



**Australian Medicines Terminology v3 Model
Editorial Rules v2.0**

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1 Introduction

1.1 Purpose

This document specifies the editorial rules for the Australian Medicines Terminology (AMT) v3 model, and focuses on the naming conventions and rules associated with all description types for concepts¹ in the AMT model.

Changes to this document may occur according to stakeholder and user feedback, AMT model refinement and independent editorial rule reviews.

Note: For ease of reference, “AMT v3” is used as a short form for “Australian Medicines Terminology v3 Model” in the remainder of this document.

1.2 Intended audience

This document is intended to provide health sector managers, terminology analysts and software vendors with a practical understanding of the editorial rules that are applied in the creation of AMT v3 descriptions.

It is designed for use by those who wish to understand the process and rules necessary for the creation of AMT descriptions, both from a technical and a practical point of view. It may also be relevant to clinical health software vendors and end users.

1.3 Overview

1.3.1 Scope of the AMT

1.3.1.1 In scope

The scope of the AMT is to include medicines that are available in Australia for the treatment of human patients. The AMT includes:

- medicines registered by the TGA;
- medicines listed by the TGA;
- items which are available under the PBS; and
- other medicines and therapeutic products required to support AMT use cases. For example, enteral feeds which are available under the PBS.

The AMT may also include some non-approved therapeutic goods, where they are specifically requested by a stakeholder, and sufficient detail is available for them to be accurately described. For example, some of the medicines available under the Special Access Scheme.

At present the AMT does not contain all of the products in the categories listed above. The addition of new products is prioritised based on feedback from end users.

The AMT may also include some in scope products which were previously available in Australia and included in the AMT, but which are no longer available.

¹ See Section 4.1.2 for an explanation of clinical terminology concepts.

1.3.1.2 Out of scope

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

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

- Adverse effects
- Cautionary and advisory label recommendations
- Contraindications
- Counselling instructions
- Dose checking
- Drug: Allergy interactions
- Drug: Drug interactions
- Drug: Food interactions
- Indications
- Normal dose ranges
- Physiological equivalence
- Precautions for use
- Storage or supply chain related information
- Excipients will not be modelled in the AMT unless presented with a clear use case that is agreed to by the relevant NEHTA 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.

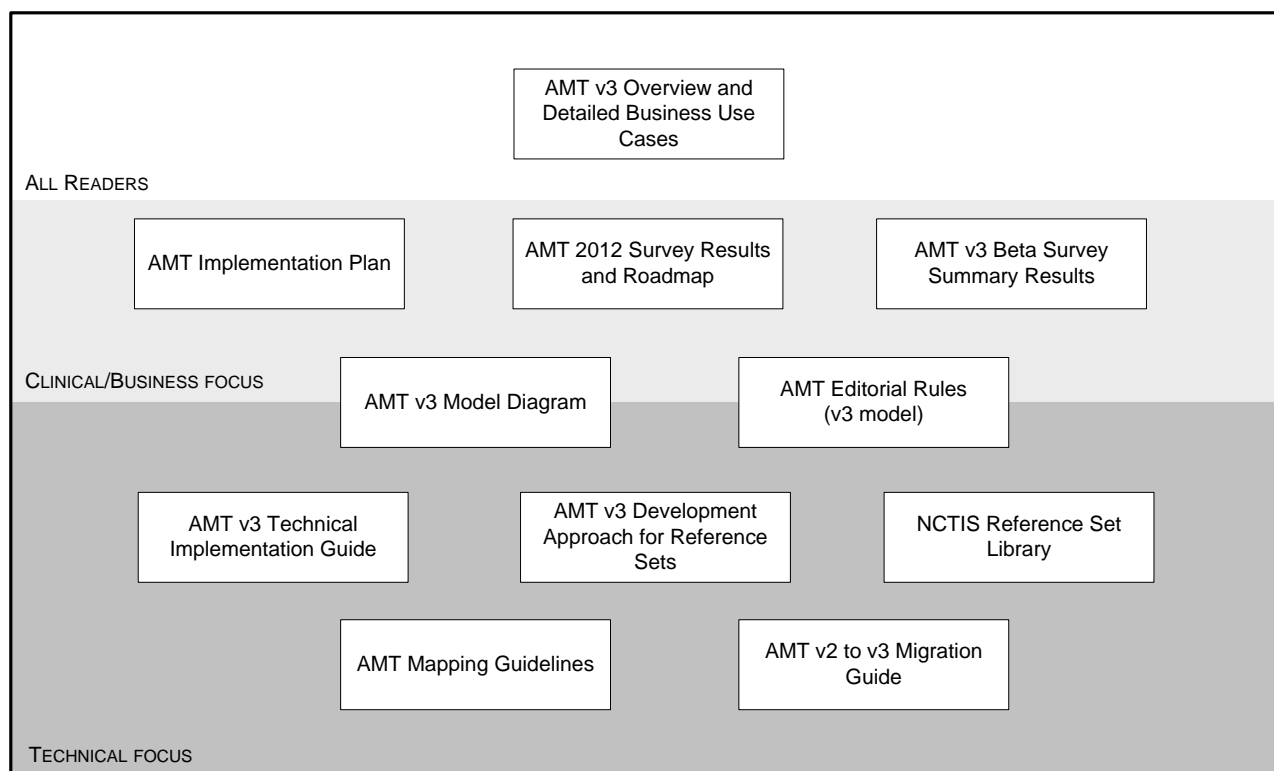
1.3.2 Governance

Details on the governance of AMT may be found at <http://www.nehta.gov.au/our-work/clinical-terminology>.

1.4 AMT v3 documentation map

The AMT documentation suite is summarised in the following map, categorised into the following readerships:

<i>Business:</i>	Business owners, product managers, project managers, policy makers.
<i>Clinical:</i>	Healthcare professionals and other end users.
<i>Technical:</i>	Programmers, content developers, testers, information system suppliers, analysts, terminology/classification specialists, health IT professionals and researchers.



Recommended reading lists for the different types of readers are as follows. Items with asterisks need only be read if relevant to the reader's needs.

Doc Name	Business	Clinical	Technical
<i>AMT v3 Overview and Use Cases</i> [1]	Y	Y	Y
<i>AMT Implementation Plan</i> [2]	Y	Y	
<i>AMT Survey Results and Roadmap</i> [3]	Y*	Y*	Y*
<i>AMT v3 Beta Feedback Summary</i> [4]	Y*	Y*	Y*
<i>AMT v3 Model Diagram</i> [5]		Y	Y
<i>AMT v3 Editorial Rules (this document)</i>		Y	Y
<i>AMT v3 Technical Implementation Guide</i> [6]			Y
<i>AMT v3 Reference Set Development Approach</i> [7]			Y*
<i>NCTIS Reference Set Library</i> [8]			Y*
<i>AMT Mapping Guidelines</i> [9]			Y*
<i>AMT v2 to v3 Migration Guide</i> [10]			Y*

The prerequisites for each document are described in their respective introductions.

1.5 Background

The AMT v3 model was developed following consultation with national terminology experts and stakeholders.

The v3 model is the result of feedback from and consultation with software vendors, jurisdictions, clinicians currently working on implementing prescribing and dispensing software, terminology experts, the Pharmaceutical Benefits Division and the 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 model and editorial rules have their genesis in work undertaken by the NHS Dictionary of Medicines and Devices (dm+d) team. NEHTA has further developed this work to reflect:

- the current AMT v3 model;
- the complexity of many Australian products;
- Australian clinical practice; and
- potential safety issues currently facing many Australian clinicians, that could be improved by the clear and consistent naming of medicines, especially when selection of these items is required in electronic systems.

1.6 Note about Preferred Term descriptions

Currently, some AMT descriptions may differ slightly to those expected from the relevant editorial rules, due to the automated process used in authoring the terminology. In most cases additional information has been added to the descriptions beyond the stated editorial rules. AMT v3 implementers are advised to contact the NCTIS via help@nehta.gov.au if they have any concerns about this issue. Details of any existing deviations can be found in the AMT Release Note.

1.7 Future developments

Future development of the AMT model, content, documentation and use cases will:

- continue the integration of quality processes from data inputs to final product release;
- continue the use of feedback and governance mechanisms to enable iterative development of prioritised product requirements;
- maintain consultation and review of the AMT editorial rules;
- continue to develop the AMT to support the NEHTA work programme; and
- maintain consultation with vendors and implementers to update the roadmap that forms part of the *AMT Implementation Plan* [2].

1.8 Questions and feedback

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

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(E), and uses the following characters.

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

This means that: 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/manufacture/house brand name surrounded by curved brackets.

An example of the result of this would be: Methotrexate (Ebewe)

2.2 SNOMED CT

SNOMED CT² relationships are sometimes represented as follows.

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

² IHTSDO®, SNOMED® and SNOMED CT® are registered trademarks of the International Health Terminology Standards Development Organisation.

2.3 Tables

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

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

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

3 The AMT model

3.1 AMT components

3.1.1 General constraints/data definitions

General component constraints/data definitions relate to all components within the AMT model including concepts, descriptions and relationships.

Greater detail on concepts, descriptions and relationships are found in the *SNOMED CT User Guide* [11] and *SNOMED CT Technical Implementation Guide* [12].

Table 1: General component constraints/data definition rules

Rule ID	Data Element	Constraints/Data Definition	Constraint Source
AU-COMP-1	ComponentId	All Components must have exactly one ComponentId (that is, SNOMED CT Identifier). This is the primary identifier for each component to be used in terminology implementations.	SNOMED CT
AU-COMP-2	ComponentId	All ComponentIds must be unique.	SNOMED CT
AU-COMP-3	ComponentId	Each ComponentId is a SNOMED CT identifier that complies with the SctId data type format. The permitted characters for a SctId are the digits 0-9. The minimum permitted length is six digits; the maximum length is 18 digits. The ComponentId is either an international release SctId or an Australian extension SctId. It includes a partition-identifier that indicates the type of component being identified. Australian extension SctIds include the namespace identifier "1000036" for components created in AMT v2 and retained in the current model. All new components created in v3 will include the namespace identifier of "1000168". Refer to the <i>SNOMED CT Technical Implementation Guide</i> [12] for further details of the SctId format.	SNOMED CT
AU-COMP-4	ComponentUUID	Each Component may have zero or one ComponentUUID. This is an alternative identifier for each component assigned during the terminology build process. Where a ComponentUUID was previously created during the AMT v2 terminology build process, this legacy UUID will be maintained in the Identifier file. New Component UUIDs will only be created as the primary identifier for reference set members.	AMT
AU-COMP-5	ComponentUUID	All ComponentUUIDs must be unique.	AMT
AU-COMP-6	active	All Components are specified as either active or inactive from the nominal release date as specified by the effectiveTime ("active" field with Boolean values of 1 and 0 respectively). Components have an active value of "1" when first released in the terminology. Components that are deprecated have an active value of "0".	SNOMED CT

Rule ID	Data Element	Constraints/Data Definition	Constraint Source
AU-COMP-7	effectiveTime	effectiveTime exists for all Components. It specifies the date at which a component is first released in the terminology or when the component's state has changed in subsequent releases. The effectiveTime format is represented to the day of the year, using ISO 8601 basic representation of YYYYMMDD.	SNOMED CT
AU-COMP-8	moduleId	moduleId exists for all Components. It has a SctId data type format and it specifies the module in which the component is currently maintained (that is, the SctId of the module concept "Australian Medicines Terminology module" in the <i>SNOMED CT Model Component</i> hierarchy).	SNOMED CT

3.1.2 Concepts

In the context of this document, a "concept" is a clinical meaning identified by a unique numeric identifier (conceptId) that never changes. Each concept is represented by a unique human-readable Fully Specified Name (FSN). The 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. Every concept also has a set of terms that name the concept in a human-readable way.

SNOMED CT concepts have unique numeric identifiers called conceptIds, which do not contain hierarchical or implicit meaning. The numeric identifier does not reveal any information about the nature of the concept. For example:

- 373873005 is the conceptId for the concept *Pharmaceutical/biologic product (product)*.
- Each concept in SNOMED CT has a definition, also known as a "logical definition" or "formal definition". The logical definition is an explicit representation of a concept's meaning.

3.1.2.1 AMT hierarchies

The AMT includes the following hierarchies, where concepts are arranged in a tree-like fashion, where a parent concept subsumes a child concept.

Australian product

These concepts are also known as the AMT notable product classes. They are used to identify products including both medicinal and trade representations at various levels of granularity. Additional details about the descriptions that describe these concepts are provided in Section 5.

Australian substance

These concepts represent the active ingredients within products. Additional details about the descriptions that describe these concepts are provided in Section 6.

Australian qualifier

These concepts will be used in the AMT to provide atomic data used to construct the name of the product and to provide additional information about an AMT product concept. Additional details about the descriptions that describe these concepts are provided in Section 7.

SNOMED CT model component

This is the metadata hierarchy in the AMT and is identical to the SNOMED CT-AU metadata hierarchy. These concepts are used to assist in the representation of the AMT data in SNOMED CT format.

Refer to the *SNOMED CT Technical Implementation Guide* [12] for further details of the metadata hierarchy. Additional details about the descriptions that describe these concepts are provided in Section 8.

The AMT concepts, attributes and relationships are further described in the *AMT v3 Technical Implementation Guide* [6].

3.1.2.2 Concept constraints/data definitions

Concept constraints relate to all concept types within the AMT model. The following table lists additional constraints/data definitions for AMT concepts beyond the general constraints/data definitions set out in Section 4.1.1.

Table 2: Concept constraints/data definition rules

Rule ID	Data Element	Constraints/Data Definition	Constraint Source
AU-CON-1	id	The partition-identifier (penultimate two-digits of the SctId) for all conceptIds in the AMT has the value of "10".	SNOMED CT
AU-CON-2	definitionStatusId	definitionStatusId exists for all concepts. It specifies if a concept is primitive or fully defined (that is, the SctId of a definition status concept in the <i>SNOMED CT Model Component</i> hierarchy).	SNOMED CT

3.1.3 Relationships

The AMT will use SNOMED CT relationships, which link concepts with other concepts within the AMT. There are four types of relationships that can be assigned to concepts:

- Defining
- Qualifying
- Historical
- Additional

Every active AMT concept (except the *SNOMED CT concept* root concept) has at least one IS A relationship to a supertype concept.

IS A relationships and defining attribute relationships are known as the “defining characteristics” of AMT concepts. They are considered defining because they are used to logically represent a concept by establishing its relationships with other concepts. This is accomplished by establishing IS A relationships with one or more defining concepts (called supertypes) and modelling the difference with those supertypes through defining attributes.

IS A relationships

IS A relationships are also known as “Supertype-Subtype relationships” or “Parent-Child relationships”. IS A relationships are the basis of the AMT’s hierarchies.

A concept can have more than one IS A relationship to other concepts. In such a case, the concept will have parent concepts in more than one sub-hierarchy of a top-level hierarchy. Subtype relationships can be multi-hierarchical.

Attribute relationships

Attributes relate two concepts and establish the type of relationship between them.

Together with IS A relationships they are considered defining characteristics, since they allow the logical representation of the meaning of a concept by establishing its relationships with other concepts. A logical concept definition includes one or more supertypes (modelled with IS A relationships), and a set of defining attributes that capture the semantics of a concept and help to differentiate it from other concept definitions, including its supertypes.

3.1.3.1 AMT relationships

The AMT will include SNOMED CT relationships and Australian relationships which are used to define a relationship between concepts.

While it is possible to represent most information about a concept in its name (via the Fully Specified Name or the Preferred Term³), it has been noted that some vendors require this data atomically (that is, as “datums”). This is particularly relevant where the name does not include all of the required information: for example, for Medicinal Products that include more than three ingredients, the Preferred Term (PT) may be modified to display something that is clinically intuitive. The AMT represents the full list of active ingredients within a Medicinal Product, using a set of HAS INTENDED ACTIVE INGREDIENT relationships between the Medicinal Product and its active ingredients. It should be noted that atomic data, which adds more information to a concept, may be represented in the AMT using either relationships (when the information is about a concept’s relationship to another concept) or using reference sets (refer to Section 4.2).

Table 3: AMT relationship types

Name	Relationship Source	Included in AMT release files ⁴
IS A	SNOMED CT	Yes
HAS AUSTRALIAN BoSS	AMT	Yes
HAS BASE FORM STRENGTH DENOMINATOR UNITS	AMT	No

³ Fully Specified Names and Preferred Terms are defined in Sections 3.1.4.3 and 3.1.4.4 respectively.

⁴ Where this column is specified as “No” these relationships exist only as part of the terminology build process but are not included in the terminology release files. The terms of the destination concepts of these relationships are used to compose the descriptions of the AMT notable product concepts.

Name	Relationship Source	Included in AMT release files ⁴
HAS BASE FORM STRENGTH NUMERATOR UNITS	AMT	No
HAS BASE FORM STRENGTH PREFERRED REPRESENTATION	AMT	No
HAS COMPONENT PACK	AMT	Yes
HAS CONTAINER TYPE	AMT	Yes
HAS DENOMINATOR UNITS	AMT	Yes
HAS MANUFACTURED DOSE FORM	AMT	Yes
HAS INTENDED ACTIVE INGREDIENT	AMT	Yes
HAS MPUU	AMT	Yes
HAS NUMERATOR UNITS	AMT	Yes
HAS SALT FORM STRENGTH DENOMINATOR UNITS	AMT	No
HAS SALT FORM STRENGTH NUMERATOR UNITS	AMT	No
HAS SALT FORM STRENGTH PREFERRED REPRESENTATION	AMT	No
HAS SUBPACK	AMT	Yes
HAS TOTAL UNIT OF USE QUANTITY UNITS	AMT	No
HAS TP	AMT	Yes
HAS TPP	AMT	Yes
HAS TPUU	AMT	Yes
HAS UNIT OF USE	AMT	Yes
IS MODIFICATION OF	AMT	Yes

These relationships are further described in the *AMT v3 Technical Implementation Guide* [6].

3.1.3.2 Relationship constraints/data definitions

Relationship types are directional and therefore should have a source concept and a target concept.

Reciprocal relationships should not explicitly be represented by rows in the Relationships table. For example, if B is a subtype of A, it follows that A is a supertype of B. The first of these relationships is represented by a row in the Relationship table. The reciprocal relationship is implied and is not restated by another row in the table.

In the case of hierarchical relationships (for example, IS A relationships), only the closest relationships should be represented explicitly. Other relationships are subsumed⁵ and are not represented by rows in the Relationship Table. For example, if C is a subtype of B and B is a subtype of A, it follows that C is a subtype of A. The relationship between C and A is not represented by a row in the Relationship Table but is subsumed by the chain of relationships between C and B and B and A.

⁵ Further details on subsumption may be found in the *SNOMED CT User Guide* [11].

Relationship constraints/data definitions relate to all Relationships within the AMT model. The following table lists additional constraints/data definition for AMT relationships beyond the general constraints/data definition set out in Section 4.1.1.

Table 4: Relationship constraint/data definition rules

Rule ID	Data Element	Constraints/Data Definition	Constraint Source
AU-REL-1	id	The partition-identifier (penultimate two-digits of the SctId) for all relationshipIds in the AMT has the value of "12".	SNOMED CT
AU-REL-2	sourceId	Each relationship must have exactly one sourceId.	SNOMED CT
AU-REL-3	sourceId	The sourceId must equal the SctId of some Concept.	SNOMED CT
AU-REL-4	typeId	Each relationship must have exactly one typeId.	SNOMED CT
AU-REL-5	typeId	The typeId must equal the SctId of an attribute concept in the <i>SNOMED CT Model Component</i> hierarchy.	SNOMED CT
AU-REL-6	destinationId	Each relationship must have exactly one destinationId.	SNOMED CT
AU-REL-7	destinationId	The destinationId must equal the SctId of some Concept.	SNOMED CT
AU-REL-8	relationshipGroup	relationshipGroup must be an integer value between 0 and 99.	SNOMED CT
AU-REL-9	relationshipGroup	relationshipGroup is an integer value between 1 and 99 for every MPUU HAS AUSTRALIAN BOSS relationship and its corresponding HAS INTENDED ACTIVE INGREDIENT relationship. For all other relationship types in the AMT relationshipGroup has a value of "0".	AMT
AU-REL-10	characteristicTypeId	The characteristicTypeId of relationships in the AMT is the SctId of the defining characteristic type concept "Stated relationship" in the <i>SNOMED CT Model Component</i> hierarchy.	AMT
AU-REL-11	modifierId	The modifierId must equal the SctId of the modifier concept "Some" in the <i>SNOMED CT Model Component</i> hierarchy.	AMT

3.1.4 Descriptions

The AMT uses SNOMED CT concept descriptions. These are the terms or names assigned to a SNOMED CT concept. "Term" in this context means a phrase used to name a concept. A unique descriptionId identifies a description. Multiple descriptions might be associated with a concept identified by its conceptId. SNOMED CT concept descriptions include FSNs and Synonyms.

3.1.4.1 AMT Description types

The following SNOMED CT description types exist for AMT concepts:

- Fully Specified Name (FSN)
- Synonym

Synonyms are further refined to preferred or acceptable terms via the *Australian English language reference set*. The former indicates a Preferred Term (PT) description for a concept and the latter indicates additional term(s) for the same concept.

Other description types are available for specific concepts in the AMT: these are described in the table below. However these additional descriptions exist only as part of the terminology build process but are not included in the terminology release files. These additional descriptions are used to compose the descriptions of the AMT notable product concepts.

Table 5: Concept description types

Concept	Australian Additional Description Type Name	Included in AMT release files	Reference
Medicinal Product Unit of Use (MPUU)	Base form strength numerator value	No	See Section 5.3.2.5
	Base form strength denominator value	No	See Section 5.3.2.6
	Base form strength other representation	No	See Section 5.3.2.7
	Salt form strength numerator value	No	See Section 5.3.2.8
	Salt form strength denominator value	No	See Section 5.3.2.9
	Salt form strength other representation	No	See Section 5.3.2.10
	Preferred term order	No	See Section 5.3.2.11
Medicinal Product Pack (MPP)	Preferred component order	No	See Section 5.4.2.5
	Total unit of use quantity value	No	See Section 5.4.2.6
	Total subpack quantity	No	See Section 5.4.2.7
Trade Product (TP)	Proprietary form	No	See Section 5.5.2.5
	Trade family supplier	No	See Section 5.5.2.6
Trade Product Unit of Use (TPUU)	Other identifying information	No	See Section 5.6.2.5
Trade Product Pack (TPP)	Other pack information	No	See Section 5.7.2.5

Concept	Australian Additional Description Type Name	Included in AMT release files	Reference
	Preferred term other identifying information	No	See Section 5.7.2.6
	Total unit of use quantity value	No	See Section 5.7.2.7
Contained Trade Product Pack (CTPP)	Manufacturer's code	No	See Section 5.8.2.5
	Other contained pack information	No	See Section 5.8.2.6
	Component container type	No	See Section 5.8.2.7
Unit of Measure (UOM)	Unit of measure	No	See Section 7.3

3.1.4.2 Description constraints/data definitions

The constraints/data definitions outlined in this section relate to all occurrences of all description types for all AMT descriptions, unless specifically noted under the rules for the concept type being described.

Table 6: Description constraint/data definition rules

Rule ID	Data Element	Constraint/Data Definition	Constraint Source
AU-DES-1	id	The partition-identifier (penultimate two-digits of the SctId) for all descriptionIds in the AMT has the value of "11".	SNOMED CT
AU-DES-2	conceptId	Each description must have exactly one conceptId.	SNOMED CT
AU-DES-3	conceptId	The conceptId must equal the SctId for some Concept.	SNOMED CT
AU-DES-4	languageCode	The languageCode specifies the language of the description text using the two character ISO-639-1 code.	SNOMED CT
AU-DES-5	languageCode	The languageCode of all descriptions in the AMT is "en".	AMT
AU-DES-6	typeId	Each description must have exactly one typeId.	SNOMED CT
AU-DES-7	typeId	The typeId must equal the SctId of a description type concept in the <i>SNOMED CT Model Component</i> hierarchy.	SNOMED CT
AU-DES-8	typeId	The valid values for typeId are the SctId of the following description type concepts: <ul style="list-style-type: none"> Fully Specified Name (FSN) Synonym 	SNOMED CT
AU-DES-9	typeId	The typeId for all AMT descriptions are the SctId for FSN or Synonym.	AMT

Rule ID	Data Element	Constraint/Data Definition	Constraint Source
AU-DES-10	term	Each description must have exactly one term, which is valid for the languageCode specified.	SNOMED CT
AU-DES-11	term	Some terms may be applied to more than one concept. In this case each instance of a term must be represented by a separate row in the Description file with the same description text but with different description and concept identifiers (id field of these files). The description text may look identical but the meaning conveyed for the separate concepts are different.	SNOMED CT
AU-DES-12	term	The description text value is represented in UTF-8 encoding. The term field has a maximum length of 2048 bytes.	AMT
AU-DES-13	caseSignificanceId	The caseSignificanceId must equal the SctId of a case significance concept in the <i>SNOMED CT Model Component</i> hierarchy.	SNOMED CT
AU-DES-14	caseSignificanceId	The caseSignificanceId of all descriptions in the AMT is the SctId of the case significance concept "Case sensitive".	AMT

3.1.4.3 Fully Specified Name definition and rules

Each concept has one unique FSN 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.

