial or ampoule) is administered.

K.3 Immunoglobulins

Descriptors such as animal origin or the biotech descriptor will be included in the Preferred Term for immunoglobulins, only where this is considered to be clinically necessary to differentiate between otherwise similar products.

K.4 Diagnostic agents

Diagnostic agents included in the AMT currently comprise of such products as listed in the PBS and RPBS. The ingredient names for this class of products generally describe the intended use of the product as well as the target for the diagnostic test (for example, glucose indicator blood, glucose and ketone indicator urine). They do not routinely display a strength.

K.5 Dressings and bandages

Dressings and bandages included in the AMT currently comprise of such products as listed in the PBS and RPBS. The majority of products in this class do not have an active ingredient and hence do not have strength. The ingredients for this class of products are generally expressed as a description of the type of bandage or dressing and may include general size and intended use details.

For example: bandage tubular short stocking dressing alginate superficial wound

The strength field has typically been used to express the dressing or bandage dimensions.

For example: 10 cm x 10 cm
6.25 cm x 1 m

Where the product does contain an active ingredient, this is expressed in the usual AMT format along with strength details where applicable.

K.6 Enteral feeds

Enteral feeds included in the AMT are currently comprised of such products as listed in the PBS and RPBS. This class of products routinely contains many ingredients which are often meaningless to describe down to an individual ingredient level. This type of detailed information may be sourced from decision support. As such, this class of products have been given ingredient names indicative of an overall description of the product. The ingredient may also include a relative quantitative measure of a particular ingredient (for example, low in protein) or the absence of an ingredient (for example, carbohydrate free, without phenylalanine).

K.7 Extemporaneous preparations

Extemporaneous preparations included in the AMT are modelled closely to a typical AMT generic product, where the pharmaceutical standard (but not the year or edition of the standard) is included in the Trade Product, and sponsor details are replaced by the text "extemporaneous". At present the majority of extemporaneous products modelled in the AMT are those listed on the PBS or RPBS, and as such, the pack size is representative of the quantity available on the relevant schedule.

Example: Cocaine Hydrochloride Eye Drops Strong APF (extemporaneous) 5% eye drops, 5 mL, poison bottle.

K.8 Herbal preparations

The ingredients for herbal based products may be quite complicated in their nomenclature. They may be derived from various parts of the relevant plant and may vary in the extraction process used. Specifying the plant or extraction method is not necessary but can be included if there is ambiguity.

K 8.1 Substance

Herbal substances will follow the existing Editorial Rules outlined in 5.2 Substance Descriptions. The substance name will be derived from the monograph name used in Herbs & Natural Supplements: An Evidence-based Guide [7]. Where this reference does not describe the ingredient, alternative sources such as the sponsor's Product Information or Consumer Medicine Information, or sponsor's website are used in order to assign a common ingredient name.

K 8.2 Fully Specified Name

Herbal preparations will have their FSN expressed by their botanical name.

For example, Fully Specified Name: Vaccinium myrtillus extract (AU substance)

K 8.3 Preferred Term

Herbal preparations will have their PT expressed by their common name.

For example, Preferred Term: bilberry extract

Appendix L Acronyms

Acronym	Description
AAN	Australian Approved Name
ABN	Australian Biological Name
AHN	Australian Herbal Name
AMT	Australian Medicines Terminology
ARTG	Australian Register of Therapeutic Goods
AU	Ampoule unit
BCG	Bacillus Calmette and Guerin
BoSS	Basis of Strength Substance
CMI	consumer medicine information
CTPP	Contained Trade Product Pack
dm+d	Dictionary of Medicines and Devices
EBNF	Extended Backus-Naur Form
FSN	Fully Specified Name
IAI	Intended Active Ingredient
ID	Identifier
IHTSDO	International Health Terminology Standards Development Organisation
IR	Index of reactivity
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
MP	Medicinal Product
MPP	Medicinal Product Pack
MPUU	Medicinal Product Unit of Use
PBS	Pharmaceutical Benefits Scheme