The semantic tag indicates the semantic category to which the concept belongs (for example, Medicinal Product, Trade Product Pack, AU qualifier, AU substance).

For example, "amoxicillin (medicinal product)" is a FSN that describes a product that a clinician may choose to prescribe, whereas "amoxicillin (AU substance)" is a FSN that describes an active ingredient of a product. The table below summarises the specific constraints/data definitions for the FSN.

Table 7: FSN constraint/data definition rules

Rule ID	Constraints/Data Definition	Constraint Source
AMT-FSN-1	There must be exactly one active FSN for each concept.	SNOMED CT
AMT-FSN-2	No two concepts in the AMT may have the same FSN.	SNOMED CT
AMT-FSN-3	The FSN of a concept must not be the same as its Preferred Term.	SNOMED CT
AMT-FSN-4	Each FSN must contain a suffix that indicates where it is integrated into the primary hierarchy, that is, it will include the semantic tag of its appropriate parent, for example, "(medicinal product)".	SNOMED CT

3.1.4.4 Preferred Term definition and rules

Each concept in the AMT has one Australian Preferred Term (PT), intended to capture the common word or phrase used by Australian clinicians to name that concept. The PT is a Synonym description type with an acceptability value of “preferred” defined in the *Australian English language reference set*.

If for example, the FSN concept “amoxicillin (medicinal product)” has been created based on the International Nonproprietary Name, the PT “amoxycillin” will be provided to represent a common name clinicians use to describe this product concept in Australia. Note, however, that currently both the FSN and PT are based on Australian Approved Names, which use the spelling “amoxycillin”. This means that in Australia, the current FSN and PT are “amoxycillin (medicinal product)” and “amoxycillin” respectively.

Unlike FSNs, PTs are not necessarily unique. Occasionally, the PT for one concept may also be a Synonym or the PT for a different concept. For example, “amoxycillin” may be the PT for both a Medicinal Product and a Substance concept. The table below summarises the specific constraints/data definitions for the PT.

Table 8: PT constraint/data definition rules

Rule ID	Constraints/Data Definition	Constraint Source
AMT-PT-1	There must be exactly one Synonym with an acceptability value of “preferred” for each AMT concept for the languageCode specified.	SNOMED CT
AMT-PT-2	The PT of a concept cannot be the same as the FSN.	SNOMED CT

3.1.4.5 Acceptable Synonym definition and rules

Acceptable Synonyms represent any additional terms that are used 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. An acceptable Synonym is a description type with an acceptability value of “acceptable” defined in the *Australian English language reference set*.

Acceptable Synonyms are alternative names used to refer to the concept other than the PT (for example, aspirin/acetylsalicylic acid; hypericum/St. Johns Wort) or variant spellings. The table below summarises the specific constraints/data definition for the term.

Table 9: Acceptable Synonym constraint/data definition rules

Rule ID	Constraints/Data Definition	Constraint Source
AMT-SYN-1	There may be zero or more acceptable Synonyms with an acceptability value of “acceptable” for each concept. Acceptable Synonyms are optional and will only be populated when deemed clinically relevant for a concept.	SNOMED CT
AMT-SYN-2	An acceptable Synonym cannot be the same as the FSN.	SNOMED CT

3.2 Reference sets and history mechanisms

Information on reference sets and history mechanisms for the AMT may be found in the *AMT v3 Technical Implementation Guide* [6].

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
- Containerised Trade Product Pack (CTPP).

These concepts and their principal relationships are diagrammatically represented below.

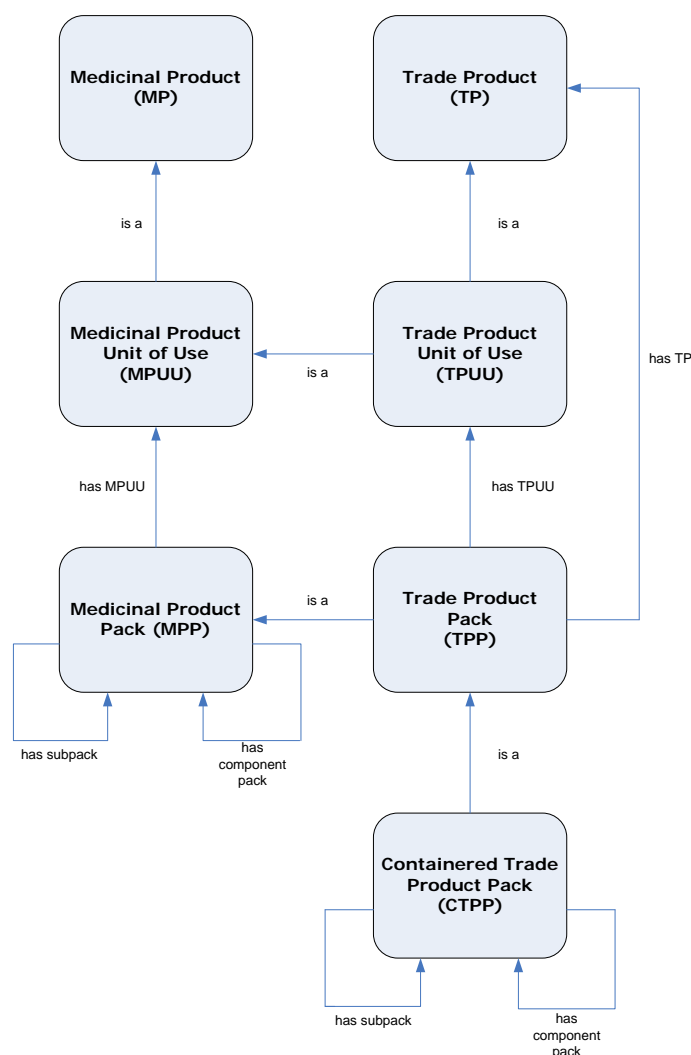


Figure 1: The AMT model (Product concepts)

4.1 Syntax

AMT terms are constructed based on syntax described by the Extended Backus-Naur Form (EBNF). For further details on EBNF, refer to Section 2.

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, active ingredient(s)⁶, strength, form, pack size and container type. This corresponds to the product concept of CTPP, which represents the product concept with the most detailed level of granularity 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

⁶ 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.

- Multi-component
- Subpacks

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

Table 10: Product matrix

	Single ingredient	Multi-ingredient	Single component	Multi-component	Subpacks
Medicinal Product (MP)	Yes	Yes	Yes		
Medicinal Product Unit of Use (MPUU)	Yes	Yes	Yes		
Medicinal Product Pack (MPP)	Yes	Yes	Yes	Yes	Yes
Trade Product (TP)	Yes	Yes	Yes	Yes	Yes
Trade Product Unit of Use (TPUU)	Yes	Yes	Yes		
Trade Product Pack (TPP)	Yes	Yes	Yes	Yes	Yes
Containerised Trade Product Pack (CTPP)	Yes	Yes	Yes	Yes	Yes

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

Brief definitions and rules for each of the product concepts are included in this chapter. Brief definitions are written in plain English and may be used when descriptions are created manually. Full definitions are written from a technical point of view and may be used by those intending to auto-generate descriptions.

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: hard (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: film-coated (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: hard (trade product unit of use)

TPP: Amoxil (amoxicillin 500 mg) capsule: hard, 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: film-coated (trade product unit of use)

TPP: Combivir (lamivudine 150 mg + zidovudine 300 mg) tablet: film-coated, 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).

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

- MP:** codeine + paracetamol + phenylephrine (medicinal product)
chlorpheniramine + paracetamol + phenylephrine (medicinal product)
- MPUU:** codeine phosphate hemihydrate 9.5 mg + paracetamol 500 mg + phenylephrine hydrochloride 5 mg tablet (medicinal product unit of use)
chlorpheniramine maleate 2 mg + paracetamol 500 mg + phenylephrine hydrochloride 5 mg tablet (medicinal product unit of use)
- MPP:** chlorpheniramine 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], 1 pack (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: film-coated (trade product unit of use)
Codral Day and Night Cold and Flu (Night) (chlorpheniramine maleate 2 mg + paracetamol 500 mg + phenylephrine hydrochloride 5 mg) tablet: film-coated (trade product unit of use)
- TPP:** Codral Day and Night Cold and Flu (chlorpheniramine maleate 2 mg + paracetamol 500 mg + phenylephrine hydrochloride 5 mg) tablet: film-coated [12 tablets] (&) (codeine phosphate hemihydrate 9.5 mg + paracetamol 500 mg + phenylephrine hydrochloride 5 mg) tablet: film-coated [36 tablets], 1 pack (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.

If a multi-component product meets all of the following criteria, it will not be treated as a multi-component product, but will be treated as a multi-ingredient product:

- Each of the components consists of at least one active ingredient; AND
- The components cannot be physically separated and then administered individually, or the components may be physically separated but are not intended to be administered individually; AND
- The components are administered concurrently in a final combined form.

This allows the product to be represented by a single MPUU and TPUU instead of multiple MPUUs and TPUUs. An example of such a product is:

Infanrix Hexa (Bordetella pertussis, acellular pertactin vaccine 8 microgram + Bordetella pertussis, acellular pertussis toxoid vaccine 25 microgram + Bordetella pertussis, filamentous haemagglutinin vaccine 25 microgram + diphtheria toxoid vaccine 30 international units + Haemophilus influenzae type b capsular polysaccharide vaccine 10 microgram + hepatitis B virus surface antigen vaccine 10 microgram + poliomyelitis virus type 1 (Mahoney) inactivated vaccine 40 D antigen units + poliomyelitis virus type 2 (MEF1) inactivated vaccine 8 D antigen units + poliomyelitis virus type 3 (Saukett) inactivated vaccine 32 D antigen units + tetanus toxoid vaccine 40 international units) injection: suspension, dose (trade product unit of use)

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 container (non-ingestible) that immediately surrounds the therapeutic good. Examples of a primary container are: blister pack, bottle, vial and cartridge. 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 4.1.5.1 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 4.1.5.2 for further details.

4.2.5.1 Subpacks

Subpacks are only represented for specific product categories. These categories include, but are not limited to, oral contraceptives and hormone replacement therapy products. Subpacks 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).

Table 11: Examples of FSNs and PTs of Subpacks

Type of pack	Fully Specified Name	Preferred Term
MPP (Subpack)	levonorgestrel 30 microgram tablet, 28 tablets (medicinal product pack)	levonorgestrel 30 microgram tablet, 28
MPP	levonorgestrel 30 microgram tablet, 112 tablets [4 x 28 tablets] (medicinal product pack)	levonorgestrel 30 microgram tablet, 112 [4 x 28]

Type of pack	Fully Specified Name	Preferred Term
CTPP (Subpack)	Microlut (levonorgestrel 30 microgram) tablet: sugar-coated, 28 tablets, blister pack (containered trade product pack)	Microlut 30 microgram tablet: sugar-coated, 28, blister pack
CTPP	Microlut (levonorgestrel 30 microgram) tablet: sugar-coated, 112 tablets [4 x 28 tablets], blister pack (containered trade product pack)	Microlut 30 microgram tablet: sugar-coated, 112 tablets [4 x 28], blister pack
MPP (Subpack)	minoxidil 20 mg / 1 g gel, 1 x 60 mL bottle (medicinal product pack)	minoxidil 2% (20 mg/g) gel, 60 mL bottle
MPP	minoxidil 20 mg / 1 g gel, 3 x 60 mL bottle (medicinal product pack)	minoxidil 2% (20 mg/g) gel, 3 x 60 mL bottle
CTPP (Subpack)	Regaine (minoxidil 20 mg / 1 g) gel, 1 x 60 mL bottle (containered trade product pack)	Regaine 2% (20 mg/g) gel, 60 mL bottle
CTPP	Regaine (minoxidil 20 mg / 1 g) gel, 3 x 60 mL bottle (containered trade product pack)	Regaine 2% (20 mg/g) gel, 3 x 60 mL bottle

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, Tritace Titration Pack). They may have the same form or have different forms.

It should be noted that some individual packs which are described as an MPP or CTPP 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).

Where each of the individual container types are the same, the CTPP representing a combination pack will have an associated specific container type (for example, blister pack, bottle, ampoule).

Where each of the individual container types are different, the CTPP representing the combination pack will have an associated container type of "composite pack".

See Appendix J Container Types for further detail on containers.

Table 12: Examples of FSNs and PTs of Combination packs

CTPP	Fully Specified Name	Preferred Term
Overall CTPP	Femazole Duo (clotrimazole 10 mg / 1 g) cream [10 g] (&) (fluconazole 150 mg) capsule: hard [1 capsule], 1 pack, composite pack (containered trade product pack)	Femazole Duo (1 x 150 mg capsule, 1 x 10 g cream), 1 pack, composite pack

CTPP	Fully Specified Name	Preferred Term
Individual CTPPs	Femazole One (fluconazole 150 mg) capsule: hard, 1 capsule, blister pack (containerised trade product pack)	Femazole Duo 150 mg capsule
	Femazole Duo 1% (clotrimazole 10 mg / 1 g) cream, 10 g, tube (containerised trade product pack)	Femazole Duo 1% cream, 10 g
Overall CTPP	Nexium Hp7 (amoxicillin (as trihydrate) 500 mg) capsule: hard [28 capsules] (&) (clarithromycin 500 mg) tablet: film-coated [14 tablets] (&) (esomeprazole (as magnesium trihydrate) 20 mg) tablet: enteric [14 tablets], 1 pack, composite pack (containerised trade product pack)	Nexium Hp7 (14 x 20 mg enteric tablets, 14 x 500 mg tablets, 28 x 500 mg capsules), 1 pack, composite pack
Individual CTPPs	Nexium (esomeprazole (as magnesium trihydrate) 20 mg) tablet: enteric, 14 tablets, blister pack (containerised trade product pack)	Nexium 20 mg tablet: enteric, 14 tablets, blister pack
	Klacid (clarithromycin 500 mg) tablet: film-coated, 14 tablets, blister pack (containerised trade product pack)	Klacid 500 mg tablet: film-coated, 14 tablets, blister pack
	Amoxil (amoxicillin (as trihydrate) 500 mg) capsule: hard, 28 capsules, blister pack (containerised trade product pack)	Amoxil 500 mg capsule: hard, 28 capsules, blister pack

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-only medicines.

Excipients will not be modelled in the AMT unless presented with a clear use case that is agreed to by the relevant NEHTA 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).

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 salt ingredient but may also be another salt.

Table 13: 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
	amoxycillin trihydrate	amoxycillin	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. 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

Note also that 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 FSN will always include all of the individual substances, while the MP PT will show ingredients according to AMT-MP-PT-4 in Section 5.2.2.4.

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 14: Examples of Medicinal Product FSNs and PTs

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

4.3.2 Medicinal Product descriptions

4.3.2.1 Medicinal Product Fully Specified Name brief definition

The Fully Specified Name of a Medicinal Product follows the syntax⁷:

MP FSN := MP_Ingredient_Details " (medicinal product) "

where the component parts are described as follows.

Table 15: MP description

Description Component	Description
MP_Ingredient_Details	<p>A list of the FSNs (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.</p> <p>Ingredients are ordered alphabetically, irrespective of casing.</p> <p>Where the intended active ingredient is “inert substance”, this will always be shown last.</p> <p>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.</p>
(medicinal product)	The semantic tag used in the FSN of all Medicinal Product concepts.

4.3.2.2 Medicinal Product Fully Specified Name rules

Table 16: MP FSN rules

Rule ID	Description
AMT-MP-FSN-1	<p>All rules in Section 3.1.4.3 (FSN Definition and Rules) apply.</p> <p>Capitalisation rules as defined in Appendix A apply.</p>

⁷ For an explanation of syntax conventions, refer to Section 3.

Rule ID	Description
AMT-MP-FSN-2	<p>The Medicinal Product FSN will be derived from the Australian Approved Name (AAN), followed by other approved or clinically intuitive names as specified in the <i>TGA Approved Terminology for Medicines</i> [13].</p> <p>EXCEPTION</p> <p>This may, however, differ to meet requirements of clinical practice.</p> <p>Current exceptions are listed in Appendix C and will be added to on a case-by-case basis.</p>
AMT-MP-FSN-3	<p>The MP FSN will be derived from the intended active ingredients.</p> <p>EXCEPTION</p> <p>The full name of an ingredient (that is, including the modification) will be used in the case of discernible therapeutic differences to the base.</p> <p>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.</p> <p>See Appendix B for further information.</p>
AMT-MP-FSN-4	<p>The MP FSN will include all intended active ingredients for a multi-ingredient preparation.</p> <p>The MP FSN 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.</p>
AMT-MP-FSN-5	The MP FSN will describe a single component MP concept.

4.3.2.3 Medicinal Product Preferred Term brief definition

The Preferred Term of a Medicinal Product will, by default, follow the syntax:

MP PT := Ingredient_Details

where the component parts are described as follows.

Table 17: MP PT description

Description Component	Description
Ingredient_Details	<p>A list (alphabetical by default) of the PTs of each of the MP's intended active ingredients, with:</p> <ul style="list-style-type: none"> • ingredients of the same MP component separated by a " + " and grouped together; • MP components, which contain exactly the same ingredients, only shown once. <p>By default the order of this list is alphabetical, irrespective of casing, however if every MPUU associated with one of the components of the MP (through the MPUU IS A MP relationship) has the same "Preferred term order" for the corresponding ingredients, then this order is used instead.</p> <p>For multi-ingredient products, the order of the ingredients will be based on the order used by the innovator product. All subsequent products with the same combination of ingredients will follow the order of the innovator product.</p> <p>Where the intended active ingredient is "inert substance", this will always be shown last.</p>

Description Component	Description
	<p>Refer to Appendix C.6 for further details on exceptions to alphabetical MP ingredient order.</p> <p>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.</p>

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 PT of MPs with more than three active ingredients per component may be manually created (refer to rule AMT-MP-PT-4 below for more details, and to Appendix D for exceptions).

4.3.2.4 Medicinal Product Preferred Term rules

Table 18: Medicinal Product Preferred Term rules

Rule ID	Description
AMT-MP-PT-1	All rules defined in Section 3.1.4.4 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.
AMT-MP-PT-2	<p>The Medicinal Product PT will be derived from the Australian Approved Name (AAN), followed by other approved or clinically intuitive names as specified in the <i>TGA Approved Terminology for Medicines</i> [13].</p> <p>EXCEPTION</p> <p>This may, however, differ to meet requirements of clinical practice.</p> <p>Current exceptions are listed in Appendix C and will be added to on a case-by-case basis.</p>
AMT-MP-PT-3	<p>The Medicinal Product PT will be derived from the intended active ingredients.</p> <p>EXCEPTION</p> <p>The full name of an ingredient (that is, including the modification) will be used in the case of discernible therapeutic differences to the base.</p> <p>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.</p> <p>See Appendix B for further information.</p>

Rule ID	Description								
AMT-MP-PT-4	<p>For Medicinal Products with greater than three intended active ingredients, the AMT authors may create a clinically intuitive name based on the review of each individual product.</p> <p>EXCEPTION</p> <p>Groups of products that will retain more than three active ingredients in the creation of the name include:</p> <ul style="list-style-type: none"> • 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. <p>The addition of items to the exceptions list will be reviewed on a case-by-case basis.</p> <p>Note: The identification of all intended active ingredients is available from the Medicinal Product (MP) HAS INTENDED ACTIVE INGREDIENT relationship with Substance (SUB).</p> <p>The current exception list is attached as Appendix D.</p> <p>The MP PT 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.</p>								
AMT-MP-PT-5	<p>The sequence of ingredients in the Medicinal Product PT will, by default, be based on the alphabetic order of the ingredient names. However, if every MPUU associated with the component(s) of the MP (through the MPUU IS A MP relationship) has a “Preferred term order” for the corresponding ingredients, then this order is used instead.</p> <p>EXCEPTION</p> <p>The order sequence for multi-ingredient products will be alphabetical, unless an altered sequence is determined as in Appendix C. This will be developed on a case-by-case basis.</p> <p>For multi-ingredient products, the order of the ingredients will be based on the order used by the innovator product. All subsequent products with the same combination of ingredients will follow the order of the innovator product.</p> <p>The complete list of exceptions may be found in Appendix C.6.</p> <p>Example:</p> <table data-bbox="408 1384 1139 1563"> <tr> <td>MP FSN:</td><td>aspirin + clopidogrel (medicinal product)</td></tr> <tr> <td>MP PT:</td><td>clopidogrel + aspirin</td></tr> <tr> <td>MP FSN:</td><td>clavulanic acid + ticarcillin (medicinal product)</td></tr> <tr> <td>MP PT:</td><td>ticarcillin + clavulanic acid</td></tr> </table>	MP FSN:	aspirin + clopidogrel (medicinal product)	MP PT:	clopidogrel + aspirin	MP FSN:	clavulanic acid + ticarcillin (medicinal product)	MP PT:	ticarcillin + clavulanic acid
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-6	The Medicinal Product PT 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 (TPUU). 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 BoSS⁸ representation of the active ingredient. 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 Basis of Strength Substance is the modified base. Although the modified base is not clinically significant, this needs to be represented as it is relevant to decisions concerning dose.

Example (MPUU PT): perindopril arginine 5 mg tablet
 perindopril erbumine 4 mg tablet

- Where the primary or secondary modified base must be administered at a dose that differs from other modifications of the same base, for example, amphotericin B lipid complex. In this case, the dose of the lipid complex product is higher than the dose of the base alone.

In these instances the ingredient may not necessarily be represented as the full primary modified base name. Where the Basis of Strength Substance is the base, the modification detail would still appear in the MPUU, but in brackets. Note that this detail is not captured in the creation on the term, but is added separately.

Example (MPUU PT): amphotericin B (as lipid complex) 100 mg/20 mL injection, vial

Note that 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.

⁸ 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.

Table 19: Examples of MPUU FSNs and PTs

Type of product	Fully Specified Name	Preferred Term
Single ingredient	amoxycillin 500 mg capsule (medicinal product unit of use)	amoxycillin 500 mg capsule
Single ingredient – clinically relevant modified base (refer to Appendix B)	diclofenac sodium 50 mg tablet: enteric (medicinal product unit of use)	diclofenac sodium 50 mg tablet: enteric
Single ingredient – clinically significant modified base (refer to Appendix B)	sodium chloride 9 g / 1 L injection, 1 L bag (medicinal product unit of use)	sodium chloride 0.9% (9 g/1 L) injection, bag
Multi-ingredient	codeine phosphate 30 mg + paracetamol 500 mg tablet (medicinal product unit of use)	paracetamol 500 mg + codeine phosphate 30 mg tablet
Multi-component	<ul style="list-style-type: none"> risedronate sodium 35 mg tablet: enteric (medicinal product unit of use) calcium (as carbonate) 500 mg tablet (medicinal product unit of use) 	<ul style="list-style-type: none"> risedronate sodium 35 mg tablet: enteric calcium (as carbonate) 500 mg tablet
Multi-ingredient Multi-component	<ul style="list-style-type: none"> ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet (medicinal product unit of use) ethinylloestradiol 40 microgram + levonorgestrel 75 microgram tablet (medicinal product unit of use) ethinylloestradiol 30 microgram + levonorgestrel 125 microgram tablet (medicinal product unit of use) inert substance tablet (medicinal product unit of use) 	<ul style="list-style-type: none"> ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet ethinylloestradiol 40 microgram + levonorgestrel 75 microgram tablet ethinylloestradiol 30 microgram + levonorgestrel 125 microgram tablet inert substance tablet
Combination pack	<ul style="list-style-type: none"> esomeprazole 20 mg tablet: enteric (medicinal product unit of use) clarithromycin 500 mg tablet (medicinal product unit of use) amoxycillin 500 mg capsule (medicinal product unit of use) 	<ul style="list-style-type: none"> esomeprazole 20 mg tablet: enteric clarithromycin 500 mg tablet amoxycillin 500 mg capsule
patch	oestradiol 100 microgram / 24 hours patch (medicinal product unit of use)	oestradiol 100 microgram/24 hours patch
injection solution	fluphenazine decanoate 12.5 mg / 0.5 mL injection, 0.5 mL ampoule (medicinal product unit of use)	fluphenazine decanoate 12.5 mg/0.5 mL injection, ampoule

Type of product	Fully Specified Name	Preferred Term
injection powder with diluent	<ul style="list-style-type: none"> lanreotide 30 mg injection: modified release, 30 mg vial (medicinal product unit of use) inert substance diluent, 2 mL ampoule (medicinal product unit of use) 	<ul style="list-style-type: none"> lanreotide 30 mg injection: modified release, vial inert substance diluent, 2 mL ampoule

The following table provides a few examples of Medicinal Product Unit of Use FSNs and PTs for all different strength representation rules. Refer to Appendix E for further details.

Table 20: Examples of Medicinal Product Unit of Use FSNs and PTs for different strength representation rules

Type of product	Fully Specified Name	Preferred Term
applications, creams and ointments, ear preparations, enemas, gels, eye preparations, intravenous infusions, injection solutions, lotions, mouthwashes, dusting powders, sachets	hydrocortisone 10 mg / 1 g cream (medicinal product unit of use)	hydrocortisone 1% cream
capsules and tablets, sunscreens, inhalations, powders for injection, nasal drops, oral liquids, spray solutions	diclofenac sodium 50 mg tablet: enteric (medicinal product unit of use)	diclofenac sodium 50 mg tablet: enteric
hormone replacement therapy patch	oestradiol 100 microgram / 24 hours patch (medicinal product unit of use)	oestradiol 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 Medicinal Product Unit of Use descriptions

4.4.2.1 Medicinal Product Unit of Use Fully Specified Name brief definition

The Fully Specified Name of a Medicinal Product Unit of Use 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 21: MPUU description

Description Component	Description
Ingredients_With_Strength	<p>An alphabetical list of the name and strength (if available) of each of the intended active ingredients of the MPUU, where:</p> <ul style="list-style-type: none"> 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 ingredient (that is, the Preferred Term of the Substance (SUB) concept that is the destination of MPUU HAS AUSTRALIAN BoSS relationship(s)). 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 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	<p>The manufactured dose form of the MPUU, defined in a non-proprietary way.</p> <p>This is the PT of the Form (F) concept that is the destination of the MPUU HAS MANUFACTURED DOSE FORM F relationship.</p>
Unit_Of_Use_Details	<p>A list of the Unit of Use details , which may include:</p> <ul style="list-style-type: none"> Unit of Use Size (UOUS) Unit of Use: The unit dose item that can be physically handled. <p>When these values are shown, the first of these is preceded by a comma followed by a space.</p> <p>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 PT of the MPUU's Form (or one of this Form's parents in the "Form is a Form" hierarchy).</p>
(medicinal product unit of use)	<p>The semantic tag used in the FSN of all Medicinal Product Unit of Use concepts.</p>

Note that the PT of MPUUs with more than three intended active ingredients will be manually created in most cases, using the manually created MP ingredient details (refer to rule AMT-MP-PT-4 in Section 5.2.2.2 and Appendix D for more details).

4.4.2.2 Medicinal Product Unit of Use Fully Specified Name rules

Table 22: MPUU FSN rules

Rule ID	Description
AMT-MPUU-FSN-1	All rules in Section 3.1.4.3 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.
AMT-MPUU-FSN-2	The Medicinal Product Unit of Use will be derived from the intended active ingredients, as defined for MP FSN. EXCEPTION 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.
AMT-MPUU-FSN-3	Strength expression. The MPUU FSN 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 (Chapter 5 of the <i>TGA Approved Terminology for Medicines</i> [13]). 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 "tablet: modified release" would be included in the MPUU but a non-significant form such as "tablet: uncoated" would appear as the parent form of "tablet".

4.4.2.3 Medicinal Product Unit of Use Preferred Term brief definition

The Preferred Term of a Medicinal Product Unit of Use, by default, follows the syntax:

MPUU PT := Ingredients_With_Strength " " Form
[", " Unit_Of_Use_Details]

where the component parts are described as follows.

Table 23: MPUU PT description

Description Component	Description
Ingredients_With_Strength	The name and strength (if available) of each of the ingredients of the MPUU, where: <ul style="list-style-type: none"> the name string and strength string (for the same ingredient) are separated by a space; AND the name and strength pairs for different ingredients are separated by a " + "; AND

Description Component	Description
	<ul style="list-style-type: none"> the list, by default, is in alphabetical order of the ingredient names. However, when the "PreferredTermOrder" description of the associated MPUU is populated, this order is used instead. <p>The ingredient(s) are based on the MPUU's BoSS ingredients (that is, the Preferred Term of the Substance (SUB) concept that is the destination of MPUU HAS AUSTRALIAN BoSS relationship(s)). This may be a base or a modified base substance.</p> <p>The strength component is based on the strength of the MPUU's BoSS ingredient. The strength component may be one of the following:</p> <ul style="list-style-type: none"> 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. <p>If the strength component includes a representation of the numerator and denominator strength components of the BoSS, then the associated strength units (UOM) are plural units if the associated strength value > 1.</p> <p>Exceptions: For the units of measure of "microgram" the PT is used instead of the plural units.</p>
Form	<p>The manufactured dose form of the MPUU, defined in a non-proprietary way.</p> <p>This is the PT of the Form (F) concept that is the destination of the MPUU HAS MANUFACTURED DOSE FORM F relationship.</p>
Unit_Of_Use_Details	<p>A list of the Unit of Use details, which may include:</p> <ul style="list-style-type: none"> Unit of Use Size (UOUS) Unit of Use: The unit dose item that can be physically handled. <p>When these values are shown, the first of these is preceded by a comma followed by a space.</p> <p>Note that the Unit of Use Size (value and units) is not shown when:</p> <ul style="list-style-type: none"> it has a value of "1" and a unit that matches the PT of the MPUU's Form (or one of this Form's parents in the "Form is a Form" hierarchy); OR it is the same as the strength denominator (value and units) for all of its ingredients; OR there is only one ingredient and the base strength denominator value does not exist and the base strength numerator (value and units) are the same as Unit of Use Size.

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

Table 24: 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 PT of MPUUs with more than three active ingredients may be manually created (refer to rule AMT-MP-PT-4 in Section 5.2.2.4 for more details).

For example: for a product containing potassium available from multiple sources (for example, Chlorvescent) the MPP 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 tablet: effervescent

- Created term:**

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

4.4.2.4 Medicinal Product Unit of Use Preferred Term rules

Table 25: MPUU PT rules

Rule ID	Description
AMT-MPUU-PT-1	All rules defined in Section 3.1.4.4 (Preferred Term Definition and Rules) apply. 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 Basis of Strength Substance (BoSS), the MPUU will represent that ingredient name, otherwise the MPUU will represent the ingredient name as defined by the MP (that is, a modified base will only be displayed if it is the BoSS).

Rule ID	Description
AMT-MPUU-PT-3	<p>Strength expression.</p> <p>The MPUU PT will include strength expression (if available). The strength expression general rules and application to specific medication forms is outlined in Appendix E.</p> <p>EXCEPTION</p> <p>See AMT-APP-STR-9 in Appendix E.</p> <p>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.1 and E.2.</p>
AMT-MPUU-PT-4	<p>Form.</p> <p>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).</p> <p>EXCEPTION</p> <p>Where the specific form is deemed therapeutically necessary to support clinical decisions at the MPUU level, the form is expressed as the specific form.</p> <p>For example a therapeutically significant form such as "tablet: modified release" would be included in the MPUU but a non-significant form such as "tablet: uncoated" would appear as the parent form of "tablet".</p>

4.4.2.5 Medicinal Product Unit of Use "Base form strength numerator value" definition and rules

Definition

The MPUU Base form strength numerator value is the numerical value that represents the numerator strength of the base ingredient.

Note that as per Section 3.1.4.1 this is an additional description type which is not released in the terminology release files.

Table 26: MPUU "Base form strength numerator value" rules

Rule ID	Description
AMT-MPUU-BFSNV-1	This term is only to be populated with integers or decimal numbers (for example, 6, 0.25).
AMT-MPUU-BFSNV-2	This value is optional, but must be populated if "Base form strength denominator value" is populated.

4.4.2.6 Medicinal Product Unit of Use "Base form strength denominator value" definition and rules

Definition

The MPUU Base form strength denominator value is the numerical value that represents the denominator strength of the base ingredient.

Note that as per Section 3.1.4.1 this is an additional description type which is not released in the terminology release files.

Table 27: MPUU “Base form strength denominator value” rules

Rule ID	Description
AMT-MPUU-BFSDV-1	This term is only to be populated with integers or decimal numbers (for example, 6, 0.25).
AMT-MPUU-BFSDV-2	This value is optional, but may only be populated if “Base form strength numerator value” is populated.

4.4.2.7 Medicinal Product Unit of Use “Base form strength other representation” definition and rules

Definition

The MPUU Base form strength other representation is a valid alternative strength representation for the base ingredient.

Note that as per Section 3.1.4.1 this is an additional description type which is not released in the terminology release files.

Table 28: MPUU “Base form strength other representation” rules

Rule ID	Description
AMT-MPUU-BFSOR-1	This term can be populated with a text string.
AMT-MPUU-BFSOR-2	This value is optional, but may only be populated if “Base form strength numerator value” is populated.
AMT-MPUU-BFSOR-3	If populated this value is represented only in the associated MPUU’s Preferred Term.

4.4.2.8 Medicinal Product Unit of Use “Salt form strength numerator value” definition and rules

Definition

The MPUU Salt form strength numerator value is the numerical value that represents the numerator strength of the salt ingredient.

Note that as per Section 3.1.4.1 this is an additional description type which is not released in the terminology release files.

Table 29: MPUU “Salt form strength numerator value” rules

Rule ID	Description
AMT-MPUU-SFSNV-1	This term is only to be populated with integers or decimal numbers (for example, 6, 0.25).
AMT-MPUU-SFSNV-2	This value is optional, but must be populated if “Salt form strength denominator value” is populated.

4.4.2.9 Medicinal Product Unit of Use “Salt form strength denominator value” definition and rules

Definition

The MPUU Salt form strength denominator value is the numerical value that represents the denominator strength of the salt ingredient.

Note that as per Section 3.1.4.1 this is an additional description type which is not released in the terminology release files.

Table 30: MPUU “Salt form strength denominator value” rules

Rule ID	Description
AMT-MPUU-SFSDV-1	This term is only to be populated with integers or decimal numbers (for example, 6, 0.25).
AMT-MPUU-SFSDV-2	This value is optional, but may only be populated if “Salt form strength numerator value” is populated.

4.4.2.10 Medicinal Product Unit of Use “Salt form strength other representation” definition and rules

Definition

The MPUU Salt form strength other representation is a valid alternative strength representation for the salt ingredient.

Note that as per Section 3.1.4.1 this is an additional description type which is not released in the terminology release files.

Table 31: MPUU “Salt form strength other representation” rules

Rule ID	Description
AMT-MPUU-SFSOR-1	This term can be populated with a text string.
AMT-MPUU-SFSOR-2	This value is optional, but may only be populated if “Salt form strength numerator value” is populated.
AMT-MPUU-SFSOR-3	If populated, this value is represented only in the associated MPUU’s Preferred Term.

4.4.2.11 Medicinal Product Unit of Use “Preferred term order” definition and rules

Definition

The MPUU Preferred term order is used to define an ingredient order other than alphabetical for multi-ingredient products.

Note that as per Section 3.1.4.1 this is an additional description type which is not released in the terminology release files.

Table 32: MPUU “Preferred term order” rules

Rule ID	Description
AMT-MPUU-PTO-1	This term can only be populated with positive integers.
AMT-MPUU-PTO-2	This value is optional and may only be populated for MPUUs with two or more active ingredients, that is, those representing multi-ingredient items.
AMT-MPUU-PTO-3	If populated, this value specifies the ingredient order only in the associated MPUU’s Preferred Term.

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), as well as the same strength, dose form and pack size.

Note that for every TPP, a corresponding MPP will exist which will have one or more TPPs linked to it.

Table 33: Examples of MPP FSNs and PTs

Type of product	Fully Specified Name	Preferred Term
Single ingredient	amoxycillin 500 mg capsule, 20 capsules (medicinal product pack)	amoxycillin 500 mg capsule, 20
Single ingredient – clinically relevant modified base (refer to Appendix B)	diclofenac sodium 50 mg tablet: enteric, 50 tablets (medicinal product pack)	diclofenac sodium 50 mg tablet: enteric, 50
Single ingredient – clinically significant modified base (refer to Appendix B)	sodium chloride 9 g / 1 L injection, 1 x 1 L bag (medicinal product pack)	sodium chloride 0.9% (9 g/1 L) injection, 1 L bag
Multi-ingredient	codeine phosphate 30 mg + paracetamol 500 mg tablet, 20 tablets (medicinal product pack)	paracetamol 500 mg + codeine phosphate 30 mg tablet, 20

Type of product	Fully Specified Name	Preferred Term
Multi-component	<ul style="list-style-type: none"> calcium (as carbonate) 500 mg tablet [24 tablets] (&) risedronate sodium 35 mg tablet: enteric [4 tablets], 1 pack (medicinal product pack) 	<ul style="list-style-type: none"> risedronate sodium 35 mg tablet: enteric [4] (&) calcium (as carbonate) 500 mg tablet [24], 1 pack
Multi-ingredient Multi-component	<ul style="list-style-type: none"> ethinylloestradiol 30 microgram + levonorgestrel 125 microgram tablet [40 tablets] (&) ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet [24 tablets] (&) ethinylloestradiol 40 microgram + levonorgestrel 75 microgram tablet [20 tablets] (&) inert substance tablet [28 tablets], 112 tablets [4 x 28 tablets] (medicinal product pack) ethinylloestradiol 30 microgram + levonorgestrel 125 microgram tablet [10 tablets] (&) ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet [6 tablets] (&) ethinylloestradiol 40 microgram + levonorgestrel 75 microgram tablet [4 tablets] (&) inert substance tablet [7 tablets], 28 tablets (medicinal product pack) 	<ul style="list-style-type: none"> ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet [24] (&) ethinylloestradiol 40 microgram + levonorgestrel 75 microgram tablet [20] (&) ethinylloestradiol 30 microgram + levonorgestrel 125 microgram tablet [40] (&) inert substance tablet [28], 112 [4 x 28] ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet [6] (&) ethinylloestradiol 40 microgram + levonorgestrel 75 microgram tablet [5] (&) ethinylloestradiol 30 microgram + levonorgestrel 125 microgram tablet [10] (&) inert substance tablet [7], 28
Combination pack	<ul style="list-style-type: none"> amoxicillin 500 mg capsule [28 capsules] (&) clarithromycin 500 mg tablet [14 tablets] (&) esomeprazole 20 mg tablet: enteric [14 tablets], 1 pack (medicinal product pack) amoxicillin 500 mg capsule, 28 capsules (medicinal product pack) clarithromycin 500 mg tablet, 14 tablets (medicinal product pack) esomeprazole 20 mg tablet: enteric, 14 tablets (medicinal product pack) 	<ul style="list-style-type: none"> esomeprazole 20 mg tablet: enteric [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxicillin 500 mg capsule [28 capsules], 1 pack esomeprazole 20 mg tablet: enteric, 14 clarithromycin 500 mg tablet, 14 amoxicillin 500 mg capsule, 28
patch	oestradiol 100 microgram / 24 hours patch, 8 patches (medicinal product pack)	oestradiol 100 microgram/24 hours patch, 8
injection solution	<ul style="list-style-type: none"> fluphenazine decanoate 12.5 mg / 0.5 mL injection, 5 x 0.5mL ampoules (medicinal product pack) 	<ul style="list-style-type: none"> fluphenazine decanoate 12.5 mg/0.5 mL injection, 5 x 0.5 mL ampoules
injection powder with diluent	<ul style="list-style-type: none"> inert substance diluent [1 x 2 mL ampoule] (&) lanreotide 30 mg injection: modified release [1 x 30 mg vial], 1 pack (medicinal product pack) 	<ul style="list-style-type: none"> lanreotide 30 mg injection; modified release [30 mg vial] (&) inert substance diluent [2 mL ampoule], 1 pack

4.5.2 Medicinal Product Pack descriptions

4.5.2.1 Medicinal Product Pack Fully Specified Name brief definition

The Fully Specified Name of a Medicinal Product Pack 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 34: MPP FSN description

Description Component	Description
MPUU_Details	<p>The details about an individual MPUU that is contained within the MPP, including:</p> <ul style="list-style-type: none"> the list of ingredients and strengths (formatted as per MPUU FSN's "Ingredients_With_Strength" component) contained in the given MPUU component (where "MPP has MPUU"); this list is ordered alphabetically on the ingredients, followed (if necessary) by descending strength order; and the dose form of the MPUU, for prescribing, dispensing or administration, as defined for the corresponding MPUU; and optionally, the quantity and size of this MPUU in the given MPP, separated by " x " and placed inside square brackets. For example: [1 x 250 mg vial]. This detail is defined by the value and unitId fields of Unit of Use quantity reference set, and optionally the value and unitId fields of Unit of Use Size reference set. This detail will be populated only for MPPs representing multi-component products. If value field of Unit of Use quantity reference set is greater than 1, plural units description is used for the associated quantity units for example, tablets, capsules, vials; with the exception of "microgram"; 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).
Total_Quantity_Size_Details	<ul style="list-style-type: none"> This component usually includes the quantity value and units, derived from the value and unitId fields of Unit of Use quantity reference set (for example, 25 tablets). In all instances, if the value field is greater than "1", plural units description is 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 reference set.value, followed by a space, "x", followed by a space, the Unit of Use Size reference set.value followed by a space, the Unit of Use Size reference set.unitId followed by a space, and the Unit of Use quantity reference set.unitId. (for example, 5 x 2 mL vials). Note that the Unit of Use Size reference set.value and Unit of Use Size reference set.unitId are included when Unit of Use Size reference set.value is not null (e.g. 25 tablets). If the MPP has an associated subpack concept, then Total_Quantity_Size_Details is represented by the Total_Subpack_Quantity_Value (for example, 112) followed by a space, and the Total_Subpack_Quantity_Units (for example, tablets). This is then followed by the Subpack_Details, enclosed in square brackets (for example, [4 x 28 tablets]). The Subpack_Details is represented by the MPP.Subpack quantity reference set.value (for example, 4) followed by a space, " x " followed by a space, and then the result of the calculation of the Total_Subpack_Quantity_Value (for example, 112) divided by the MPP.Subpack quantity reference set.value (for example, 4), followed by a space, and then the Total_Subpack_Quantity_Units (for example, tablets). For example: 112 tablets [4 x 28 tablets] If the MPP represents a multi-component product and the MPP is a

Description Component	Description
	<p>subpack concept, then Total_Quantity_Size_Details is represented by the Total_Subpack_Quantity_Value (for example, 112) followed by a space, and the Total_Subpack_Quantity_Units (for example, tablets). For example: 112 tablets.</p> <ul style="list-style-type: none"> If the MPP represents a multi-component product which does not have an associated subpack and is not itself a subpack, then Total_Quantity_Size_Details is represented by the text " 1 pack".
(medicinal product pack)	The semantic tag used in the FSN of all Medicinal Product Pack concepts.

4.5.2.2 Medicinal Product Pack Fully Specified Name rules

Table 35: MPP FSN rules

Rule ID	Description
AMT-MPP-FSN-1	All rules in Section 3.1.4.3 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.
AMT-MPP-FSN-2	<p>The Medicinal Product Unit of Use will be derived from the intended active ingredients, as defined for MP FSN.</p> <p>EXCEPTION</p> <p>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.</p>
AMT-MPP-FSN-3	<p>Form.</p> <p>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).</p> <p>EXCEPTION</p> <p>Where the specific form is deemed therapeutically necessary to support clinical decisions at the MPUU level, the form is expressed as the specific form.</p> <p>For example a therapeutically significant form such as "tablet: modified release" would be included in the MPUU but a non-significant form such as "tablet: uncoated" would appear as the parent form of "tablet".</p>

Rule ID	Description
AMT-MPP-FSN-4	<p>Pack quantity:</p> <p>If the Pack quantity is greater than one, then the Pack quantity units will be expressed as a plural form with the exception of “microgram”. See Appendix I for appropriate Pack Quantity Units of Measure.</p> <p>If all the components have the same unit dose form, and the pack is a subpack, or contains subpacks, the pack size is the total number of unit dose forms (for example, if both components are tablets, the pack size = x tablets). For example:</p> <ul style="list-style-type: none"> Triphasil 4 month pack contains 4 x 28 tablets Pack size = 112 tablets <p>If all the components have the same unit dose form, and the pack is not a subpack, or does not contain subpacks, the pack size is “1 pack”. For example:</p> <ul style="list-style-type: none"> Actonel EC Combi contains 4 tablets + 24 tablets but it is not a subpack and does not contain subpacks Pack size = 1 pack <p>If the components are different forms will equal “1 pack”. For example:</p> <ul style="list-style-type: none"> Nexium Hp7 contains 14 tablets + 28 capsules + 14 tablets Pack size = 1 pack Canesoral Duo (1 x 150 mg capsule, 1 x 10 g cream) Pack size = 1 pack

4.5.2.3 Medicinal Product Pack Preferred Term brief definition

The Preferred Term of a Medicinal Product Pack, by default, follows the syntax:

```
MPP PT := MPUU_Details { " (& " MPUU_Details } ", "
          Total_Quantity_Size_Details
```

where the component parts are described as follows.

Table 36: MPP PT description

Description Component	Description
MPUU_Details	<p>The details about an individual MPUU that is contained within the MPP, including:</p> <ul style="list-style-type: none"> The list of ingredients and strengths (formatted as per MPUU PT's “Ingredients_With_Strength” component) contained in the given MPUU component (where MPP HAS MPUU); this list is ordered based on the associated MPP.preferred component order (if this exists – otherwise alphabetically, as per the MPP.FSN). (Note that as per Section 3.1.4.1 “preferred component order” is an additional description type which is not released in the terminology release files.) The dose form of the MPUU, for prescribing, dispensing or administration, as defined for the corresponding MPUU. Optionally, the quantity and size of this MPUU in the given MPP, placed inside square brackets. This component is defined by the value and unitId fields of Unit of Use quantity reference set, and optionally the value and unitId fields of Unit of Use Size reference set. This component will be populated only for MPPs representing multi-component products. If value field of Unit of Use quantity reference set is greater than “1”, plural units description is used for the associated quantity units for example, tablets, capsules, vials; with the exception of “microgram”. 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).

Description Component	Description
	<ul style="list-style-type: none"> For those MPUU components with manually created PTs (for example, those containing more than three active ingredients where an MP has been created manually), the MPUU's PT (without the form) will be used here instead. <p>Unit of Use quantity is only shown for multi-component MPPs.</p>
Total_Quantity_Size_Details	<ul style="list-style-type: none"> This component usually includes the quantity value and units, derived from the value and unitId fields of Unit of Use quantity reference set (for example, 25 tablets). In all instances, if the value field is greater than "1", plural units description is used for the associated quantity units, for example, tablets, capsules, vials; with the exception of "microgram". If the MPP represents a single ingredient and single component product, then Total_Quantity_Size_Details is represented by the Unit of Use quantity reference set.value, followed by a space, "x", followed by a space, the Unit of Use Size reference set.value followed by a space, the Unit of Use Size reference set.unitId followed by a space, and the Unit of Use quantity reference set.unitId. (for example, 5 x 2 mL vials). Note that the Unit of Use Size reference set.value and Unit of Use Size reference set.unitId are included when Unit of Use Size reference set.value is not null (e.g. 25 tablets). If the MPP represents a multi-component product and the MPP has an associated subpack concept, then Total_Quantity_Size_Details is represented by the Total_Subpack_Quantity_Value (for example, 112) followed by a space, and the Total_Subpack_Quantity_Units (for example, tablets). This is then followed by the Subpack_Details, enclosed in square brackets (for example, [4 x 28 tablets]). The Subpack_Details is represented by the MPP.Subpack quantity reference set.value (for example, 4) followed by a space, " x " followed by a space, and then the result of the calculation of the Total_Subpack_Quantity_Value (for example, 112) divided by the MPP.Subpack quantity reference set.value (for example, 4), followed by a space, and then the Total_Subpack_Quantity_Units (for example, tablets). Example: 112 tablets [4 x 28 tablets] If the MPP represents a multi-component product and the MPP is a subpack concept, then Total_Quantity_Size_Details is represented by the Total_Subpack_Quantity_Value (for example, 112) followed by a space, and the Total_Subpack_Quantity_Units (for example, tablets). Example: 112 tablets. If the MPP represents a multi-component product which does not have an associated subpack and is not itself a subpack, then Total_Quantity_Size_Details is represented by the text " 1 pack".

4.5.2.4 Medicinal Product Pack Preferred Term rules

Table 37: MPP PT rules

Rule ID	Description
AMT-MPP-PT-1	All rules defined in Section 3.1.4.4 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.

Rule ID	Description
AMT-MPP-PT-2	<p>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 Basis of Strength Substance (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).</p> <p>The MPP PT 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.</p>
AMT-MPP-PT-3	<p>Strength expression</p> <p>All MPP PT will include a strength expression when available. The strength expression general rules and application to specific medication forms are outlined in Appendix E.</p> <p>EXCEPTION</p> <p>There are occasions when this is not applicable. Examples of this include Calamine lotion, Vitamin B compound tablets, Aqueous cream.</p> <p>Note: The addition to the exceptions list will be reviewed on a case-by-case basis. Refer to Appendix E.</p> <p>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.1 and E.2.</p>
AMT-MPP-PT-4	<p>Form.</p> <p>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).</p> <p>EXCEPTION</p> <p>Where the specific form is deemed therapeutically necessary to support clinical decisions at the MPUU level, the form is expressed as the specific form.</p> <p>For example a therapeutically significant form such as “tablet: modified release” would be included in the MPUU but a non-significant form such as “tablet: uncoated” would appear as the parent form of “tablet”.</p>
AMT-MPP-PT-5	<p>Pack quantity:</p> <p>If the Pack quantity is greater than one, then the Pack quantity units will be expressed as a plural form with the exception of “microgram”. See Appendix I for appropriate Pack Quantity Units of Measure.</p> <p>If all the components have the same unit dose form, and the pack is a subpack, or contains subpacks, the pack size is the total number of unit dose forms (for example, if both components are tablets, the pack size = x tablets). For example:</p> <ul style="list-style-type: none"> Triphasil 4 month pack contains 4 x 28 tablets Pack size = 112 tablets <p>If all the components have the same unit dose form, and the pack is not a subpack, or does not contain subpacks, the pack size is “1 pack”. For example:</p> <ul style="list-style-type: none"> Actonel EC Combi contains 4 tablets + 24 tablets but it is not a subpack and does not contain subpacks Pack size = 1 pack <p>If the components are different forms will equal “1 pack”. For example:</p> <ul style="list-style-type: none"> Nexium Hp7 contains 14 tablets + 28 capsules + 14 tablets Pack size = 1 pack Canesoral Duo (1 x 150 mg capsule, 1 x 10 g cream) Pack size = 1 pack

4.5.2.5 Medicinal Product Pack “Preferred component order”

Definition

The MPP Preferred component order is used to define a component order other than alphabetical for the MPP PT only. The MPP FSN will always show components in alphabetical order, unless the intended active ingredient for a component is “inert substance”, in which case this component will always be shown last.