Acronym	Description
PI	product information
PT	Preferred Term
RPBS	Repatriation Pharmaceutical Benefits Scheme
SCTID	SNOMED Clinical Terms Identifier
SNOMED	Systematized Nomenclature of Medicine
SNOMED CT	Systematized Nomenclature of Medicine, Clinical Terms
SNOMED CTAU	SNOMED CT Australian Release
TF	Trade Family
TGA	Therapeutic Goods Administration
TP	Trade Product
TPP	Trade Product Pack
TPUU	Trade Product Unit of Use
UoM	Unit of Measure
UoU	Unit of Use
UoUS	Unit of Use Size
UTF-8	Unicode Transformation Format (8-bit)
UUID	Universally Unique Identifier

Appendix M Glossary

Term	Meaning
alphanumeric order	The sorting of text and number strings, based on the letter of the alphabet, ignoring capital letters, followed by the individual digits (for example, 1, 10, 11, 12, 2, 20, 3, 4) (as opposed to natural sort order which would sort as 1, 2, 3, 4, 10, 11, 12, 20).
Australian Approved Name	This is the name of a substance as approved by the Therapeutic Goods Administration (TGA), for use on product labelling and information in Australia.
Australian Register of Therapeutic Goods	The central point of control for the legal supply of therapeutic goods in Australia.
Base	Within the AMT a "base" is defined as the active moiety of the ingredient name (that is, the segment of the molecule which has an intended therapeutic effect on the body).
Basis of Strength Substance	The name of the ingredient that the strength of the product is based on. It may be a base, primary modified base or secondary modified base.
Diluent	A single substance or preparation usually in liquid form, supplied individually or as part of a pack, intended to be mixed with one or more specified active ingredients before administration to produce required dosage form. It may be used to dissolve a powder or dilute a concentrated solution, prior to administration.
Fully Specified Name	A unique, unambiguous description of a concept to convey its meaning, and is not intended to be displayed in clinical records, but to disambiguate the different concepts which may be referred to by the same commonly used word or phrase.[15]
Generic	A generic product is one in which the name of the product is a substance name or an indication for treatment.
Intended Active Ingredient	The intended active ingredient is that part of the molecule that is intended to have a therapeutic action on or within the body. In the majority of cases this is the base active moiety, however this may be a secondary modification in certain circumstances, where this is deemed to be therapeutically necessary as described in Appendix B.1

[15] Source: *SNOMED CT Starter Guide*. [9]

Term	Meaning
Preferred Term	Each concept has one synonym which is marked as "Preferred" in a given language, dialect on context of use. This is known as the "Preferred Term" and is a word or phrase commonly used by clinicians to name that concept. In each language, dialect or context of use one and only one synonym can be marked as "Preferred".[16]
Primary modified base	Within the AMT a "primary modified base" is defined as a base plus an additional entity which is combined with the base (but does not have an intended therapeutic effect on the body). Primary modified bases may include salts, esters or waters of hydration. It may be a modification to the base molecule to assist with stability, solubility, bioavailability, or so on.
Product	A medicinal preparation that can be attributed to a specific sponsor.
Secondary modified base	Within the AMT a "secondary modified base" is a primary modified base which has been further modified in some way (but this modification does not have an intended therapeutic effect on the body). This modification frequently indicates the hydration status of the modified base ingredient but may also be another modification.
Synonym	A synonym represents a term that can be used to display or select a concept. A concept may have several synonyms and this allows users of SNOMED CT to apply the terms they prefer to use for a specific clinical meaning. Concepts can have multiple synonyms and the synonyms are not necessarily unique – thus two concepts can have the same synonym.[17]
Therapeutic Goods Administration	Australia's regulatory agency for medical drugs and devices.
Unit of Use	The Unit of Use describes the smallest possible constituent which can be handled. It is either a discrete unit (for example, tablet, capsule) or a continuous unit (for example, cream, liquid products).
Unit of Use Size	The Unit of Use Size describes the size of the individual UoU. For example, for an injection this would be the volume of the ampoule or vial, for a tablet this would be 1 tablet.

[16] Source: *SNOMED CT Starter Guide*. [9]
[17] Source: *SNOMED CT Starter Guide* [9].

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