Note that as per Section 3.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 38: MPP “Preferred component order” rules

Rule ID	Description
AMT-MPP-PCO-1	This term can only be populated with positive integers.
AMT-MPP-PCO-2	This value is optional and may only be populated for multi-component MPPs.

4.5.2.6 Medicinal Product Pack “Total unit of use quantity value” definition and rules

Definition

This is the numeric value of the quantity of the Total Unit of Use units in the given MPP. This is equivalent to the pack size of the product defined by the MPP.

Note that as per Section 3.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 39: MPP “Total unit of use quantity value” rules

Rule ID	Rule
AMT-MPP-TUUQV-1	This term is only to be populated with integers or decimal numbers (for example, 6, 0.25).
AMT-MPP-TUUQV-2	This value is optional.

4.5.2.7 Medicinal Product Pack “Total subpack quantity” definition and rules

Definition

Within each pack (MPP) there may be multiple subpacks (for example, each in a container, such as a bottle, a tube, or a blister pack). These subpacks are supported by a recursive relationship between the composite pack's MPP and the subpack's MPP. This approach allows description in the model of packs at multiple levels. For example, for oral contraceptives, the top level MPP may be a box, which contains four blister subpacks, each of which contains 28 tablets (with different hormone combinations).

This is the numeric value of the quantity of the MPP, which is the Subpack (MPP.Subpack).

Note: This is based on the assumption that a pack contains multiples of the same subpack.

Note that as per Section 3.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 40: Examples of MPP “has subpack quantity” FSN and PT

Trade Product Preferred Term	Fully Specified Name	Preferred Term
Triphasil	<ul style="list-style-type: none"> ethinylloestradiol 30 microgram + levonorgestrel 125 microgram tablet [40 tablets] (&) ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet [24 tablets] (&) ethinylloestradiol 40 microgram + levonorgestrel 75 microgram tablet [20 tablets] (&) inert substance tablet [28 tablets], 112 tablets [4 x 28 tablets] (medicinal product pack) ethinylloestradiol 30 microgram + levonorgestrel 125 microgram tablet [10 tablets] (&) ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet [6 tablets] (&) ethinylloestradiol 40 microgram + levonorgestrel 75 microgram tablet [5 tablets] (&) inert substance tablet [7 tablets], 28 tablets (medicinal product pack) 	<ul style="list-style-type: none"> ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet [24] (&) ethinylloestradiol 40 microgram + levonorgestrel 75 microgram tablet [20] (&) ethinylloestradiol 30 microgram + levonorgestrel 125 microgram tablet [40] (&) inert substance tablet [28], 112 [4 x 28] ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet [6] (&) ethinylloestradiol 40 microgram + levonorgestrel 75 microgram tablet [5] (&) ethinylloestradiol 30 microgram + levonorgestrel 125 microgram tablet [10] (&) inert substance tablet [7], 28

In the above example, the MPP will have a “Total subpack quantity” description with a value of “4”. This indicates that it has four subpacks, which are defined by the MPP HAS SUBPACK MPP relationship.

Table 41: MPP “Total subpack quantity” rules

Rule ID	Rule
AMT-MPP-TSQ-1	This term can only to be populated with an integer value greater than “1”.
AMT-MPP-TSQ-2	This value is optional and may only be populated when the subpack exists or is required by the PBS.

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 42: Examples of Trade Product FSNs and PTs

Type of product	Fully Specified Name	Preferred Term
Single ingredient	Amoxil (trade product)	Amoxil
Single ingredient (generic)	Morphine Sulfate (Mayne) (trade product)	Morphine Sulfate (Mayne)
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	<ul style="list-style-type: none"> Nexium Hp7 (trade product) Nexium (trade product) Klacid (trade product) Amoxil (trade product) 	<ul style="list-style-type: none"> Nexium Hp7 Nexium Klacid Amoxil

4.6.1.1 Trade Product details

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

The following additional information will be included in the Trade Product name for both the FSN and the PT as indicated below.

Table 43: TP description

Additional Information	Include in Trade Product name	Preferred Term Example
Textual description that is logically part of the brand name	yes	Abbocillin VK
Brand name where textual description is necessary to distinguish between items in a product range	yes	Accu-Chek Advantage II Pegatron Combination Therapy

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)
Strength representation for single ingredient items where the strength representation matches the BoSS strength representation of the associated product	no	Not applicable.
Strength representation for single ingredient items where the strength representation has different units to the BoSS strength representation of the associated product	yes	Calsource Ca 1000 (Note that strength of the ingredient for this product would be represented at 1 g.)
Strength representation for multi-ingredient items	yes (only as per AMT-TP-FSN-2)	Accuretic 20/12.5
Strength representation for multi-component items	no	Not applicable.
Form where detail is equal to the AMT form	no	Not applicable.
Form where detail is not equal to the AMT form	yes	Aerius Syrup (Note that the TGA form for this product is "oral liquid: solution".)
Proprietary form	yes	Tropicamide Minims (Bausch & Lomb) Risperdal Quicklet
Proprietary delivery device	yes	Bricanyl Turbuhaler Enbrel Auto-injector
Proprietary container	yes	Atrovent UDV
Information that denotes a route of administration and the dose form of the associated product does not infer the route of administration	yes	Diffiam Anti-Inflammatory Throat Spray (Note that the dose form for this product is "spray: solution")
Information that denotes a route of administration and the dose form of the associated product infers the route of administration	no	Not applicable.
Indication	yes	Aciclovir Cold Sore (Your Pharmacy) Nurofen Migraine Pain Nurofen Period Pain Nurofen Tension Headache
Information that denotes a manufacturer's product code that is relevant at the unit of use or pack levels	no	Not applicable.

Additional Information	Include in Trade Product name	Preferred Term Example
Information that denotes a particular monograph (for example, APF, BP) the product formulation is based on	no	Not applicable.
Information that denotes a release or pharmacokinetic characteristic of the product	yes	Ritalin LA
Information that denotes a characteristic of the product that is clinically relevant	yes	Comfeel Plus Pressure Relieving

4.6.2 Trade Product descriptions

4.6.2.1 Trade Product Fully Specified Name brief definition

The Fully Specified Name of a Trade Product follows the syntax:

TP FSN := TF_Name " (trade product)"

where the component parts are described as follows.

Table 44: TP FSN description

Description Component	Description
TF_Name	<p>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 4.6.1.1.</p> <p>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.</p>
Other_Identifying_Information	<p>Additional details that are required to avoid ambiguity or duplication in the constructed description. This information should be descriptive information that is specific to the Trade Product Unit of Use (for example, "sugar free", "refill", "strawberry").</p>
Ingredient_Strength	<p>The details about an individual MPUU that is contained within the MPP, including:</p> <ul style="list-style-type: none"> the list of ingredients and strengths (formatted as per MPUU FSN's "Ingredients_With_Strength" component) contained in the given MPUU component (where "MPP has MPUU"); this list is ordered alphabetically on the ingredients, followed (if necessary) by descending strength order. The ingredients and strengths are surrounded by curved brackets; and the dose form as described below; and optionally, the quantity and size of this MPUU in the given MPP, separated by " x " and placed inside square brackets. For example: [1 x 250 mg vial]. This detail is defined by the value and unitId fields of Unit of Use quantity reference set, and optionally the value and unitId fields of Unit of Use Size reference set. This detail will be populated only for MPPs representing multi-component products. If value field of Unit of Use quantity reference set is greater than 1,

Description Component	Description
	<p>plural units description is used for the associated quantity units for example, tablets, capsules, vials; with the exception of "microgram"; and</p> <ul style="list-style-type: none"> 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).
Form	<p>This is a child form where appropriate, otherwise it is the PT of the Form (F) concept that is the destination of the MPUU HAS MANUFACTURED DOSE FORM F relationship.</p> <p>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) should be included here.</p>
Component_Details	<p>This component describes the details of each TPUU that is related to this TPP and is included for multicomponent products only.</p> <p>The component details are enclosed by curved brackets.</p> <p>One set of component details is represented for each component present.</p> <p>Plural Units of Use are used where appropriate.</p> <p>Component details are represented by the total number of Units of Use, " x ", the BoSS strength of the Unit of Use, a space, the Unit of Use.</p> <p>Specific Product Types</p> <p>If the product is a Day and Night Cold and Flu product, then the component details will be represented by "(", the total number of "Day" Units of Use, " x ", the Unit of Use for the "Day" component, ", ", the total number of "Night" Units of Use, " x ", the Unit of Use for the "Night" component, ")". For example: (18 x Day tablets, 6 x Night tablets)</p> <p>If the product is a vaccine, then the component details will be represented by "(", the total number of Units of Use for the vaccine component, " x ", the Unit of Use size, " vaccine ", the Unit of Use, ", ", the total number of units of use for the diluent component, " x ", the Unit of Use size, " diluent ", the Unit of Use, ")". For example: (1 x 10 microgram vaccine vial, 1 x 0.5 mL diluent syringe)</p> <p>Where more than one vaccine component is present, then each component is represented individually.</p>
Total_Quantity_Size_Details	<ul style="list-style-type: none"> This component usually includes the quantity value and units, derived from the value and unitId fields of Unit of Use quantity reference set (for example, 25 tablets). In all instances, if the value field is greater than "1", plural units description is 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 reference set.value, followed by a space, "x", followed by a space, the Unit of Use Size reference set.value followed by a space, the Unit of Use Size reference set.unitId followed by a space, and the Unit of Use quantity reference set.unitId. (for example, 5 x 2 mL vials).

Description Component	Description
	<p>Note that the Unit of Use Size reference set.value and Unit of Use Size reference set.unitId are included when Unit of Use Size reference set.value is not null (e.g. 25 tablets).</p> <ul style="list-style-type: none"> If the MPP has an associated subpack concept, then Total_Quantity_Size_Details is represented by the Total_Subpack_Quantity_Value (for example, 112) followed by a space, and the Total_Subpack_Quantity_Units (for example, tablets). This is then followed by the Subpack_Details, enclosed in square brackets (for example, [4 x 28 tablets]). The Subpack_Details is represented by the MPP.Subpack quantity reference set.value (for example, 4) followed by a space, " x " followed by a space, and then the result of the calculation of the Total_Subpack_Quantity_Value (for example, 112) divided by the MPP.Subpack quantity reference set.value (for example, 4), followed by a space, and then the Total_Subpack_Quantity_Units (for example, tablets). For example: 112 tablets [4 x 28 tablets] If the MPP represents a multi-component product and the MPP is a subpack concept, then Total_Quantity_Size_Details is represented by the Total_Subpack_Quantity_Value (for example, 112) followed by a space, and the Total_Subpack_Quantity_Units (for example, tablets). For example: 112 tablets. If the MPP represents a multi-component product which does not have an associated subpack and is not itself a subpack, then Total_Quantity_Size_Details is represented by the text " 1 pack".
(trade product)	The semantic tag used in the FSN of all Trade Product concepts.

4.6.2.2 Trade Product Fully Specified Name rules

Table 45: TP FSN rules

Rule ID	Description
AMT-TP-FSN-1	All rules in Section 3.1.4.3 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.
AMT-TP-FSN-2	<p>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 4.6.1.1. 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.</p> <p>Each TF_Name will consist of products with the same Medicinal Product (for example, Canesten Clotrimazole and Canesten Bifonazole will be created as two TF_Names).</p> <p>The TF_Name may differentiate between different available strengths (for example, Panadeine and Panadeine Forte).</p> <p>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).</p> <p>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).</p>

Rule ID	Description
AMT-TP-FSN-3	<p>A generic product is one in which the name of the product is a substance name or an indication for treatment.</p> <p>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 ")". For example:</p> <ul style="list-style-type: none"> • Simvastatin (GenRx) • Methotrexate (Ebewe) <p>Where a generic product name includes an abbreviation for sponsor/manufacturer/house brand name as a hyphenated suffix, the TF_Name will be populated with generic name and the TF_Supplier will be populated by a " " and the abbreviation for the sponsor/manufacturer/house brand name surrounded by "(" and ")". For example: Meloxicam (GA).</p> <p>Modified bases will only be included as part of the TF_Name where the strength of the product is expressed in terms of the modified base, that is, the modified base is the basis of strength substance. For example: Perindopril Erbumine (GenRx).</p> <p>Where a modified base is included as part of the Trade Product Name, the first letter will be uppercased.</p> <p>NOTE: This rule also applies to products that consist of a standard formulation, for example, Calamine Lotion.</p>
AMT-TP-FSN-4	<p>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 TF_Supplier will not be populated. For example: Magmin, not Magmin (Blackmores).</p>

4.6.2.3 Trade Product Preferred Term brief definition

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

TP PT := TF_Name

where the component parts are described as follows.

Table 46: TP PT description

Description Component	Description
TF_Name	<p>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 4.6.1.1.</p> <p>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.</p>

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 suffix. The ingredients shall appear in the same order in which they are referred to in the suffix, 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: uncoated, 30 is ambiguous as it is not possible to distinguish it from Coveram 10 mg/5 mg tablet: uncoated, 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)

4.6.2.4 Trade Product Preferred Term rules

Table 47: TP PT rules

Rule ID	Description
AMT-TP-PT-1	All rules defined in Section 3.1.4.4 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.
AMT-TP-PT-2	<p>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 4.6.1.1. 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.</p> <p>Each TF_Name will consist of products with the same Medicinal Product (for example, Canesten Clotrimazole and Canesten Bifonazole will be created as two TF_Names).</p> <p>The TF_Name may differentiate between different available strengths (for example, Panadeine and Panadeine Forte).</p> <p>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).</p> <p>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).</p>

Rule ID	Description
AMT-TP-PT-3	<p>A generic product is one in which the name of the product is a substance name or an indication for treatment.</p> <p>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 ")". For example:</p> <ul style="list-style-type: none"> • Simvastatin (GenRx) • Methotrexate (Ebewe) <p>Where a generic product name includes an abbreviation for sponsor/manufacturer/house brand name as a hyphenated suffix, the TF_Name will be populated with generic name and the TF_Supplier will be populated by a " " and the abbreviation for the sponsor/manufacturer/house brand name surrounded by "(" and ")". For example: Meloxicam (GA).</p> <p>Modified bases will only be included as part of the TF_Name where the strength of the product is expressed in terms of the modified base, that is, the modified base is the basis of strength substance. For example: Perindopril Erbumine (GenRx).</p> <p>Where a modified base is included as part of the Trade Product Name, the first letter will be uppercased.</p> <p>NOTE: This rule also applies to products that consist of a standard formulation, for example, Calamine Lotion.</p>

4.6.2.5 Trade Product "Proprietary form" definition and rules

Definition

The Proprietary form is a form assigned to a particular product by a manufacturer or sponsor, where the manufacturer or sponsor has copyright protection over the naming of the form.

Note that as per Section 3.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 48: TP "Proprietary form" rules

Rule ID	Description
AMT-TP-PF-1	All rules defined in Section 3.1.4.4 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.
AMT-TP-PF-2	Population of this field is optional.

4.6.2.6 Trade Product "Trade family supplier" definition and rules

Definition

The Trade family supplier is the name of the manufacturer of a product, or if a housebrand exists, then the name of the housebrand is used (for example, Terry White Chemists, Chemmart).

Note that as per Section 3.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 49: TP "Trade family supplier" rules

Rule ID	Description
AMT-TP-TFS-1	All rules defined in Section 3.1.4.4 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.
AMT-TP-TFS-2	This value is mandatory for all generic products.

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.

Note: This is the medicinal object or unit that is able to be physically handled for example, tablet, capsule, vial, ampoule or patch.

Table 50: Examples of TPUU FSNs and PTs

Type of product	Fully Specified Name	Preferred Term
Single ingredient	Amoxil (amoxycillin 500 mg) capsule: hard (trade product unit of use)	Amoxil 500 mg capsule: hard
Single ingredient – clinically relevant modified base (see Appendix B)	Voltaren (diclofenac sodium 50 mg) tablet: enteric (trade product unit of use)	Voltaren 50 mg tablet: enteric
Single ingredient – clinically significant modified base (see Appendix B)	Sodium Chloride (Baxter) (sodium chloride 9 g / 1 L) injection: solution, 1 L bag (trade product unit of use)	Sodium Chloride (Baxter) 0.9% (9 g/1 L) solution, 1 L bag
Multi-ingredient	Panadeine Forte (codeine phosphate 30 mg + paracetamol 500 mg) tablet: uncoated (trade product unit of use)	Panadeine Forte tablet: uncoated
Multi-component	<ul style="list-style-type: none"> Actonel EC Once-a-Week (risedronate sodium 35 mg) tablet: enteric (trade product unit of use) Calcium Carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg) tablet: film-coated (trade product unit of use) 	<ul style="list-style-type: none"> Actonel EC Once-a-Week 35 mg tablet: enteric Calcium Carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg) tablet: film-coated

Type of product	Fully Specified Name	Preferred Term
Multi-ingredient Multi-component	<ul style="list-style-type: none"> • Triphasil (ethinylloestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated (trade product unit of use) • Triphasil (ethinylloestradiol 40 microgram + levonorgestrel 75 microgram) tablet: sugar-coated (trade product unit of use) • Triphasil (ethinylloestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated (trade product unit of use) • Triphasil (inert substance) tablet: sugar-coated (trade product unit of use) 	<ul style="list-style-type: none"> • Triphasil (ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet) tablet: sugar-coated • Triphasil (ethinylloestradiol 40 microgram + levonorgestrel 75 microgram) tablet: sugar-coated • Triphasil (ethinylloestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated • Triphasil (inert substance) tablet: sugar-coated
Combination pack	<ul style="list-style-type: none"> • Nexium (esomeprazole 20 mg) tablet: enteric (trade product unit of use) • Klacid (clarithromycin 500 mg) tablet: film-coated (trade product unit of use) • Amoxil (amoxycillin 500 mg) capsule: hard (trade product unit of use) 	<ul style="list-style-type: none"> • Nexium 20 mg tablet: enteric • Klacid 500 mg tablet: film-coated • Amoxil 500 mg capsule: hard
patch	Estraderm (oestradiol 100 microgram / 24 hours) patch (trade product unit of use)	Estraderm 100 microgram/24 hour patch
injection solution	Modecate (fluphenazine decanoate 12.5 mg / 0.5 mL) injection: solution, 0.5 mL ampoule (trade product unit of use)	Modecate 12.5 mg/0.5 mL injection: solution, 0.5 mL ampoule
injection powder with diluent	<ul style="list-style-type: none"> • Somatuline LA (lanreotide 30 mg) injection: modified release, 30 mg vial (trade product unit of use) • Somatuline LA (inert substance) diluent, 2 mL ampoule (trade product unit of use) 	<ul style="list-style-type: none"> • Somatuline LA 30 mg injection: modified release, 30 mg vial • Somatuline LA diluent, 2 mL ampoule

Exceptions to TPUU PT descriptions

Note that a small number of TPUUs will show additional detail in the PT. This is to avoid:

- terms which may result in an incorrect expression of strength; or
- duplicate or identical PTs (which may have different conceptIds); or
- misleading terms which would be created for those units of use containing "inert substance" as the ingredient.

Exception for single ingredient products

There may be instances of a TPUU PT which would need to show the ingredient to avoid an incorrect expression of strength. For example: The calcium carbonate component (TPUU) for Actonel Combi.

TPUU FSN: Calcium Carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg)
tablet: film-coated (trade product unit of use)

TPUU PT: Calcium Carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg)
tablet: film-coated

Note that without the ingredient detail the TPUU PT would be "Calcium Carbonate (Sanofi-Aventis) 500 mg tablet: film-coated".

Exceptions for products with "inert substance" ingredients

For multi-component products in which one of the components has an intended active ingredient of "inert substance" the ingredients should be included in every component. For example the TPP PT of "Brevinor 28 day, 112 tablets [4 x 28 tablets]".

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

TPUU PT: Brevinor 28 Day (norethisterone 500 microgram + ethinyloestradiol 35 microgram) tablet: uncoated

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

TPUU PT: Brevinor 28 Day (inert substance) tablet: uncoated

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

4.7.2 Trade Product Unit of Use descriptions

4.7.2.1 Trade Product Unit of Use Fully Specified Name brief definition

The Fully Specified Name of a Trade Product Unit of Use 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 51: TPUU FSN description

Description Component	Description
TF_Name	<p>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 4.6.1.1.</p> <p>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.</p>
Other_Identifying_Information	Additional details that are required to avoid ambiguity or duplication in the constructed description. This information should be descriptive information that is specific to the Trade concept (for example, "sugar free", "refill", "strawberry").
Ingredient_Strength	An alphabetical list of the name and strength (if available) of each of the active ingredients in the TPUU, derived from the associated MPUU FSN.
Form	<p>This is a child form where appropriate, otherwise it is the PT of the Form (F) concept that is the destination of the MPUU HAS MANUFACTURED DOSE FORM F relationship.</p> <p>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) should be included here.</p>
Unit_Of_Use_Details	The Unit_Of_Use_Details are derived exactly from the associated MPUU FSN.
(trade product unit of use)	The semantic tag used in the FSN of all Trade Product Unit of Use concepts.

4.7.2.2 Trade Product Unit of Use Fully Specified Name rules

Table 52: TPUU FSN rules

Rule ID	Description
AMT-TPUU-FSN-1	All rules in Section 3.1.4.3 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.
AMT-TPUU-FSN-2	<p>Strength expression.</p> <p>The strength expression general rules and application to specific medication forms is outlined in Appendix E.</p> <p>For multi-ingredient products when the constructed description does not include a representation of strength (either trade product suffix or strength expression), then the missing details will be added to produce the description and prevent ambiguity.</p>

Rule ID	Description
AMT-TPUU-FSN-3	<p>Form</p> <p>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).</p> <p>Where the TF_Name includes a proprietary form, the corresponding form, as shown in Appendix H must be used.</p> <p>When the constructed description does not include a representation of form, then to prevent ambiguity, the missing details will always be added to produce the description; for example, "Flo Nozoil" will become "Flo Nozoil nasal spray".</p>
AMT-TPUU-FSN-4	<p>No additional name segments will be added to the constructed description.</p> <p>EXCEPTION</p> <p>In instances where the constructed description may result in ambiguity or duplication, additional details may be added in Other_Identifying_Information (for example, sugar free, refill, flavour).</p> <p>For example:</p> <ul style="list-style-type: none"> Lemsip Max Cold and Flu Blackcurrant 1 g oral liquid: powder for, 1 sachet (trade product unit of use) Dimetapp 12 Hour Refill 500 microgram / 1 mL nasal spray (trade product unit of use)

4.7.2.3 Trade Product Unit of Use Preferred Term brief definition

The Preferred Term of a Trade Product Unit of Use, 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 53: TPUU PT description

Description Component	Description
TF_Name	<p>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 4.6.1.1.</p> <p>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.</p>
Other_Identifying_Information	<p>Additional details that are required to avoid ambiguity or duplication in the constructed description. This information should be descriptive information that is specific to the Trade concept (for example, "sugar free", "refill", "strawberry").</p>

Description Component	Description
Ingredient_Strength	<p>For single ingredient products, ingredient strength (but not ingredient name) is displayed.</p> <p>For multi-ingredient products, neither ingredient strength nor ingredient name are displayed.</p> <p>EXCEPTIONS: There are a small number of exceptions to inclusion of ingredient name. Refer to Section 5.6.1.</p>
Form	<p>This is a child form where appropriate, otherwise it is the PT of the Form (F) concept that is the destination of the MPUU HAS MANUFACTURED DOSE FORM F relationship.</p> <p>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) should be included here.</p>
Unit_Of_Use_Details	The Unit_Of_Use Details are derived exactly from the associated MPUU FSN.

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 5.6.1.

4.7.2.4 Trade Product Unit of Use Preferred Term rules

Table 54: TPUU PT rules

Rule ID	Description
AMT-TPUU-PT-1	All rules defined in Section 3.1.4.4 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.
AMT-TPUU-PT-2	If the Trade Product represents different strengths then the subsequent strength expressions as defined in AMT-TPUU-PT-3 may not be populated (for example, Marcaïn 0.25% with Adrenaline 1 in 400 000).
AMT-TPUU-PT-3	<p>Strength expression.</p> <p>The TPUU PT 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.</p> <p>EXCEPTIONS</p> <p>See AMT-APP-STR-9 in Appendix E.</p> <p>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.1 and E.2.</p>
AMT-TPUU-PT-4	<p>Form</p> <p>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).</p> <p>Where the TF_Name includes a proprietary form, the corresponding form, as shown in Appendix H must be used.</p> <p>When the constructed description does not include a representation of form, then to prevent ambiguity, the missing details will ALWAYS be added to produce the description, for example, "Flo Nozoil" will become "Flo Nozoil nasal spray".</p>

Rule ID	Description
AMT-TPUU-PT-5	<p>No additional name segments will be added to the constructed description.</p> <p>EXCEPTION</p> <p>In instances where the constructed description may result in ambiguity or duplication, additional details may be added in Other_Identifying_Information (for example, sugar free, refill, flavour).</p> <p>For example:</p> <ul style="list-style-type: none"> • Lemsip Max Cold and Flu blackcurrant 1 g oral liquid: powder for, 1 sachet • Dimetapp 12 Hour refill 0.05% nasal spray

4.7.2.5 Trade Product Unit of Use “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, 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 and/or Consumer Medicine Information.

Note that as per Section 3.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 55: TPUU “Other identifying information” rules

Rule ID	Rule
AMT-TPUU-OII-1	All rules defined in Section 4.1.4.2 (Description constraints/data definitions) 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 Trade Product Pack 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 Containerised Trade Product Pack (CTPP). It may, however, imply a container type, when this information is included in the Total Quantity Size Details.

Table 56: Examples of TPP FSNs and PTs

Type of product	Fully Specified Name	Preferred Term
Single ingredient	Amoxil (amoxycillin 500 mg) capsule: hard, 20 capsules (trade product pack)	Amoxil 500 mg capsule: hard, 20
Single ingredient – clinically relevant modified base (refer to Appendix B)	Voltaren (diclofenac sodium 50 mg) tablet: enteric, 50 tablets (trade product pack)	Voltaren 50 mg tablet: enteric, 50
Single ingredient – clinically significant modified base (refer to Appendix B)	Sodium Chloride (Baxter) (sodium chloride 9 g / 1 L) injection: solution, 1 x 1 L bag (trade product pack)	Sodium Chloride (Baxter) 0.9% (9 g/1 L) injection: solution, 1 L bag
Multi-ingredient	Panadeine Forte (codeine phosphate 30 mg + paracetamol 500 mg) tablet: uncoated, 20 tablets (trade product pack)	Panadeine Forte tablet: uncoated, 20
Multi-component	Actonel EC Combi (calcium (as carbonate) 500 mg) tablet: film-coated [24 tablets] (& (risedronate sodium 35 mg) tablet: enteric [4 tablets], 1 pack (trade product pack)	Actonel EC Combi, 1 pack
Multi-ingredient Multi-component	<ul style="list-style-type: none"> Triphasil (ethinylestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated [10 tablets] (& (ethinylestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated [6 tablets] (& (ethinylestradiol 40 microgram + levonorgestrel 75 microgram) tablet: sugar-coated [5 tablets] (& (inert substance) tablet: sugar-coated [7 tablets], 28 tablets (trade product pack) Triphasil (ethinylestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated [40 tablets] (& (ethinylestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated [24 tablets] (& (ethinylestradiol 40 microgram + levonorgestrel 75 microgram) tablet: sugar-coated [20 tablets] (& (inert substance) tablet: sugar-coated [28 tablets], 112 tablets [4 x 28 tablets] (trade product pack) 	<ul style="list-style-type: none"> Triphasil, 28 tablets Triphasil, 112 tablets [4 x 28]

Type of product	Fully Specified Name	Preferred Term
Combination pack	<ul style="list-style-type: none"> Nexium Hp7 (amoxicillin 500 mg) capsule: hard [28 capsules] (&) (clarithromycin 500 mg) tablet: film-coated [14 tablets] (&) (esomeprazole 20 mg) tablet: enteric [14 tablets], 1 pack (trade product pack) Klacid (clarithromycin 500 mg) tablet: film-coated, 14 tablets (trade product pack) Amoxil (amoxicillin 500 mg) capsule: hard, 28 capsules (trade product pack) Nexium (esomeprazole 20 mg) tablet: enteric, 14 tablets (trade product pack) <p><i>Note that whilst TPPs exist for the Nexium and Amoxil components, they do not exist as stand alone products in this pack size.</i></p>	<ul style="list-style-type: none"> Nexium Hp7, 1 pack Klacid 500 mg tablet: film-coated, 14 Amoxil 500 mg capsule: hard, 28 Nexium 20 mg tablet: enteric, 14 <p><i>Note that whilst TPPs exist for the Nexium and Amoxil components, they do not exist as stand alone products in this pack size.</i></p>
patch	Estraderm (oestradiol 100 microgram / 24 hours) patch, 8 patches (trade product pack)	Estraderm 100 microgram/24 hours patch, 8
injection solution	Modecate (fluphenazine decanoate 12.5 mg / 0.5 mL) injection: solution, 5 x 0.5 mL ampoules (trade product pack)	Modecate 12.5 mg/0.5 mL injection: solution, 5 x 0.5 mL ampoules
injection powder with diluent	Somatuline LA (inert substance) diluent [1 x 2 mL ampoule] (&) (lanreotide 30 mg) injection: modified release [1 x 30 mg vial], 1 pack (trade product pack)	Somatuline LA (1 x 30 mg vial, 1 x 2 mL diluent ampoule), 1 pack

4.8.2 Trade Product Pack descriptions

4.8.2.1 Trade Product Pack Fully Specified Name brief definition

The Fully Specified Name of a Trade Product Pack follows the syntax:

TPP_FSN := TF_Name " " MPP_FSN_Details " (trade product pack)"

where the component parts are described as follows.

Table 57: TPP FSN 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 4.6.1.1. 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.
MPP_FSN_Details	This is derived from the MPP FSN but without the semantic tag. (that is, " (medicinal product pack)" is not shown).
(trade product pack)	The semantic tag used in the FSN of all Trade Product Pack concepts.

4.8.2.2 Trade Product Pack Fully Specified Name rules

Table 58: TPP FSN rules

Rule ID	Description
AMT-TPP-FSN-1	All rules in Section 3.1.4.3 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.
AMT-TPP-FSN-2	If the Trade Product represents different strengths then the following strength expressions as defined in AMT-TPP-FSN-3 may not be populated. The Trade Product 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 Trade Product will include a representation of the strength (for example, Caduet 10/10 and Caduet 5/20). Strength representation in the Trade Product may be omitted for multi-ingredient products when only one strength is currently marketed in Australia (for example, Moduretic tablets).
AMT-TPP-FSN-3	Strength expression The strength expression general rules and application to specific medication forms are outlined in Appendix E. For multi-ingredient products when the constructed description does not include a representation of strength (either trade product suffix or strength expression), then the missing details will be added to produce the description and prevent ambiguity.
AMT-TPP-FSN-4	No additional name segments will be added to the constructed description. EXCEPTION In instances where the constructed description may result in ambiguity or duplication, additional details may be added in Other_Pack_Information (for example, sugar free, refill, flavour). For example: Panadol Rapid Handipak (paracetamol 500 mg) tablet: film-coated, 20 tablets (trade product pack).

Rule ID	Description
AMT-TPP-FSN-5	<p>Pack quantity:</p> <p>If the Pack quantity is greater than one, then the Pack quantity units will be expressed as a plural form with the exception of "microgram". See Appendix I for appropriate Pack Quantity Units of Measure.</p> <p>If all the components have the same unit dose form, and the pack is a subpack, or contains subpacks, the pack size is the total number of unit dose forms (for example, if both components are tablets, the pack size = x tablets). For example:</p> <ul style="list-style-type: none"> Triphasil 4 month pack contains 4 x 28 tablets Pack size = 112 tablets <p>If all the components have the same unit dose form, and the pack is not a subpack, or does not contain subpacks, the pack size is "1 pack". For example:</p> <ul style="list-style-type: none"> Actonel EC Combi contains 4 tablets + 24 tablets but it is not a subpack and does not contain subpacks Pack size = 1 pack <p>If the components are different forms will equal "1 pack". For example:</p> <ul style="list-style-type: none"> Nexium Hp7 contains 14 tablets + 28 capsules + 14 tablets Pack size = 1 pack Canesoral Duo (1 x 150 mg capsule, 1 x 10 g cream) Pack size = 1 pack

4.8.2.3 Trade Product Pack Preferred Term brief definition

The Preferred Term of a Trade Product Pack, 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 59: TPP PT description

Description Component	Description
TF_Name	<p>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 4.6.1.1.</p> <p>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.</p>
Other_Identifying_Information	<p>Additional details that are required to avoid ambiguity or duplication in the constructed description. This information should be descriptive information that is specific to the Trade Product Unit of Use (for example, "sugar free", "refill", "strawberry").</p>
Ingredient_Strength	<p>Ingredient_Strength will be derived from the TPUU PT.</p>
Form	<p>This is only populated if the TPP has a single TPUU, or if all TPUUs in the pack have the same form.</p> <p>If populated, it is derived from the TPUU PT.</p>

Description Component	Description
Total_Quantity_Size_Details	This is derived from the Total_Quantity_Size_Details of the related MPP PT.

4.8.2.4 Trade Product Pack Preferred Term rules

Table 60: TPP PT rules

Rule ID	Description
AMT-TPP-PT-1	All rules defined in Section 3.1.4.4 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.
AMT-TPP-PT-2	If the Trade Product represents different strengths then the following strength expressions as defined in AMT-TPP-PT-3 may not be populated. The Trade Product 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 Trade Product will include a representation of the strength (for example, Caduet 10/10 and Caduet 5/20). Strength representation in the Trade Product may be omitted for multi-ingredient products when only one strength is currently marketed in Australia (for example, Moduretic tablets).
AMT-TPP-PT-3	Strength expression The strength expression general rules and application to specific medication forms is outlined 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 Appendices E.1 and E.2. For multi-ingredient products when the constructed description does not include a representation of strength (either trade product suffix or strength expression) then the missing details will be added to produce the description and prevent ambiguity. EXCEPTION Strength may be omitted for multi-ingredient products as there is no relationship visible between strength expression and intended active ingredients at this level and only one strength is currently marketed in Australia. For example: Moduretic tablets.
AMT-TPP-PT-4	FORM When the constructed description does not include a representation of form then the missing details will ALWAYS be added to produce the description and prevent ambiguity, for example, "Flo Nozoil" will become "Flo Nozoil nasal spray". EXCEPTION If the Multi-component pack contains multiple forms then form will not be included.
AMT-TPP-PT-5	No additional name segments will be added to the constructed description. EXCEPTION In instances where the constructed description may result in ambiguity or duplication, additional details may be added in Other_Pack_Information (for example, "sugar free", "refill", "flavour"). For example: Panadol Rapid Handipak 500 mg tablet: film-coated, 20 tablets.

Rule ID	Description
AMT-TPP-PT-6	<p>Pack quantity:</p> <p>If the Pack quantity is greater than one, then the Pack quantity units will be expressed as a plural form with the exception of "microgram". See Appendix I for appropriate Pack Quantity Units of Measure.</p> <p>If all the components have the same unit dose form, and the pack is a subpack, or contains subpacks, the pack size is the total number of unit dose forms (for example, if both components are tablets, the pack size = x tablets). For example:</p> <ul style="list-style-type: none"> • Triphasil 4 month pack contains 4 x 28 tablets Pack size = 112 tablets <p>If all the components have the same unit dose form, and the pack is not a subpack, or does not contain subpacks, the pack size is "1 pack". For example:</p> <ul style="list-style-type: none"> • Actonel EC Combi contains 4 tablets + 24 tablets but it is not a subpack and does not contain subpacks Pack size = 1 pack <p>If the components are different forms will equal "1 pack". For example:</p> <ul style="list-style-type: none"> • Nexium Hp7 contains 14 tablets + 28 capsules + 14 tablets Pack size = 1 pack • Canesoral Duo (1 x 150 mg capsule, 1 x 10 g cream) Pack size = 1 pack

4.8.2.5 Trade Product Pack "Other identifying information" definition and rules

Definition

The TPP "Other identifying information" allows optional descriptive information about the TPP to be displayed (for example, sugar free, refill, flavour). This information is required to avoid ambiguity or duplication in the constructed descriptions for TPP. This will be sourced from TGA data, Sponsor's Product Information and/or Consumer Medicine Information. This information appears in both the TPP FSN and the TPP PT terms.

Note that as per Section 3.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 61: TPP "Other identifying information" rules

Rule ID	Rule
AMT-TPP-OII-1	All rules defined in Section 4.1.4.2 (Description constraints/data definitions) apply.
AMT-TPP-OII-2	A TPP may not have more than one Other_Identifying_Information descriptor.
AMT-TPP-OII-3	Population of this field is optional.

4.8.2.6 Trade Product Pack “Preferred term other identifying information” definition and rules

Definition

The TPP “Preferred term other identifying information” specifies information (usually strength and pack size) only about multi-component products, where there is more than one different denomination of that multi-component product being available. This information only appears in TPP PT terms.

Note that as per Section 3.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 62: TPP “Preferred term other identifying information” rules

Rule ID	Rule
AMT-TPP-OPTII-1	All rules defined in Section 4.1.4.2 (Description constraints/data definitions) apply.
AMT-TPP-OPTII-2	A TPP may not have more than one Preferred term other identifying information descriptor.
AMT-TPP-OPTII-3	This value is populated only for multi-component TPPs.
AMT-TPP-OPTII-4	Population of this field is optional.

4.8.2.7 Trade Product Pack “Total unit of use quantity value” definition and rules

Definition

This is the numeric value of the quantity of the Total unit of use units in the given TPP. This is equivalent to the pack size of the product defined by the TPP.

Note that as per Section 3.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 63: TPP “Total unit of use quantity value” rules

Rule ID	Rule
AMT-TPP-TUUQV-1	This term is only to be populated with integers or decimal numbers (for example, 6, 0.25).
AMT-TPP-TUUQV-2	This value is optional.

4.9 Containered Trade Product Pack (CTPP)

4.9.1 Containered Trade Product Pack 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.

Table 64: Examples of Containered Trade Product Pack FSNs and PTs

Type of product	Fully Specified Name	Preferred Term
Single ingredient	Amoxil (amoxycillin 500 mg) capsule: hard, 20 capsules, blister pack (containered trade product pack)	Amoxil 500 mg capsule: hard, 20, blister pack
Single ingredient – clinically relevant modified base (refer to Appendix B)	Voltaren (diclofenac sodium 50 mg) tablet: enteric, 50 tablets, bottle (containered trade product pack)	Voltaren 50 mg tablet: enteric, 50, bottle
Single ingredient – clinically significant modified base (refer to Appendix B)	Sodium Chloride (Baxter) (sodium chloride 9 g / 1 L) injection: solution, 1 x 1 L bag, bag (containered trade product pack)	Sodium Chloride (Baxter) 0.9% (9 g/1 L) injection: solution, 1 L bag (AHB1324)
Multi-ingredient	Panadeine Forte (codeine phosphate 30 mg + paracetamol 500 mg) tablet: uncoated, 20 tablets, blister pack (containered trade product pack)	Panadeine Forte tablet: uncoated, 20, blister pack
Multi-component	<ul style="list-style-type: none"> Actonel EC Combi (calcium (as carbonate) 500 mg) tablet: film-coated [24 tablets] (& (risedronate sodium 35 mg) tablet: enteric [4 tablets], 1 pack, blister pack (containered trade product pack) 	<ul style="list-style-type: none"> Actonel EC Combi (4 x 35 mg enteric tablets, 24 x 500 mg tablets), 1 pack, blister pack
Multi-ingredient Multi-component	<ul style="list-style-type: none"> Triphasil (ethinylestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated [10 tablets] (& (ethinylestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated [6 tablets] (& (ethinylestradiol 40 microgram + levonorgestrel 75 microgram) tablet: sugar-coated [5 tablets] (& (inert substance) tablet: sugar-coated [7 tablets], 28 tablets, blister pack (containered trade product pack) Triphasil (ethinylestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated [40 tablets] (& (ethinylestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated [24 tablets] (& (ethinylestradiol 40 microgram + levonorgestrel 75 microgram) tablet: sugar-coated [20 tablets] (& (inert substance) tablet: sugar-coated [28 tablets], 112 tablets [4 x 28 tablets], blister pack 	<ul style="list-style-type: none"> Triphasil, 112 tablets [4 x 28], blister pack Triphasil, 28 tablets, blister pack

Type of product	Fully Specified Name	Preferred Term
	(containered trade product pack)	
Combination pack	<ul style="list-style-type: none"> Nexium Hp7 (amoxicillin 500 mg) capsule: hard [28 capsules] (&) (clarithromycin 500 mg) tablet: film-coated [14 tablets] (&) (esomeprazole 20 mg) tablet: enteric [14 tablets], 1 pack, composite pack (containered trade product pack) Amoxil (amoxicillin 500 mg) capsule: hard, 28 capsules, blister pack (containered trade product pack) Klacid (clarithromycin 500 mg) tablet: film-coated, 14 tablets, blister pack (containered trade product pack) Nexium (esomeprazole 20 mg) tablet: enteric, 14 tablets, blister pack (containered trade product pack) 	<ul style="list-style-type: none"> Nexium Hp7 (14 x 20 mg enteric tablets, 14 x 500 mg tablets, 28 x 500 mg capsules), 1 pack, composite pack Amoxil 500 mg capsule: hard, 28, blister pack Klacid 500 mg tablet: film-coated, 14, blister pack Nexium 20 mg tablet: enteric, 14, blister pack
patch	Estraderm (oestradiol 100 microgram / 24 hours) patch, 8 patches, sachet (containered trade product pack)	Estraderm 100 microgram/24 hours patch, 8, sachet
injection solution	Modecate (fluphenazine decanoate 12.5 mg / 0.5 mL) injection: solution, 5 x 0.5 mL ampoules (containered trade product pack)	Modecate 12.5 mg/0.5 mL injection: solution, 5 x 0.5 mL ampoules
injection powder with diluent	<ul style="list-style-type: none"> Somatuline LA (inert substance) diluent [1 x 2 mL ampoule] (&) (lanreotide 30 mg) injection: modified release [1 x 30 mg vial], 1 pack, composite pack (containered trade product pack) 	<ul style="list-style-type: none"> Somatuline LA (1 x 30 mg vial, 1 x 2 mL diluent ampoule), 1 pack, composite pack

4.9.2 Containered Trade Product Pack descriptions

4.9.2.1 Containered Trade Product Pack Fully Specified Name brief definition

The Fully Specified Name of a Containered Trade Product Pack follows the syntax:

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

where the component parts are described as follows.

Table 65: CTPP FSN description

Description Component	Description
TPP_FSN_Details	The details included in the FSN of the associated TPP, but without the semantic tag (that is, without "(trade product pack)").
Container	The PT of the container type of the CTPP, as defined by the relationship CTPP "HAS CONTAINER TYPE". If the Unit of Use exactly matches the container type, then the container type is not shown.
(containered trade product pack)	The semantic tag used in the FSN of all Containered Trade Product Pack concepts.

4.9.2.2 Containered Trade Product Pack Fully Specified Name rules

Table 66: CTPP FSN rules

Rule ID	Description
AMT-CTPP-FSN-1	All rules in Section 3.1.4.3 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.
AMT-CTPP-FSN-2	ContainerType Container type will be populated, as defined by the TGA. See Appendix J. If the Unit of Use exactly matches the container type, then the container type is not shown.

4.9.2.3 Containered Trade Product Pack Preferred Term brief definition

The Preferred Term of a Containered Trade Product Pack, by default, follows the syntax:

CTPP PT := TPP_PT_Details [", " Container]

where the component parts are described as follows.

Table 67: CTPP PT description

Description Component	Description
TPP_PT_Details	The details included in the PT of the associated TPP.
Container	The PT of the container type of the CTPP, as defined by the relationship CTPP HAS CONTAINER TYPE. If the Unit of Use exactly matches the container type, then the container type is not shown.

4.9.2.4 Containered Trade Product Pack Preferred Term rules

Table 68: CTPP PT rules

Rule ID	Description
AMT-CTPP-PT-1	All rules defined in Section 3.1.4.4 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.
AMT-CTPP-PT-2	ContainerType Container type will be populated as defined by the TGA. If the Unit of Use exactly matches the container type, then the container type is not shown.

4.9.2.5 Containered Trade Product Pack “Manufacturer’s code” definition and rules

Definition

Where a manufacturer or sponsor assigns a code to a particular product and this code appears on the product label, then this code will be included.

Note that as per Section 3.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 69: CTPP “Manufacturer’s code” rules

Rule ID	Rule
AMT-CTPP-MC-1	Exact replication of the manufacturer’s code, including casing and punctuation, should be followed.
AMT-CTPP-MC-2	The code shall be enclosed by “(” and “)”.
AMT-CTPP-MC-3	This code must be relevant to the containered trade product pack level.
AMT-CTPP-MC-4	Population of this field is optional.

4.9.2.6 Containered Trade Product Pack “Other identifying information” definition and rules

Definition

The CTPP “Other identifying information” allows optional descriptive information about the CTPP to be displayed (for example, sugar free, refill, or flavour). This information is required to avoid ambiguity or duplication in the constructed descriptions for CTPP. This will be sourced from TGA data, Sponsor’s Product Information and/or Consumer Medicine Information. This information appears in both the TPP FSN and the CTPP PT terms. Note that as per Section 3.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 70: CTPP “Other identifying information” rules

Rule ID	Rule
AMT-CTPP-OPI-1	All rules defined in Section 4.1.4.2 (Description constraints/data definitions) apply.
AMT-CTPP-OPI-2	A CTPP may not have more than one Other_Identifying_Information descriptor.
AMT-CTPP-OPI-3	Population of this field is optional.

4.9.2.7 Containered Trade Product Pack “Component container type” definition and rules

Definition

The CTPP Component container type describes the container immediately surrounding the individual component in a multi-component pack.

Note that as per Section 3.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 71: CTPP “Component container type” rules

Rule ID	Rule
AMT-CTPP-CCT-1	Container type will always be populated for each component, as defined by the TGA. See Appendix J.
AMT-CTPP-CCT-2	A CTPP may not have more than one Component container type.

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.
- Basis of Strength Substance (BoSS) 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 composite 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 medicinal substance hierarchy (for example, acamprosate calcium is a modification of acamprosate). An IS MODIFICATION OF relationship also exists to link a secondary modified base (that is, an ingredient that is further modified than the initial primary modified base) to its related primary modified base ingredient (for example, piperazine oestrone sulfate is modification of oestrone sulfate sodium).

Table 72: Examples of Substance FSNs and PTs

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

5.1.2 Substance descriptions

5.1.2.1 Substance Fully Specified Name definition

The Fully Specified Name of a Substance follows the syntax:

SUB FSN := Ingredient_Name " (AU substance)"

where the component parts are described as follows.

Table 73: 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.

5.1.2.2 Substance Fully Specified Name rules

Table 74: Substance FSN rules

Rule ID	Description
AMT-SUB-FSN-1	All rules in Section 3.1.4.3 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.
AMT-SUB-FSN-2	The substance FSN will be derived from the Australian Approved Name (AAN) ⁹ , followed by other approved or clinically intuitive names as specified in the <i>TGA Approved Terminology for Medicines</i> [13]. The base form of the substance as well as the modification will be represented. EXCEPTION This may, however, differ to meet requirements of clinical practice. 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: <ul style="list-style-type: none">• bovine• equine• fruit• human• human-bovine• husk• leaf• porcine• root Additions to the exceptions list will be reviewed on a case-by-case basis.

5.1.2.3 Substance Preferred Term definition

The Preferred Term of a Substance follows the syntax:

SUB PT := Ingredient_Name

where the component parts are described as follows.

⁹ See: www.tga.gov.au/pdf/medicines-approved-terminology.pdf.

Table 75: Substance PT description

Description Component	Description
Ingredient_Name	The name of the substance.

5.1.2.4 Substance Preferred Term rules

Table 76: Substance PT rules

Rule ID	Description
AMT-SUB-PT-1	All rules defined in Section 3.1.4.4 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A apply.
AMT-SUB-PT-2	The substance PT will be derived from the Australian Approved Name (AAN) ¹⁰ , followed by other approved or clinically intuitive names 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 meet requirements of clinical practice. 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: <ul style="list-style-type: none"> • bovine • equine • fruit • human • human-bovine • husk • leaf • porcine • root Additions to the exceptions list will be reviewed on a case-by-case basis.

¹⁰ See: www.tga.gov.au/pdf/medicines-approved-terminology.pdf.

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 77: Australian Qualifier concepts

Concept Name	Definition	Source of Data
Container Type (CT)	This qualifier concept defines the type of containers that immediately cover the medicine. It does not include an article intended for ingestion. Examples include ampoule, bottle, blister pack, vial and so on.	The name is derived from the TGA Approved Terminology for Medicines.
Form (F)	<p>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.</p> <p>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: suspension, which is reconstituted from the manufactured dose form of powder for reconstitution.)</p> <p>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.</p>	The form name is derived from the Dosage Forms specified in the TGA Approved Terminology for Medicines. Where possible, dosage forms will be drawn from this TGA list, however, additional dosage forms may be defined to meet the requirements of clinical practice.
Unit of Measure (UOM)	<p>Unit of Measure is used to describe the units used to measure various quantities within the AMT. Units of Measure are used to describe the following:</p> <ul style="list-style-type: none"> • Base form strength numerator units • Base form strength denominator units • Proportion units (see Appendix F.4) • Salt form strength numerator units • Salt form strength denominator units • Unit of Use quantity units • Unit of Use Size units 	This data is sourced from the TGA.

Concept Name	Definition	Source of Data
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).	The Unit of Use name is derived from the Dosage Forms and Container Types specified in Chapter 5 of the <i>TGA Approved Terminology for Medicines</i> [13]. Where possible, Unit of Use names will be drawn from these TGA lists, however, additional Unit of Use names may be defined to meet the requirements of clinical practice.

Table 78: Examples of Australian Qualifier concepts

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

6.2 Australian Qualifier descriptions

6.2.1 Australian Qualifier Fully Specified Name definition and rules

Definition

The Fully Specified Name of an Australian Qualifier follows the syntax:

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

where the component parts are described as follows.

Table 79: 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.

Rules

Rule ID	Description
AMT-AQ-FSN-1	All rules defined in Section 3.1.4.3 (Fully Specified Name Definition and Rules) apply.

6.2.2 Australian Qualifier Preferred Term definition and rules

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 80: Australian Qualifier PT description

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

Table 81: Australian Qualifier PT rules

Rule ID	Description
AMT-AQ-PT-1	All rules defined in Section 3.1.4.4 (Preferred Term definition and Rules) apply.
AMT-AQ-PT-2	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.

6.3 Plural name description

Definition

The plural name used when the value of the unit of measure is greater than one.

Note that as per Section 3.1.4.1, this is an additional description type which is not released in the terminology release files.

7 SNOMED CT Model Component hierarchy

The *SNOMED CT Model Component* hierarchy in the AMT contains various metadata concepts including those that define the allowed values for concept enumerations supporting the RF2 release file format; concepts that support the reference set extensibility mechanism and the AMT concept model.

The metadata hierarchy is consistent with that of SNOMED CT-AU. Therefore it also contains metadata concepts specific to SNOMED CT, such as those supporting the SNOMED CT concept model.

The current sub-hierarchies of *SNOMED CT Model Component* are:

- |900000000000442005 *Core metadata concept*|
- |900000000000454005 *Foundation metadata concept*|
- |106237007 *Linkage concept*|

For further details of the concepts within the *SNOMED CT Model Component hierarchy*, refer to the *SNOMED CT Technical Implementation Guide* [12].

7.1 Core metadata concept

This sub-hierarchy contains metadata concepts that define the allowed values for concept enumerations supporting the RF2 release file format.

This hierarchy has seven sub-hierarchies:

- *Case significance*
- *Characteristic type*
- *Definition status*
- *Description type*
- *Identifier scheme*
- *Modifier*
- *Module*

Examples of the various types of concepts contained in these sub-hierarchies are: *Case insensitive*, *Case sensitive*, *Defining characteristic type*, *Defined*, *Primitive*, *Fully specified name*, *Synonym*, *SNOMED CT integer ID*, *SNOMED CT UUID*, *Australian Medicines Terminology module* and *SNOMED Clinical Terms Australian Extension*.

7.2 Foundation metadata concept

This sub-hierarchy contains metadata concepts that define types of reference sets, specific reference sets that support the AMT model and attributes for reference set fields.

This hierarchy has two sub-hierarchies:

- *Reference set*
- *Reference set attribute*

Examples of concepts within the *Reference set* sub-hierarchy are: *Annotation type*, *Association type*, *Attribute value type*, *Concrete domain type*, *Language type*, *Medicinal product reference set*, *Trade product unit of use reference set*, *Strength reference set* and *Australian English language reference set*.

Examples of concepts within the *Reference set attribute* sub-hierarchy are *Acceptability*, *Attribute type*, *Attribute value*, *Description format* and *Operator id value*.

7.3 Linkage concept

This sub-hierarchy contains metadata concepts that define the AMT and SNOMED CT concept models.

This hierarchy has two sub-hierarchies:

- *Attribute*
- *Link assertion*

Examples of concepts within the *Attribute* sub-hierarchy are: *CONCEPT HISTORY ATTRIBUTE*, *MOVED FROM*, *REPLACED BY*, *WAS A*, *HAS AUSTRALIAN BoSS*, *HAS COMPONENT PACK*, *HAS CONTAINER TYPE*, *HAS DOSE FORM*, *HAS INTENDED ACTIVE INGREDIENT*, *HAS SUBPACK* and *HAS UNIT OF USE*.

Examples of concepts within the *Link assertion* sub-hierarchy are *Has explanation*, *Has reason* and *Is manifestation of*.

Appendix A Capitalisation

Table 82: 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	<p>Trade Product names will have each word in the name expressed as title case, including the form, where it appears as part of the TF_Name or TF_Suffix (for example, Dimetapp Chesty Cough Elixir).</p> <p>Individual words which appear as all upper or all lower cased will be title cased (for example, Ganfort not GANFORT, Elevit not elevit).</p> <p>Each word in a hyphenated name will be expressed as title case (for example, Duro-Tuss, Anti-Inflammatory).</p> <p>EXCEPTIONS</p> <p>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).</p> <p>Articles such as "the" will be in lower case.</p> <p>Conjunctions such as "and" and prepositions such as "with" will be in lower case.</p> <p>Certain words, such as "plus" may be either in title case or lower case, depending on their use (for example, Coversyl Plus, Day plus Night).</p>
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)).
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	Scientific names used to describe an organism will be expressed in full, using title case for the first word of the name, according to convention (for example, Haemophilus influenzae).
AMT-APP-CAP-8	<p>Organic chemical names.</p> <p>Each name will be expressed in lower case and will have any digits or single letters preceded and/or followed (as appropriate) immediately by a hyphen with no space (for example, methyl-2-methoxy-3-pyrazine).</p> <p>Chemical ring position will always be expressed in lower case (for example, ortho-dichlorobenzene, para-dichlorobenzene).</p> <p>Isomeric prefixes D, L, S, R, E or Z will be indicated using a capital letter followed by a hyphen. The name of the entity itself will be entirely in lower case. Where a name is broken up using descriptors, the entity names are in lower case (for example, D-alpha tocopherol, L-lysine, N-acetyl, 2-methyl, N-acetyl-L-cysteine).</p> <p>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).</p> <p>Greek letters will be expressed as the actual English spelling of the word rather</p>

Rule ID	Description
	than using the traditional Greek symbol (for example, “alpha” and not “α”).
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.)
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.)

Appendix B Exception examples for MP and MPUU

As previously described in Section 5.2.1 (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 Medicinal Product name will consist of the base name with modification, where it is deemed to be discernibly therapeutically different from the base.

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, hexamine 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).

Modifications to the following bases may be considered:

- erythromycin
- fluorometholone
- heparin
- hyoscine
- norethisterone
- orphenadrine

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.

Examples include:

- doxorubicin, pegylated liposomal

Current exception examples include:

- amphotericin B liposomal
- atropine sulfate
- dexamethasone acetate
- diltiazem malate
- erythromycin ethylsuccinate
- erythromycin lactobionate
- fluorometholone acetate
- haloperidol decanoate
- hyoscine butylbromide
- hyoscine hydrobromide
- lithium carbonate
- lithium chloride
- norethisterone acetate

- oestrone sulfate sodium
- paclitaxel nanoparticle albumin bound
- prednisolone acetate
- prednisolone hexanoate
- prednisolone sodium phosphate
- zuclopenthixol acetate
- zuclopenthixol decanoate

(Note that this list contains examples only and is not definitive.)

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* [14] 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
- ethacrynic 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 Clinically significant portion of ingredient name

Ingredients shall have the order of their name changed where necessary, so that the clinically significant part of the modified base name is represented first.

For ingredients which contribute a different active moiety in different products (that is, a different portion of the moiety may be considered to be the base in different products) the order of the name will be represented with the portion of the most commonly used base first. For example "potassium bicarbonate" would always be assigned an ingredient name of "potassium bicarbonate" and an active moiety of "potassium", based on the assertion that it is more commonly used for its potassium content than for its bicarbonate content. The ingredient name would not change to "bicarbonate potassium" even when the ingredient is present to provide bicarbonate.

The table below shows some examples only, and is not considered to be exhaustive.

Table 83: Examples of clinically significant portions of ingredient names

TGA Ingredient Name	AMT Ingredient Name
calcium folinate	folinate calcium
disodium etidronate	etidronate disodium
disodium pamidronate	pamidronate disodium
potassium clavulanate	clavulanate potassium
sodium citrate	citrate sodium
sodium clodronate	clodronate sodium
sodium cromoglycate	cromoglycate sodium
sodium fusidate	fusidate sodium

TGA Ingredient Name	AMT Ingredient Name
sodium valproate	valproate sodium

In some instances it may not be appropriate for the portions of the ingredient name to be changed. For example “shark cartilage” would not have the name order changed to “cartilage shark”.

C.3 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 84: Examples of clinically significant portions of ingredient names

Ingredient Name	Base	IngredientMinusBase
ferric pyrophosphate	iron	ferric pyrophosphate
ferrous fumarate	iron	ferrous fumarate
piperazine oestrone sulfate	oestrone	piperazine sulfate

C.4 Waters of hydration

Waters of hydration shall only be expressed for each ingredient in the Fully Specified Name 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.

Example:

MP FSN: atropine sulfate monohydrate (medicinal product)

MP PT: atropine sulfate

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

MPUU PT: atropine sulfate 600 microgram tablet

C.5 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.6 Medicinal Product Preferred Term sequence of ingredients

Ingredients will be sequenced in alphabetical order within the FSN.

For multi-ingredient products, the order of the ingredients in the PT will be based on the order used by the innovator product. All subsequent products with the same combination of ingredients will follow the order of the innovator product.

C.7 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 AMT. These names are used only in the PT and where used, the relevant strength (where it would normally be present) is omitted.

Table 85 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
brown snake (<i>Pseudonaja textilis</i>) antivenom + death adder (<i>Acanthophis antarcticus</i>) antivenom + king brown snake (<i>Pseudechis australis</i>) antivenom + taipan snake (<i>Oxyuranus scutellatus</i>) antivenom + tiger snake (<i>Notechis scutatus</i>) antivenom (medicinal product)	polyvalent Australian snake antivenom
poliomyelitis virus type 1 (Sabin strain (LS-c, 2ab)) live attenuated oral vaccine + poliomyelitis virus type 2 (Sabin strain (P712, Ch, 2ab)) live attenuated oral vaccine + poliomyelitis virus type 3 (Sabin strain (Leon 12a1b)) live oral attenuated vaccine (medicinal product)	poliomyelitis live attenuated oral vaccine
pneumococcal (<i>Streptococcus pneumoniae</i>) polysaccharide conjugate (serotype 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, 23F) vaccine (medicinal product)	pneumococcal 10 valent polysaccharide conjugate vaccine

C.7.1 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 virus vaccine 2014 injection, 0.5 mL syringe

C.7.2 Example: antivenom injection

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

C.7.3 Example: oral vaccine

FSN	poliomyelitis virus type 1 (Sabin strain (LS-c, 2ab)) live attenuated oral vaccine 1000000 CCID50 units + poliomyelitis virus type 2 (Sabin strain (P712, Ch, 2ab)) live attenuated oral vaccine 100000 CCID50 units + poliomyelitis virus type 3 (Sabin strain (Leon 12a1b)) live attenuated oral vaccine 600000 CCID50 units oral liquid, 1 vial (medicinal product unit of use)
PT	poliomyelitis virus type 1 (Sabin strain (LS-c, 2ab)) live attenuated oral vaccine 1000000 CCID50 units + poliomyelitis virus type 2 (Sabin strain (P712, Ch, 2ab)) live attenuated oral vaccine 100000 CCID50 units + poliomyelitis virus type 3 (Sabin strain (Leon 12a1b)) live attenuated oral vaccine 600000 CCID50 units oral liquid, 1 vial
PT using intuitive ingredient name	poliomyelitis live attenuated oral vaccine oral liquid, 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 86: 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	(parenteral nutrition solutions)
cobicistat + elvitegravir + emtricitabine + tenofovir disoproxil fumarate	Stribild

Appendix E General strength formats

Table 87: General strength format rules

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 Strength reference set details, refer to the *AMT v3 Technical Implementation Guide* [6].

Table 88: General strength format rules

Rule ID	Description
AMT-APP-STR-1	Strength is to be expressed in accordance with the requirements stipulated by the <i>General requirements for labels for medicines</i> [15].
AMT-APP-STR-2	The strength units will be consistent with the <i>Unit of Measure</i> .
AMT-APP-STR-3	Note that any overage contained in the product to allow the formulated amount to be administered is not specified.
AMT-APP-STR-4	<p>In general, the strength of an active ingredient should be expressed by a number between 1 and 999 metric units.</p> <p>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).</p> <p>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).</p> <p>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.</p> <p>Where the Trade name or suffix 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) tablet: modified release, 1 tablet (trade product unit of use)).</p> <p>EXCEPTIONS</p> <p>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:</p> <ul style="list-style-type: none"> • fentanyl will always be expressed as micrograms, for example, fentanyl 1600 microgram lozenge. <p>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).</p> <p>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 international units/0.5 mL injection, syringe.</p> <p>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.</p> <p>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.</p>

Rule ID	Description
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.
AMT-APP-STR-6	Strength units of measure will be expressed as singular if the value is less than or equal to unity, and will be expressed as plural if the value is greater than unity. 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.
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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ◦ 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: <ul style="list-style-type: none"> ◦ 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. For example: BCG Vaccine (Sanofi Pasteur) (Bacillus Calmette and Guerin (Connaught strain) live attenuated vaccine 8 to 32 x 10 ⁶ CFU) injection: powder for, vial.
AMT-APP-STR-11	Where the strength or volume of a product is expressed with a lower limit only (that is, contains not less than, contains equal to or greater than, more than) the strength or volume will be expressed with the word “minimum” followed by the relevant strength or volume. For example: Meruvax II (rubella virus live attenuated vaccine minimum 1000 TCID ₅₀ units) injection: powder for, vial.
AMT-APP-STR-12	The percentage strength of a product, where included as defined in Appendix F.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 89: Examples of exceptions and associated rules for strength expressions

Medication Form	Rules
Solid unit dose forms – For example: tablets, capsules, pessaries, suppositories, urethral stick, lozenge, pastille, chewing gum	Strength is to be expressed as the amount per unit dose form. For example: amoxicillin 500 mg capsule; fentanyl 400 microgram lozenge
Liquid unit dose forms – 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. For example: gentamicin 80 mg/2 mL injection: solution. 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. For example: water for injection 10 mL injection: solution.
Liquid unit dose forms – 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. For example: insulin aspart 100 units/mL injection: solution.
Liquid unit dose forms – For example: large volume injections for electrolyte replacement, nutritional therapy, plasma volume expander, and so on.	For the Preferred Term, strength will be expressed as a percentage. For example: sodium chloride 0.9% infusion. Note that for large volume parenteral preparations, the strength will be expressed as the amount of ingredient in the total volume.
Liquid unit dose forms – others For example: sachets of liquid	Strength is to be expressed as the amount of drug per mL. For example: chlorhexidine gluconate 1.2 mg/mL sachet.
Continuous solid unit doses – granules, powder	Granules, powder Strength is to be expressed as the weight of the active ingredient. For example: sodium bicarbonate 1.76 g sachet.
Continuous semi-solid preparations – 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. For example: aciclovir 5% 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.

Medication Form	Rules
Continuous liquid preparations – other than for ingestion – For example: mouthwash, paints, eye drops, ear drops, nasal drops	Strength is to be expressed as weight or volume per gram and/or mL (or other weight or volume of the product as appropriate). For example: gentamicin 0.3% (3 mg/mL) eye drops. If a product is applied locally and is intended to have a local effect then a single strength as % should be displayed. For example: chlorhexidine gluconate 0.2% mouthwash 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.
Continuous liquid preparations – for ingestion – 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. For example: erythromycin 200 mg/5 mL oral liquid; cyclosporin 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. For example: amoxycillin 250 mg/5 mL oral liquid: powder for.
Continuous solid preparations – granules, powders	Strength will usually be expressed as weight per weight or weight per volume. For example: psyllium husk powder 535 mg/g powder: oral.
Patches	Strength will be expressed as the amount of active drug released over a stated time. For example: oestradiol 25 microgram/24 hours patch.
Inhalers and sprays – 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. For example: beclomethasone 50 microgram/actuation inhalation: powder for. Other inhalers: The strength is expressed as per mL or per mg, whichever is appropriate to the form of the inhaler.
Implants	The strength is expressed either as the amount per implant or device. For example: oestradiol 20 mg implant.
Dry powder injections	The strength is expressed as the amount per vial (usually as a weight). For example: amoxycillin 500 mg injection: powder for.

E.2 Dual representation

Dual representation of strength will be considered to meet clinical requirements. Examples of items where this may be used include:

- adrenaline for parenteral use, for example, adrenaline 1 in 1000 (1 mg/mL) injection, ampoules.
- parenteral solutions containing electrolytes – the number of mmol of electrolytes will be stated as well as the amount of the modified base (where possible).
- eye drops, creams and ointments – the percentage of active ingredient may be stated as well as the amount of active ingredient per unit measure. Note that dual representation is only used according to the above rules in Table 87.

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

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 90: Units of Measure rules

Rule ID	Rule
AMT-APP-UOM-1	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	<ul style="list-style-type: none"> 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). If the value is less than one millilitre do not convert. If the value is less than one micromole do not convert.

F.2 Preferred Terms

AMT Preferred Terms will not state the descriptor for units of measure where the measure is International unit, pressor unit or Kallikrein Inactivator units. These are expressed in the PT as "units". All other Preferred Term units of measure are represented with the same description as the Fully Specified Name.

Table 91: Examples of Preferred Terms

Fully Specified Name	Preferred Term
international units	units
kallikrein inactivator units	units
pressor units	units

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.

Table 92: Area

Description	Abbreviation
square centimetre unit	square cm

Table 93: Biological units

Description	Abbreviation
antigen unit	antigen unit
anti-Xa international unit	anti-Xa international 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
unit	unit

Table 94: Mass

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

Table 95: Microbiological cultures

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

Table 96: Time

Description	Abbreviation
hour unit	hour

Table 97: Type of International Units

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

Table 98: Type of Pharmacopoeial Units

Description	Abbreviation
British Pharmacopoeial unit	BP unit

Table 99: Volume

Description	Abbreviation
litre unit	L
millilitre unit	mL

Table 100: Radiation Activity Units

Description	Abbreviation
kilobecquerel unit	kilobecquerel unit

Table 101: Miscellaneous Units

Description	Abbreviation
each unit	each
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.

Table 102: Proportions

Description	Unit/Proportion
antigen unit per millilitre unit	antigen unit/mL
anti-Xa international unit per millilitre unit	anti-Xa international unit/mL
billion organisms per each unit	billion organisms/each
billion vibrios per each unit	billion vibrios/each
British Pharmacopoeial unit per each unit	BP unit/each
cell culture infectious dose 50% unit per each unit	CCID50 unit/each

Description	Unit/Proportion
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
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 hour 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
mouse lethal dose 50% unit per each unit	MLD 50 unit/each
percentage per each unit	%/each

Description	Unit/Proportion
plaque forming unit per each unit	PFU/each
tissue culture infectious dose 50% unit per each unit	TCID50 unit/each
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 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
- inhaler
- 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, 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 at the start of the relevant entries. The general term for the dosage form is in capitals. 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) injection: intraocular, injection: intrathecal, nasal cream, paste: oromucosal

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

Table 103: Examples of Forms

Fully Specified Name	Description	Preferred Term
application	A liquid or semi-liquid preparation containing one or more active ingredients intended for application to the skin.	application
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	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	A bandage made up of four layers.	bandage: four layer
bandage: high stretch	A bandage which has a high degree of stretch.	bandage: high stretch
bandage: large D/E size	A bandage available in a large D/E size.	bandage: large D/E size
bandage: large limb size	A bandage available in a large limb size.	bandage: large limb size
bandage: large size	A bandage available in a large size.	bandage: large size
bandage: lightweight	A bandage available in a light weight.	bandage: lightweight
bandage: medium C/D size	A bandage available in a medium C/D size.	bandage: medium C/D size
bandage: medium limb size	A bandage available in a medium limb size.	bandage: medium limb size

Fully Specified Name	Description	Preferred Term
bandage: medium size	A bandage available in a medium size.	bandage: medium size
bandage: short stretch	A bandage which has a short degree of stretch.	bandage: short stretch
bandage: small B/C size	A bandage available in a small B/C size.	bandage: small B/C size
bandage: small limb size	A bandage available in a small limb size.	bandage: small limb size
bandage: small size	A bandage available in a small size.	bandage: small size
bandage: straight	A bandage available in a straight length.	bandage: straight
bandage: triangular	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.	bandage: triangular
bandage: two layer	A bandage made up of two layers.	bandage: two layer
bandage: XX/large size	A bandage available in an XX/large size.	bandage: XX/large size
bar	A solid preparation containing one or more active ingredients in bar form.	bar
bar: soap	A solid preparation derived from the action of a solution of alkali on fats or oils of animal or vegetable origin and containing one or more active ingredients in bar form.	bar: soap
block	A solid (food) substance usually chocolate, serving as a vehicle for one or more active ingredients.	block
CAPSULE	A solid preparation with hard or soft shell, of variable shape and capacity, usually containing a single dose of active ingredient(s).	
capsule	A solid preparation with hard or soft shell, of variable shape and capacity, usually containing a single dose of active ingredient(s).	capsule
capsule: enteric	A capsule prepared in such a manner that the shell, or the pelletised contents, resists the action of the gastric fluid but is attacked by the intestinal fluid to release the contents.	capsule: enteric-coated
capsule: hard	A capsule with a hard shell consisting of two prefabricated cylindrical sections one of which fits over the other. The active ingredients are usually in solid form.	capsule: hard
capsule: modified release	A capsule in which the rate or place of release of the active ingredients in the gastrointestinal tract has been modified.	capsule: modified release
capsule: soft	A capsule, the contents of which are liquid or semi-liquid. The shells are usually thicker than those of hard capsules and consist of a single part.	capsule: soft

Fully Specified Name	Description	Preferred Term
collodion	A liquid preparation usually containing pyroxylin and one or more active substances in a mixture of volatile solvents, usually ether and ethanol, intended for application to the skin. When allowed to dry, a flexible film is formed at the site of application.	collodion
conditioner	A liquid solution, cream or emulsion that is generally applied to wet hair, head and/or scalp areas. It is massaged in and may be left in for a period of time before being rinsed out.	conditioner
cream	A homogeneous, viscous or semi-solid preparation, usually an emulsion, consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable base.	cream
cream: modified	A homogeneous, viscous or semi-solid preparation, usually an emulsion, consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable base, with a formula that has been modified from the standard formula to provide additional therapeutic benefits.	cream: modified
diluent	A single substance or preparation usually in liquid form, supplied individually or as part of a composite pack, intended to be mixed with one or more specified active ingredients before administration to produce required dosage form.	diluent
DRESSING	A clean or sterile covering applied directly to a wound or diseased tissue.	
dressing	A clean or sterile covering applied directly to a wound or diseased tissue.	dressing
dressing: hydroactive	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.	dressing: hydroactive
dressing: island	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.	dressing: island
dressing: medicated	A dressing containing one or more active ingredients.	dressing: medicated
dressing: sacral	A dressing intended to be applied directly to the sacral area.	dressing: sacral
dressing: tulle	A dressing composed of a soft fine weave or net which is generally non-adherent.	dressing: tulle
DRUG DELIVERY SYSTEM	A system containing active ingredients for releasing or targeting these ingredients to the body at a constant rate over a period of time.	
drug delivery system	A system containing active ingredients for releasing or targeting these ingredients to the body at a constant rate over a period of time.	drug delivery system

Fully Specified Name	Description	Preferred Term
drug delivery system: intrauterine	A system containing active ingredients for release of these ingredients in the uterus at constant rate over a long period of time.	drug delivery system: intrauterine
drug delivery system: vaginal	A system containing active ingredients for release of these ingredients in the vagina at a constant rate over a period of time.	drug delivery system: vaginal
EAR DROPS	A suspension, emulsion or solution of one or more active ingredients in a vehicle suitable for instillation into the aural canal.	
ear drops	A suspension, emulsion or solution of one or more active ingredients in a vehicle suitable for instillation into the aural canal.	ear drops
ear drops: solution	A liquid preparation composed of or containing one or more active ingredients dissolved in a suitable vehicle.	ear drops: solution
ear drops: suspension	A liquid preparation containing one or more active ingredients dispersed as solid particles throughout a liquid phase. In addition it may contain other active ingredients which are dissolved. It is intended for instillation into the ear.	ear drops: suspension
enema	A liquid preparation composed of, or containing, one or more active ingredients for rectal administration.	enema
eye and ear	A dose form intended for use via either the ophthalmic/eye route or otic/ear route.	eye and ear
eye and ear drops	A sterile solution, suspension or emulsion of one or more active ingredients intended for instillation into the conjunctival sac or aural canal. (Also see separate headings for EYE DROPS, EAR DROPS).	eye/ear drops
EYE DROPS	A sterile solution, suspension or emulsion of one or more active ingredients intended for instillation into the conjunctival sac.	
eye drops	A sterile solution, suspension or emulsion of one or more active ingredients intended for instillation into the conjunctival sac.	eye drops
eye drops: solution	A liquid preparation composed of or containing one or more active ingredients dissolved in a suitable vehicle.	eye drops: solution
eye drops: suspension	A liquid preparation containing one or more active ingredients dispersed as solid particles throughout a liquid phase. In addition it may contain other active ingredients which are dissolved. It is intended for instillation into the eye.	eye drops: suspension
eye gel	A semi-solid preparation usually consisting of a solution or dispersion in a suitable base, prepared with the aid of a suitable gelling agent, intended for application to the conjunctiva.	eye gel
eye ointment	A sterile semi-solid preparation of homogeneous appearance intended for application to the conjunctiva. It may contain one or more active ingredients dissolved or dispersed in a suitable base.	eye ointment
eye pad	A pad used specifically for the eye area.	eye pad

Fully Specified Name	Description	Preferred Term
eye solution	A liquid preparation composed of, or containing, one or more active substances dissolved in a suitable vehicle used specifically for the eye and eye area.	eye solution
eye spray	A liquid preparation for application after dispersion with a spraying device, intended for use on the eyelid or in the eye area.	eye spray
eye strip	A strip made from paper or other material, impregnated with one or more active ingredients, which is moistened and used by gently stroking the impregnated end across the conjunctiva.	eye strip
FILM	A thin flat flexible solid preparation containing one or more active ingredients. It is usually intended to disintegrate or dissolve rapidly in contact with body fluids.	
film	A thin flat flexible solid preparation containing one or more active ingredients. It is usually intended to disintegrate or dissolve rapidly in contact with body fluids.	film
film: sublingual	A thin flat flexible solid preparation containing one or more active ingredients. It is intended to disintegrate or dissolve rapidly when placed under the tongue.	film: sublingual
foam	A dispersion of gas in a liquid or solid creating a semi-solid substance.	foam
foam dressing	A soft, open cell hydrophobic and hydrophilic dressing for exuding wounds that is absorbent and nonadherent and can take the shape of the wound cavity and which may consist of single or multiple layers.	foam dressing
gas	An aeriform fluid possessing complete molecular mobility and the property of infinite expansion.	gas
gas: medicinal	A gas for therapeutic use.	gas: medicinal
GEL	A semi-solid preparation usually consisting of a solution or dispersion in a suitable base, prepared with the aid of a suitable gelling agent.	
gel	A semi-solid preparation usually consisting of a solution or dispersion in a suitable base, prepared with the aid of a suitable gelling agent.	gel
gel: intestinal	A semi-solid preparation usually consisting of a solution or dispersion in a suitable base, prepared with the aid of a suitable gelling agent, intended to be administered directly into the gastrointestinal tract.	gel: intestinal
gel: modified	A semi-solid preparation usually consisting of a solution or dispersion in a suitable base, prepared with the aid of a suitable gelling agent with a formula that has been modified from the standard formula to provide additional therapeutic benefits.	gel: modified
GLOVE	A sterile or clean fitted covering for the hands, usually with a separate sheath for each finger and thumb.	
glove	A sterile or clean fitted covering for the hands, usually with a separate sheath for each finger and thumb.	glove

Fully Specified Name	Description	Preferred Term
glove: large	A sterile or clean fitted covering for the hands, usually with a separate sheath for each finger and thumb, available in a large size.	glove: large
glove: medium	A sterile or clean fitted covering for the hands, usually with a separate sheath for each finger and thumb, available in a medium size.	glove: medium
glove: small	A sterile or clean fitted covering for the hands, usually with a separate sheath for each finger and thumb, available in a small size.	glove: small
GRANULES	A preparation of one or more active ingredients usually in the form of irregular particles 2mm to 4mm in diameter. Some granules are intended to be dissolved or dispersed in water before issuing or before taking; others are chewed or placed on the tongue and swallowed with a draught of water.	
granules	A preparation of one or more active ingredients usually in the form of irregular particles 2mm to 4mm in diameter. Some granules are intended to be dissolved or dispersed in water before issuing or before taking; others are chewed or placed on the tongue and swallowed with a draught of water.	granules
granules: effervescent	Granules which evolve carbon dioxide when added to water. They are intended to be dissolved or dispersed in water before administration.	granules: effervescent
granules: enteric	Granules which resist the action of gastric fluid but are attacked by intestinal fluid to release the active ingredients.	granules: enteric
granules: modified release	Granules in which the rate or place of release of active ingredients in the gastrointestinal tract has been modified.	granules: modified release
gum	A preparation containing one or more active ingredients in a gum base.	gum
gum: chewing	A preparation containing one or more active ingredients in a gum base, to be chewed and subsequently discarded.	gum: chewing
implant	A sterile solid or semi-solid preparation containing one or more active ingredients for introduction or grafting into body tissue.	implant
INHALATION	A preparation composed of, or containing, active ingredients which, when vaporised or dispersed in a suitable manner, is intended to be administered into the lungs or into the nasal, paranasal or ethmoid sinuses via the nasal or oral respiratory route. Inhalations may be intended for local or systemic effect.	

Fully Specified Name	Description	Preferred Term
inhalation	A preparation composed of, or containing, active ingredients which, when vaporised or dispersed in a suitable manner, is intended to be administered into the lungs or into the nasal, paranasal or ethmoid sinuses via the nasal or oral respiratory route. Inhalations may be intended for local or systemic effect.	inhalation
inhalation: breath activated	A preparation intended for inhalation usually consisting of a gas or vapour, or pressurised solution, suspension, emulsion of one or more active ingredients, which is released on inhalation or the drawing of air through the mouthpiece of the device.	inhalation: breath activated
inhalation: powder for	A powder preparation composed of, or containing, active ingredients which when dispersed in a suitable manner is intended to be self-administered by inhalation via the nasal or the oral route for local or systemic effect. It is usually inhaled in controlled amounts.	inhalation: powder for
inhalation: pressurised	A metered dose preparation usually consisting of a solution, suspension or emulsion of one or more active ingredients held under pressure with a suitable propellant or a suitable mixture of propellants. They are intended to be inhaled in controlled amounts and are delivered by the actuation of an appropriate metering valve.	inhalation: pressurised
inhalation: solution for	A clear liquid preparation composed of, or containing, active ingredient(s) which when vaporised or dispersed in a suitable manner (for example, hand-actuated pump, nebuliser) is intended to release the constituents for inhalation.	inhalation: solution
INJECTION	A sterile solution, emulsion or suspension which is a suitable vehicle for containing, or which contains, one or more active ingredients. It is intended to be administered parenterally.	
injection	A sterile solution, emulsion or suspension which is a suitable vehicle for containing, or which contains, one or more active ingredients. It is intended to be administered parenterally.	injection
injection: concentrated	A sterile solution which must be diluted with another sterile liquid in order to prepare an injection.	injection: concentrated
injection: emulsion	A sterile dispersion of an oily liquid in an aqueous liquid either of which may contain dissolved solids, in which the aqueous liquid forms the continuous phase. Solids may be suspended in the emulsion.	injection: emulsion
injection: intraocular	A sterile injection intended to be administered intraocularly.	injection: intraocular
injection: intrathecal	A sterile injection intended to be administered intrathecally.	injection: intrathecal
injection: intravenous infusion	A sterile injection designed to be infused intravenously into the body.	injection: intravenous infusion

Fully Specified Name	Description	Preferred Term
injection: modified release	An injection in which the rate of diffusion of the active ingredients into the systemic circulation has been modified.	injection: modified release
injection: powder for	A sterile, solid substance to be reconstituted in an appropriate sterile liquid before injection.	injection: powder for
injection: solution	A sterile, clear liquid preparation containing one or more active ingredients dissolved in one or more suitable solvents.	injection: solution
injection: subcutaneous infusion	A sterile injection designed to be infused subcutaneously into the body.	injection: subcutaneous infusion
injection: suspension	A sterile liquid preparation containing one or more active ingredients dispersed as solid particles throughout a liquid phase in which the particles are not soluble. It may also contain dissolved active ingredients.	injection: suspension
intratracheal suspension	A liquid preparation containing one or more active ingredients dispersed as solid particles throughout a liquid phase. In addition it may contain other active ingredients which are dissolved. It is intended for intratracheal use.	intratracheal suspension
jelly	A gel that contains a high proportion of water, in combination with a drug substance and a thickening agent.	jelly
liniment	A liquid or semi-liquid preparation composed of or containing one or more active ingredients intended to be applied to the unbroken skin with friction.	liniment
LIQUID	A state of matter, intermediate between solid and gas.	
liquid	A state of matter, intermediate between solid and gas.	liquid
liquid: multipurpose	A liquid (or oily) preparation composed of, or containing one or more active ingredients intended for multipurpose use. For example, aroma therapy oils can be used for inhalation, topically or orally.	liquid: multi-purpose
lotion	A liquid or semi-liquid preparation composed of or containing one or more active ingredients usually intended to be applied to the unbroken skin without friction.	lotion
lozenge	A solid preparation, containing one or more active ingredients, usually in a flavoured base, which is intended to dissolve or disintegrate slowly in the mouth to effect a local action.	lozenge
lozenge with integral application	A lozenge placed on a short handle or stick, designed to be held in the hand while the lozenge is sucked to release the active ingredient.	lozenge on handle
mouthwash	An aqueous solution of one or more active ingredients intended, usually after dilution with warm water, for use in contact with the mucous membranes of the oral cavity, in some cases including gargling.	mouthwash

Fully Specified Name	Description	Preferred Term
mouthwash: powder for	One or more active ingredients in a dry form intended, after reconstitution with water, for use in contact with the mucous membranes of the oral cavity, in some cases including gargling.	mouthwash: powder for
nasal cream	A homogeneous, viscous or semi-solid preparation, usually an emulsion, consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable base, for use via the nasal route.	nasal cream
NASAL DROPS	A liquid preparation for instillation into the nostrils by means of a dropper.	
nasal drops	A liquid preparation for instillation into the nostrils by means of a dropper.	nasal drops
nasal drops: powder for	One or more active ingredients in a dry form to be reconstituted for use as nasal drops.	nasal drops: powder for
nasal drops: solution	A liquid preparation composed of or containing one or more active ingredients dissolved in a suitable vehicle.	nasal drops: solution
nasal gel	A semi-solid preparation usually consisting of a solution or dispersion in a suitable base, prepared with the aid of a suitable gelling agent, intended for application via the nasal route.	nasal gel
nasal ointment	A semi-solid preparation usually consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable base, usually nonaqueous and intended for use via the nasal route.	nasal ointment
nasal spray	A liquid preparation for application after dispersion with a spraying device, intended for use via the nostrils.	nasal spray
OIL	A greasy liquid substance, not miscible with water.	
oil	A greasy liquid substance, not miscible with water.	oil
oil: bath	A greasy liquid substance, not miscible with water, intended for topical administration in a bath or shower, or may be applied directly to the skin.	oil: bath
oil: oral	A greasy liquid substance not miscible with water intended for oral administration.	oil: oral
OINTMENT	A semi-solid preparation intended for topical use, usually consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable base, usually nonaqueous.	
ointment	A semi-solid preparation intended for topical use, usually consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable base, usually nonaqueous.	ointment
ointment: fatty	A semi-solid preparation intended for topical use, usually consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable fatty, non-aqueous base.	ointment: fatty

Fully Specified Name	Description	Preferred Term
oral gel	A semi-solid preparation usually consisting of a solution or dispersion in a suitable base, prepared with the aid of a suitable gelling agent, intended for oral administration or use within the oral cavity.	oral gel
ORAL LIQUID	A preparation usually consisting of a solution, a suspension or an emulsion of one or more active ingredients in a suitable vehicle. They are intended to be swallowed either undiluted or after dilution.	
oral liquid	A preparation usually consisting of a solution, a suspension or an emulsion of one or more active ingredients in a suitable vehicle. They are intended to be swallowed either undiluted or after dilution.	oral liquid
oral liquid: emulsion	A dispersion of an oily liquid in an aqueous liquid either of which may contain dissolved solids, in which the aqueous liquid forms the continuous phase. Solids may be suspended in the emulsion.	oral liquid: emulsion
oral liquid: for freezing	A preparation usually consisting of a solution of one or more active ingredients in a suitable vehicle, intended to be frozen and then sucked as an iceblock until consumed.	oral liquid: for freezing
oral liquid: powder for	One or more active ingredients in a dry form to be reconstituted for use as an oral liquid.	oral liquid: powder for
oral liquid: solution	A liquid preparation composed of or containing one or more active ingredients dissolved in a suitable vehicle.	oral liquid: solution
oral liquid: suspension	A liquid preparation containing one or more active ingredients dispersed as solid particles throughout a liquid phase. In addition it may contain other active ingredients which are dissolved.	oral liquid: suspension
oral semi-solid	A highly viscous preparation which has a viscosity and rigidity intermediate between that of a solid and a liquid, which is intended for oral ingestion.	oral semi-solid
oral spray	A liquid preparation for application after dispersion with a spraying device, intended for administration within the oral cavity.	oral spray
PAD	A mass of soft material used to cushion shock, prevent wear or absorb moisture.	
pad	A mass of soft material used to cushion shock, prevent wear or absorb moisture.	pad
pad: waterproof	A pad that has a waterproof surface.	pad: waterproof
PAINT	A liquid preparation containing one or more active ingredients for application to broken skin or mucous surfaces.	
paint	A liquid preparation containing one or more active ingredients for application to broken skin or mucous surfaces.	paint
paste	A semi-solid preparation for external application usually containing a high proportion of finely powdered active ingredients mixed with soft or liquid paraffin or with a non-greasy base made with glycerol, mucilage or soap.	paste

Fully Specified Name	Description	Preferred Term
paste: oromucosal	A paste that is generally used as an adhesive vehicle for applying medication to the oral mucosal surfaces of the mouth and/or throat.	paste: oromucosal
PATCH	A system containing active ingredients which is affixed to the skin and produces an effect by diffusion of the active ingredients through the skin at a constant rate over a period of time or produces a local effect by diffusion of the active ingredients to the skin.	
patch	A system containing active ingredients which is affixed to the skin and produces an effect by diffusion of the active ingredients through the skin at a constant rate over a period of time.	patch
patch: dermal	A system containing active ingredients which is affixed to the skin and is intended to produce a local effect by diffusion of the active ingredients to the skin.	patch: dermal
PESSARY	A solid preparation containing one or more active ingredients intended for vaginal administration.	
pessary	A solid preparation containing one or more active ingredients intended for vaginal administration.	pessary
pessary: compressed	A solid preparation, generally similar to an uncoated tablet, but intended for vaginal administration. Also known as a vaginal tablet.	pessary: compressed
pessary: modified release	A pessary in which the rate of release of active ingredients in the vagina has been modified.	pessary: modified release
pessary: moulded	A solid preparation, prepared by allowing a liquefied mass to cool in a mould of suitable size and shape. It contains one or more active ingredients and is intended for vaginal administration.	pessary: moulded
pessary: shell	A solid preparation, similar to a soft capsule, but intended for vaginal administration. Also known as a vaginal capsule.	pessary: shell
POWDER	A mixture of solid, finely divided substances containing one or more active ingredients intended for internal or external use.	
powder	A mixture of solid, finely divided substances containing one or more active ingredients intended for internal or external use.	powder
powder: dusting	A finely divided powder composed of or containing one or more active ingredients intended for application to the skin, mucous membranes or wounds.	powder: dusting
powder: dusting-sterile	A sterile finely divided powder composed of or containing one or more active ingredients intended for application to the skin, mucous membranes or wounds.	powder: dusting sterile
ribbon	A dressing available in a ribbon intended for packing a wound.	ribbon
roll	A long tightly wound strip of material.	roll
roll: wrapped pack	A roll available in a wrapped pack.	roll: wrapped pack
rope	A dressing available in a rope intended for packing a wound.	rope

Fully Specified Name	Description	Preferred Term
shampoo	A viscous liquid that is generally applied to wet hair, head and/or scalp areas. It is massaged in to form a lather before being rinsed out.	shampoo
sheet	A dressing available in a flat sheet.	sheet
SOLUTION	A liquid preparation composed of, or containing, one or more active substances dissolved in a suitable vehicle.	
solution	A liquid preparation composed of, or containing, one or more active substances dissolved in a suitable vehicle.	solution
solution: dialysis	A solution for use in dialysis by means of a dialyser.	solution: dialysis
solution: irrigation	A solution, usually sterile, of one or more active ingredients intended for flushing, or instilling followed by drainage of wounds, operation cavities, the vagina, the urinary system, or serous cavities such as abdominal and pleural cavities.	solution: irrigation
solution: perfusion	A sterile solution designed to be used for flushing or perfusion of organs and organ parts during related surgeries. It is not intended for direct injection or intravenous infusion.	solution: perfusion
solution: peritoneal dialysis	A solution for use in dialysis via the peritoneal cavity.	solution: peritoneal dialysis
solution: powder for	One or more active ingredients in a dry form to be reconstituted in a suitable liquid for use as a solution.	solution: powder for
solution: powder for intraocular irrigation	One or more active ingredients in a dry form to be reconstituted in a suitable liquid for use as an intraocular irrigation solution.	solution: powder for intraocular irrigation
SPRAY	A liquid preparation for application after dispersion with a spraying device.	
spray	A liquid preparation for application after dispersion with a spraying device.	spray
spray: pressurised	A liquid preparation usually consisting of a solution, suspension or emulsion containing one or more active ingredients held under pressure with a suitable propellant or a suitable mixture of propellants. They are intended for local application and are delivered by the actuation of an appropriate valve.	spray: pressurised
spray: solution	A liquid preparation for application after dispersion with a suitable device other than aerosol.	spray: solution
STICK	A solid preparation containing one or more active ingredients in stick form.	
stick	A solid preparation containing one or more active ingredients in stick form.	stick
stick: lip	A solid preparation containing one or more active ingredients in stick form for application to the lips.	stick: lip
STRIP	A long narrow piece of solid material intended for use in testing, screening or assaying a biological substance.	

Fully Specified Name	Description	Preferred Term
strip	A long narrow piece of solid material intended for use in testing, screening or assaying a biological substance.	strip
strip: diagnostic	A strip containing reagents or dyes or involving other means, intended to be used for diagnosis.	strip: diagnostic
SUPPOSITORY	A solid preparation containing one or more active ingredients intended for rectal administration, usually as a single dose.	
suppository	A solid preparation containing one or more active ingredients intended for rectal administration, usually as a single dose.	suppository
suppository: compressed	A solid preparation generally similar to an uncoated tablet, but intended for rectal administration.	suppository: compressed
suppository: moulded	A solid preparation, prepared by allowing a liquefied mass to cool in a mould of suitable size and shape. It contains one or more active ingredients and is intended for rectal administration, usually as a single dose.	suppository: moulded
suspension	A liquid preparation composed of, or containing one or more active substances suspended in a suitable vehicle. It may also contain dissolved active substances.	suspension
TABLET	A solid preparation containing one or more active ingredients, usually a measured quantity, with or without suitable diluents in a wide variety of sizes, shapes and surface markings prepared by moulding or compression for oral, sublingual or other use.	
tablet	A solid preparation containing one or more active ingredients, usually a measured quantity, with or without suitable diluents in a wide variety of sizes, shapes and surface markings prepared by moulding or compression for oral, sublingual or other use.	tablet
tablet: chewable	A tablet with a palatable formulation designed to be chewed rather than swallowed whole.	tablet: chewable
tablet: coated	A tablet covered with one or more layers of coatings.	tablet: coated
tablet: compound diagnostic	A solid preparation containing one or more active ingredients, usually a measured quantity, with or without suitable diluents in a wide variety of sizes, shapes and surface markings prepared by moulding or compression, intended to be used in vitro for diagnosis. It is not intended for oral human use.	tablet: compound diagnostic
tablet: dispersible	A tablet which rapidly produces a uniform dispersion in water and is intended to be dispersed prior to administration.	tablet: dispersible
tablet: effervescent	A tablet generally containing acid substances and carbonates or bicarbonates which react rapidly in the presence of water to release carbon dioxide. It is intended to be dissolved or dispersed in water before administration.	tablet: effervescent

Fully Specified Name	Description	Preferred Term
tablet: enteric	A tablet covered with one or more layers of coatings intended to resist the gastric fluid but permit disintegration in the intestinal fluid.	tablet: enteric
tablet: film-coated	A tablet surrounded by a thin layer of various substances usually polymeric in nature.	tablet: film-coated
tablet: gelatin-coated	A tablet surrounded by a layer of gelatin with or without other substances.	tablet: gelatin-coated
tablet: modified release	A coated or uncoated tablet in which the rate or place of release of the active ingredients in the gastrointestinal tract has been modified.	tablet: modified release
tablet: multilayer	A compressed tablet comprising two or more layers of different composition. The layers may be concentric (compressed coated) or parallel.	tablet: multilayer
tablet: orally disintegrating	An uncoated tablet designed to be placed in the oral cavity, where it rapidly disintegrates. It should not be swallowed whole.	tablet: orally disintegrating
tablet: soluble	An uncoated tablet that is intended to be dissolved in water prior to administration. The solution produced may be slightly opalescent due to excipients used in the manufacture of the tablet.	tablet: soluble
tablet: sublingual	An uncoated tablet designed to be placed under the tongue, where it is rapidly absorbed. It should not be swallowed whole.	tablet: sublingual
tablet: sugar-coated	A tablet surrounded by a layer of sugar with or without other substances.	tablet: sugar-coated
tablet: uncoated	A compressed solid preparation containing a unit dose of one or more active ingredients for oral administration. The tablet is not coated and not multilayer.	tablet: uncoated
tape	Strips of material, used to secure bandages.	tape
tincture	A substance in a solution diluted with alcohol.	tincture
toothpaste	A compound containing one or more active ingredients used with a toothbrush for cleaning and polishing the teeth.	toothpaste
vaginal cream	A homogeneous, viscous or semi-solid preparation, usually an emulsion, consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable base and intended for intra-vaginal use.	vaginal cream
vaginal gel	A semi-solid preparation usually consisting of a solution or dispersion in a suitable base, prepared with the aid of a suitable gelling agent and intended for intra-vaginal use.	vaginal gel
WAFER	A thin flat solid preparation containing one or more active ingredients. It is usually intended to disintegrate or dissolve rapidly in contact with body fluids.	
wafer	A thin flat solid preparation containing one or more active ingredients. It is usually intended to disintegrate or dissolve rapidly in contact with body fluids.	wafer

Fully Specified Name	Description	Preferred Term
wafer: sublingual	A thin flat solid preparation containing one or more active ingredients. It is intended to disintegrate or dissolve rapidly when placed under the tongue.	wafer: sublingual

Appendix H Dose form and associated proprietary form

Some manufacturers have dosage forms with a name that is specific to their product(s). 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 104: Examples of proprietary forms (organised by FSN)

Fully Specified Name	Preferred Term	Associated Proprietary Form(s)
capsule: hard	capsule: hard	Pulvule, Sprinkle
capsule: modified release	capsule: modified release	Spansule
eye drops: solution	eye drops: solution	Minims
inhalation: breath activated	inhalation: breath activated	Autohaler
inhalation: solution for	inhalation: solution	Nebule, Respule, Sterineb
inhalation: powder for	inhalation: powder for	Accuhaler, Rotacap, Spincap, Turbuhaler
pessary: moulded	pessary: moulded	Ovula
tablet	tablet	Caplet, Tabsule
tablet: chewable	tablet: chewable	Infatab
tablet: film-coated	tablet: film-coated	Filmstab
tablet: gelatin-coated	tablet: gelatin-coated	Capseal
tablet: modified release	tablet: modified release	Durule, Repetab, Timespan
tablet: orally disintegrating	tablet: orally disintegrating	Fastabs, Quicklet, Soltab

The following table displays similar information, presented with an emphasis on Proprietary Forms.

Table 105: Examples of proprietary forms (organised by proprietary form)

Proprietary Form	Associated Fully Specified Name	Associated Preferred Term
Accuhaler	inhalation: powder for	inhalation: powder for
Autohaler	inhalation: breath activated	inhalation: breath activated
Caplet	tablet	tablet
Capseal	tablet: gelatin-coated	tablet: gelatin-coated
Durule	tablet: modified release	tablet: modified release
Fastabs	tablet: orally disintegrating	tablet: orally disintegrating
Filmstab	tablet: film-coated	tablet: film-coated

Proprietary Form	Associated Fully Specified Name	Associated Preferred Term
Infatab	tablet: chewable	tablet: chewable
Minims	eye drops: solution	eye drops: solution
Nebule	inhalation: solution for	inhalation: solution
Ovula	pessary: moulded	pessary: moulded
Pulvule	capsule: hard	capsule: hard
Quicklet	tablet: orally disintegrating	tablet: orally disintegrating
Repetab	tablet: modified release	tablet: modified release
Respule	inhalation: solution for	inhalation: solution
Rotacap	inhalation: powder for	inhalation: powder for
Soltab	tablet: orally disintegrating	tablet: orally disintegrating
Spansule	capsule: modified release	capsule: modified release
Spincap	inhalation: powder for	inhalation: powder for
Sprinkle	capsule: hard	capsule: hard
Sterineb	inhalation: solution for	inhalation: solution for
Tabsule	tablet	tablet
Timespan	tablet: modified release	tablet: modified release
Turbuhaler	inhalation: powder for	inhalation: powder for

Appendix I Pack Quantity Unit of Measure

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

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 dose form indicator may vary between products. A discrete dose form is a form which is available as distinct or individual parts (for example, tablet, suppository). A continuous dose form is a form which 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).

Table 106: Examples of Pack Quantity Units of Measure

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
application	application	applications
bandage	bandage	bandages
bandage: four layer	bandage	bandages
bandage: high stretch	bandage	bandages
bandage: large D/E size	bandage	bandages
bandage: large limb size	bandage	bandages
bandage: large size	bandage	bandages
bandage: lightweight	bandage	bandages
bandage: medium C/D size	bandage	bandages
bandage: medium limb size	bandage	bandages
bandage: medium size	bandage	bandages
bandage: short stretch	bandage	bandages
bandage: small B/C size	bandage	bandages
bandage: small limb size	bandage	bandages
bandage: small size	bandage	bandages
bandage: straight	bandage	bandages

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
bandage: triangular	bandage	bandages
bandage: two layer	bandage	bandages
bandage: XX/large size	bandage	bandages
bar	bar	bars
bar: soap	soap bar	soap bars
block	block	blocks
capsule	capsule	capsules
capsule: enteric	capsule	capsules
capsule: hard	capsule	capsules
capsule: modified release	capsule	capsules
capsule: soft	capsule	capsules
collodion	mL	mL
conditioner	mL	mL
cream	g	g
cream: modified	g	g
diluent	ampoule, vial (dependent on container type)	ampoules, vials (dependent on container type)
dressing	dressing	dressings
dressing: hydroactive	dressing	dressings
dressing: island	dressing	dressings
dressing: medicated	dressing	dressings
dressing: sacral	dressing	dressings
dressing: tulle	dressing	dressings
drug delivery system	drug delivery system	drug delivery systems
drug delivery system: intrauterine	drug delivery system: intrauterine	drug delivery systems: intrauterine
drug delivery system: vaginal	drug delivery system: vaginal	drug delivery systems: vaginal
ear drops	mL	mL
ear drops: solution	mL	mL
ear drops: suspension	mL	mL
enema	mL	mL
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 drops: solution	mL	mL

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
eye drops: suspension	mL	mL
eye gel	g	g
eye ointment	g	g
eye pad	pad	pads
eye solution	mL	mL
eye spray	mL	mL
eye strip	strip	strips
film	film	films
film: sublingual	film	films
foam	g	g
foam dressing	dressing	dressings
gas	L	L
gas: medicinal	L	L
gel	g	g
gel: intestinal	g	g
gel: modified	g	g
glove	glove	gloves
glove: large	glove	gloves
glove: medium	glove	gloves
glove: small	glove	gloves
granules ¹¹	g or sachet	g or sachets
granules: effervescent (see note 11)	g or sachet	g or sachets
granules: enteric-coated (see note 11)	g or sachet	g or sachets
granules: modified release (see note 11)	g or sachet	g or sachets
gum	piece	pieces
gum: chewing	piece	pieces
implant	implant	implants
inhalation	mL	mL
inhalation: breath activated	activation	activation

¹¹ If the Unit Dose Form Indicator is "continuous", the Pack Unit Measure is "g"; if it is "discrete", the Pack Unit measure is "sachets".

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
inhalation: powder for	capsule, dose unit (dependent on container type)	capsules, dose units (dependent on container type)
inhalation: pressurised	actuation	actuations
inhalation: solution for	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)
injection: concentrated	ampoule, syringe, vial (dependent on container type)	ampoules, syringes, vials (dependent on container type)
injection: emulsion	ampoule, syringe, vial (dependent on container type)	ampoules, syringes, vials (dependent on container type)
injection: intraocular	ampoule, syringe, vial (dependent on container type)	ampoules, syringes, vials (dependent on container type)
injection: intrathecal	ampoule, syringe, vial (dependent on container type)	ampoules, syringes, vials (dependent on container type)
injection: intravenous infusion	ampoule, syringe, vial (dependent on container type)	ampoules, syringes, vials (dependent on container type)
injection: modified release	ampoule, syringe, vial (dependent on container type)	ampoules, syringes, vials (dependent on container type)
injection: powder for	ampoule, syringe, vial (dependent on container type)	ampoules, syringes, vials (dependent on container type)
injection: solution	ampoule, syringe, vial (dependent on container type)	ampoules, syringes, vials (dependent on container type)
injection: subcutaneous infusion	ampoule, syringe, vial (dependent on container type)	ampoules, syringes, vials (dependent on container type)
injection: suspension	ampoule, syringe, vial (dependent on container type)	ampoules, syringes, vials (dependent on container type)
jelly	g	g
liniment	mL	mL
liquid	mL	mL
liquid: multipurpose	mL	mL
lotion	mL	mL
lozenge	lozenge	lozenges
lozenge with integral application	lozenge	lozenges
mouthwash	mL	mL
mouthwash: powder for	g	g
nasal cream	g	g
nasal drops	mL	mL

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
nasal drops: powder for	mL	mL
nasal drops: solution	mL	mL
nasal gel	g	g
nasal ointment	g	g
nasal spray	mL	mL
oil	mL	mL
oil: bath	mL	mL
oil: oral	mL	mL
ointment	g	g
ointment: fatty	g	g
oral liquid	mL	mL
oral liquid: emulsion	mL	mL
oral liquid: for freezing	mL	mL
oral liquid: powder for	mL	mL
oral liquid: solution	mL	mL
oral liquid: suspension	mL	mL
oral spray	mL	mL
pad	pad	pads
pad: waterproof	pad	pads
paint	mL	mL
paste	g	g
paste: oromucosal	g	g
patch	patch	patches
patch: dermal	patch	patches
pessary	pessary	pessaries
pessary: compressed	pessary	pessaries
pessary: modified release	pessary	pessaries
pessary: moulded	pessary	pessaries
pessary: shell	pessary	pessaries
powder	g	g
powder: dusting	g	g
powder: dusting-sterile	g	g
ribbon	ribbon	ribbons

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
roll	roll	rolls
roll: wrapped pack	roll	rolls
rope	rope	ropes
shampoo	mL	mL
sheet	sheet	sheets
solution	mL	mL
solution: dialysis	mL	mL
solution: irrigation	mL	mL
solution: perfusion	mL	mL
solution: peritoneal dialysis	mL	mL
solution: powder for	mL	mL
solution: powder for intraocular irrigation	mL	mL
spray	mL	mL
spray: pressurised	mL	mL
spray: solution	mL	mL
stick	tube, stick (dependent on container type)	tubes, sticks (dependent on container type)
stick: lip	tube	tubes
strip	strip	strips
strip: diagnostic	strip	strips
suppository	suppository	suppositories
suppository: compressed	suppository	suppositories
suppository: moulded	suppository	suppositories
suspension	mL	mL
tablet	tablet	tablets
tablet: chewable	tablet	tablets
tablet: coated	tablet	tablets
tablet: compound diagnostic	tablet	tablets
tablet: dispersible	tablet	tablets
tablet: effervescent	tablet	tablets
tablet: enteric	tablet	tablets
tablet: film-coated	tablet	tablets
tablet: gelatin-coated	tablet	tablets

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
tablet: modified release	tablet	tablets
tablet: multilayer	tablet	tablets
tablet: orally disintegrating	tablet	tablets
tablet: soluble	tablet	tablets
tablet: sublingual	tablet	tablets
tablet: sugar-coated	tablet	tablets
tablet: uncoated	tablet	tablets
tape	tape	tapes
tincture	mL	mL
toothpaste	g	g
vaginal cream	g	g
vaginal gel	g	g
wafer	wafer	wafers
wafer: sublingual	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. Additional container types will be added if required.

Table 107: Examples of Container Types

Container Type	Description	Source
aerosol	A container intended to contain a substance, usually liquid, which may be released in aerosol form upon actuation.	AMT
aerosol can	A container, usually made of metal, plastic or plastic-coated glass, intended to contain a substance, usually liquid held under pressure with suitable propellant, which may be released in aerosol form upon actuation of an installed valve.	TGA
aerosol can: metered dose	A container, usually made of metal, plastic or plastic-coated glass, intended to contain a substance, usually liquid, held under pressure with suitable propellant. A metered dose is released with each valve actuation.	TGA
aerosol: pump actuated	A container, usually made of metal, plastic or plastic-coated glass, intended to contain a substance, usually liquid, which may be released on manual actuation of an installed pump. The doses are not metered.	TGA
aerosol: pump actuated metered dose	A container, usually made of metal, plastic or plastic-coated glass, intended to contain a substance, usually liquid, which may be released upon manual actuation of an installed pump. The metered dose is released with each actuation.	TGA
ampoule	A container, usually tubular in shape, made of glass or plastic and sealed by fusion after filling.	TGA
applicator	A container that acts as a device for the application of a drug dosage form to a particular site.	AMT
bag	A container made of flexible material, usually of plastic. Note that pre-filled blood and parenteral nutrition bags are drug-device combinations.	TGA
blister pack	A container in which one or more dosage units are enclosed in a preformed tray with individual pockets for the dosage units. The material of the tray is usually different from that of the lid. It must be cut or torn in order to access the contents.	TGA
bottle	A container, normally of tubular shape with a narrow neck, usually made of glass or plastic and sealed with a stopper or screw closure. In some cases the stopper may be made of flexible material such as rubber which can be penetrated with a needle.	AMT

Container Type	Description	Source
bottle: dispensing	A container, normally made of clear plastic or glass, with a narrow neck and a screw cap closure, which is used to supply extemporaneously prepared or decanted liquid medicines directly to a patient.	AMT
bottle: poison	A container, made of amber coloured plastic or glass, tubular in shape, with a narrow neck and a screw cap closure, with vertical ridges running the height of the container, with the words "Poison" or "Not to be taken" (or similar) in raised writing running vertically along the height of the container.	AMT
can	A wide container normally cylindrical in shape with a short wide neck usually made of metal and having a stopper or a screw closure.	AMT
carton	A container made from cardboard, cardboard laminate or similar material. It is normally closed but may or may not be sealed.	AMT
cartridge	A medication container typically constructed from glass or plastic that is placed in a dedicated reusable syringe-like holder and applied like an ordinary needle and syringe.	AMT
compact	A wide flat container usually made of plastic or metal and having a clip closure.	TGA
composite pack	A container for a multi-component pack that contains a number of different container types.	AMT
dial dispenser pack	A container in which each of the dosage units is located in individual pockets preformed in a circular rigid tray. Located over the tray is a close-fitting, rotatable, transparent plastic lid, which can only be rotated in one direction. By detaching a predefined portion of the lid or tray, and rotating the lid to the appropriate position, the individual dosage units can be dispensed.	TGA
dispenser pack	A container, usually made of plastic, intending to contain loose tablets or capsules, with a (re-closable) sliding closure or other dispensing mechanism designed to release individual dosage units when activated.	TGA
dropper container	A small container made of glass or plastic, designed to hold a liquid which is to be delivered drop-wise, via a dropper device which may be attached to the container or to the closure of the container.	AMT
dual chamber composite pack	A container in which the ingredients and diluents are located in individual chambers. The connection between the two chambers is breached to allow mixing of the ingredient and diluent, immediately prior to administration.	AMT
dual chamber syringe	A syringe in which the active ingredients, or ingredients and diluents, are located in two individual chambers. The connections between the two chambers are breached to allow mixing of the active ingredients, or ingredients and diluents, immediately prior to administration.	AMT

Container Type	Description	Source
gas cylinder	A gas-tight container designed to hold a gas under pressure.	TGA
inhaler	A container that acts also as a device for delivery of an inhaled dosage form.	AMT
inhaler: dry powder	A container, usually made of plastic, intended to contain a powder in a sealed drug reservoir. A metered dose is made available by actioning a mechanism within the container and is withdrawn from the reservoir under the force of the patient's inhalation.	TGA
jar	A wide container, normally cylindrical in shape, with a short wide neck usually made of glass or plastic and having a stopper or a screw closure.	AMT
jar: screw cap	A wide container, normally cylindrical in shape, with a short wide neck usually made of glass or plastic and having a screw closure.	AMT
pouch	A bag or soft flexible receptacle made of materials such as plastic or foil, in which the product is located between two layers of materials bonded together, used for packaging semi-solids or liquids.	AMT
prefilled injection device	<i>Note that this description is no longer in use within AMT and has been superseded by "injection device".</i> A drug-device combination of a syringe or cartridge which may or may not have a needle attached, which is supplied by the manufacturer already filled with a liquid for injection, which is designed for use in a particular type of injection device.	AMT
puffer pack	A container whose walls are flexible and from which the liquid or powder contents may be ejected by squeezing the container.	TGA
pump pack	A container, normally of tubular shape with a narrow neck, usually made of plastic, intended to contain a substance, usually liquid, which may be released on manual actuation of an installed pump. The doses are not metered.	AMT
sachet	A container made of flexible material such as paper, laminate or plastic where a single dosage unit is located between two layers of material(s) bonded together.	TGA
strip pack	A container in which dosage units are enclosed individually in a continuous strip made by bonding two layers of material(s) together so that the dosage units are separated and protected and can be extracted singly. It must be cut or torn in order to access the contents. It is usually more flexible than a blister pack.	TGA
syringe	A device used to inject/infuse medications. It is typically constructed of glass or plastic and consists of a barrel with measurement lines and a plunger	AMT

Container Type	Description	Source
tube	An elongated hollow cylinder which may be fabricated from rigid or flexible material and which may or may not be fused or crimped at one end, for example, rigid elongated tube for effervescent tablets, flexible tube for cream.	TGA
vial	A container normally tubular in shape and usually made of glass. It is sealed with a stopper made of flexible material such as rubber which can be penetrated with a needle.	TGA
wrapping	A thin flexible material such as paper, plastic or aluminium foil folded around the product.	TGA

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

K.1.1 Common name

Preferred Terms will be derived from the common name for the disease or infection prevented by the vaccine. In some cases the term will be derived instead from the virus or bacteria that cause the infection. This includes situations where:

- The same disease can be due to more than one causative organism (for example, meningitis may be due to *Neisseria meningitidis* (meningococci) or *Haemophilus influenzae* type B).
- A causative organism may cause more than one specific disease (for example, *Haemophilus influenzae* type B infection may cause either pneumonia or meningitis; human papillomavirus may cause either cervical cancer or genital warts).
- The vaccine is preventive against infection rather than against the consequences of that infection (for example, “human papillomavirus vaccine” will be used, not “cervical cancer vaccine”).
- There is historical familiarity with using the causative organism rather than the disease, and the resultant change would introduce confusion (for example, “BCG (*Bacillus Calmette and Guérin*) live vaccine” will be used and not “tuberculosis live vaccine”).

Vaccines that require the use of the antigenic virus or bacteria to describe the product will be identified and forwarded to an expert group for endorsement.

K.1.2 Additional information

The text descriptors “disease” and “infection” do not provide any additional identifying information and will not be included. For example the term will be “meningococcal vaccine” rather than “meningococcal disease vaccine”.

K.1.3 Formulation modifications

Formulation modifications will be included as part of the Preferred Term where they result in a discernible therapeutic difference between otherwise similar vaccines. Allowable modifications to be included in Preferred Terms are:

- acellular;
- conjugate;
- live; and
- polysaccharide.

Note: Attenuation or inactivation are implicit parts of the process of how vaccines create an immunogenic response and, as they do not influence choice or effect therapeutic differences, this detail will not be included in the description.

K.1.4 Vaccine, non-vaccine and skin test

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

Include the text "vaccine", "non-vaccine" or "skin test" in the Preferred Term as appropriate. For example: Q fever skin test injection, 1 x 0.5 mL vial.

For safety reasons, 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 similar active ingredient. For example Oncotice will be described as:

Bacillus Calmette and Guerin (Tice strain) live non-vaccine 500 million colony forming units injection, 3 x 500 million colony forming units vials

The Preferred Term for non-vaccines will reflect the toxin or microbe rather than the disease intended to be prevented and may look different to a vaccine containing the same toxin or microbe.

K.1.5 Multi-ingredient vaccines

Preferred Terms for multi-ingredient and multivalent vaccines will include the names of all the constituent vaccines, joined with a plus sign (" + "). Ingredients will always appear in alphabetical order. For example:

- measles + mumps + rubella live vaccine
- human papillomavirus (type 16 + 18) vaccine

K.1.6 Serotypes and genotypes

Serotypes will be represented in the Preferred Term when different serotypes protect against different clinical manifestations of a disease and a choice may need to be made based on those differences.

Multi-ingredient vaccines, in which the ingredients are different serotypes but active against the same disease or infection, will be represented by the name of disease/infection and the specific valency (for example, bivalent, quadrivalent, 23 valent). Where vaccines are monovalent, this will be implied rather than explicitly stated.

Where vaccines are multivalent, the Preferred Term will include the valency. If several products exist which have the same valency but different serotypes, then both the valency and the serotypes will be expressed.

Influenza vaccine will be considered an exception to the need to specify valency as the year acts as a de facto identifier (refer to "Year of issue" section below).

K.1.7 Year of issue

In cases where viruses or bacteria causing a disease change over time such that different strains may be included in the vaccine, the vaccine name will include the year of issue in Australia (or other specified date), for example, influenza vaccine 2010.

In cases where vaccines are developed in response to a specific pandemic being declared, vaccine names should include the text “pandemic”, the serotype and the year of issue in Australia (or other specified date).

Where modifications to a vaccine may occur in response to a specific strain, the Preferred Term will represent both the strain and the year, for example, H1N1 pandemic influenza vaccine 2009.

K.1.8 Discernible therapeutic differences

Vaccines for the same disease or virus/bacteria with evidence of differences in efficacy or adverse effect profile, such that recommendations (from an appropriate body) for certain populations may differ, should have different MPs.

When previous rules are insufficient to discern between vaccines where discernible therapeutic differences need to be highlighted, abbreviations in common use (based on the *Australian Immunisation Handbook* [16]) will be used to differentiate such products as exceptions.

Examples:

- *Haemophilus influenzae* type b (PRP-OMP) conjugate vaccine is preferred in high-risk populations to *Haemophilus influenzae* type b (PRP-T) conjugate vaccine as the former confers protective antibody levels after the first dose.
- Liquid PedvaxHIB will be represented as “*Haemophilus influenzae* type b conjugate (PRP-OMP) vaccine”.
- Hiberix will be represented as “*Haemophilus influenzae* type b conjugate (PRP-T) vaccine”.

K.1.9 Abbreviations in Synonyms

Where the use of an abbreviation is common clinical practice, the creation of a Synonym will be considered. The reference source for this will be the current version of the *Australian Immunisation Handbook* [16].

K.1.10 Additional information – preservatives, adjuvants, production media, microbial strains

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

K.1.11 Strength

Strength will be represented as part of the Fully Specified Name but will not be included in Preferred Terms for vaccines. Where two products exist with different amounts of antigen intended for different populations, a term describing the population, rather than strength, will be included in the MPUU.

Table 108: Examples of strength variations for different populations

Product	AMT Preferred Term
Adacel	<ul style="list-style-type: none"> MP: diphtheria + pertussis + tetanus vaccine MPUU: diphtheria + pertussis + tetanus vaccine (adult) injection, 0.5 mL vial
Tripacel	<ul style="list-style-type: none"> MP: diphtheria + pertussis + tetanus vaccine MPUU: diphtheria + pertussis + tetanus vaccine (child) injection, 0.5 mL vial
Hepatitis B vaccines	<ul style="list-style-type: none"> hepatitis B vaccine (child) hepatitis B vaccine (adult) hepatitis B vaccine (dialysis)

K.2 Antivenoms

K.2.1 Fully Specified Name

Antivenom Fully Specified Names 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 TF_Name, and sponsor details are replaced by the text "extemporaneous" (for example, Cocaine Hydrochloride Eye Drops Strong APF (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: solution, 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. As such, the plant part and extraction method are not described in the ingredient name. AMT expresses only a common ingredient name for this class of ingredients, derived from the monograph name used in *Herbs & Natural Supplements: An Evidence-based Guide* [17]. Where this reference does not describe the ingredient, alternative sources such as the sponsor's Product Information and/or Consumer Medicine Information, or sponsor's website are used in order to assign a common ingredient name. For example: "Vaccinium myrtillus" is described by its common name of "bilberry".

Appendix L Product Concepts – Full Definitions

L.1 Medicinal Product

L.1.1 Medicinal Product Fully Specified Name full definition

The Fully Specified Name of a Medicinal Product will, by default, follow the syntax:

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

The default FSN of a Medicinal Product can be more fully defined as follows.

Table 109: MP FSN description

Description Component	Definition
Medicinal Product FSN	<code>MP_Ingredient_Details</code> ¹ " (medicinal product) " 1: <code>MP_Ingredient_Details</code> represents Medicinal Products that contain one or more medicinal substances.
<code>MP_Ingredient_Details</code>	<code>Ingredient_Name { " + " Ingredient_Name }</code> ^{1 2 3} 1: An <code>Ingredient_Name</code> represents a medicinal substance. 2: Multiple instances of <code>Ingredient_Name</code> may exist. These represent multi-ingredient Medicinal Products. 3: <code>Ingredient_Name</code> are ordered alphabetically.
<code>Ingredient_Name</code>	<code>MP.has intended active ingredient.PT</code> ¹ The ingredient is the PT of the medicinal substance concept that is the destination of the MP HAS INTENDED ACTIVE INGREDIENT relationship. 1: If <code>Ingredient_Name</code> is exactly the same for more than one intended active ingredient in a multi-ingredient product, then <code>Ingredient_Name</code> is only shown once.
(medicinal product)	The semantic tag used in the FSN of all Medicinal Product concepts.

L.1.2 Medicinal Product Preferred Term full definition

The Preferred Term of a Medicinal Product will, by default, follow the syntax:

`MP PT := Ingredient_Details`

The default PT of a Medicinal Product can be more fully defined as follows.

Table 110: MP PT description

Description Component	Definition
Medicinal Product PT	<code>Ingredient_Details</code> ¹ 1: <code>Ingredient_Details</code> represents Medicinal Products that contain one or more medicinal substance.

Description Component	Definition
Ingredient_Details	<p>Ingredient_Name { " + " Ingredient_Name } ^{1 2 3}</p> <p>1: An Ingredient_Name represents a medicinal substance.</p> <p>2: Multiple instances of Ingredient_Name may exist; these represent multi-ingredient Medicinal Products.</p> <p>3: Ingredient_Names are ordered by their preferred term order.</p>
Ingredient_Name	<p>MP.has intended active ingredient.PT ¹</p> <p>The ingredient is the PT of the medicinal substance concept that is the destination of the MP HAS INTENDED ACTIVE INGREDIENT relationship.</p> <p>1: If Ingredient_Name is exactly the same for more than one intended active ingredient in a multi-ingredient product, then Ingredient_Name is only shown once.</p>

L.2 Medicinal Product Unit of Use

L.2.1 Medicinal Product Unit of Use Fully Specified Name full definition

The Fully Specified Name of a Medicinal Product Unit of Use will, by default, follow the syntax:

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

The default FSN of a Medicinal Product Unit of Use can be more fully defined as follows.

Table 111: MPUU FSN description

Description Component	Definition
Medicinal Product Unit of Use FSN	<p>Ingredients_With_Strength " " Form [" , " Unit_Of_Use_Details] ¹</p> <p>" (medicinal product unit of use)"</p> <p>1: Unit_Of_Use_Details are included if they exist, based on the definition below.</p>
Ingredients_With_Strength	<p>Ingredient_Strength { " + " Ingredient_Strength } ^{1 2 3}</p> <p>1: One Ingredient_Strength is included for each MPUU HAS INTENDED ACTIVE INGREDIENT relationship that exists for the given MPUU.</p> <p>2: The strength component of Ingredient_Strength does not exist for certain MPUU FSNs (that is, those MPUUs that do not have a HAS AUSTRALIAN BoSS relationship) for example, those representing inert substances, non-medicated dressings, diagnostic aids and nutritional supplements.</p> <p>3: The Ingredient_Strengths are ordered alphabetically, irrespective of casing.</p>

Description Component	Definition
Ingredient_Strength	IAI_Ingredient_Strength BoSS_Ingredient_Strength ^{1 2} 1: For each MPUU HAS INTENDED ACTIVE INGREDIENT relationship IAI_Ingredient_Strength BoSS_Ingredient_Strength must be included. 2: Where the HAS INTENDED ACTIVE INGREDIENT relationship is ungrouped (that is, relationshipGroup value is "0" because there is no associated BoSS_Ingredient), IAI_Ingredient_Strength is to be used. Otherwise use BoSS_Ingredient_Strength.
IAI_Ingredient_Strength	IAI_Ingredient [" " Other_Strength_Representation] ¹ 1: Other_Strength_Representation is included if it exists for the given MPUU.
IAI_Ingredient	IAI_Ingredient is the Preferred Term of the Substance concept that is the destination of the HAS INTENDED ACTIVE INGREDIENT relationship from a given MPUU.
Other_Strength_Representation	Other_Strength_Representation is the exact string derived from the internal use field Other_Strength_Representation.
BoSS_Ingredient_Strength	BoSS_Ingredient " " BoSS_Strength ^{1 2} 1: BoSS_Ingredient is the Preferred Term of the Substance concept that is the destination of the HAS AUSTRALIAN BoSS relationship, within that (relationship) group. 2: BoSS_Strength will be derived from the HAS AUSTRALIAN BoSS reference in MPUU.StrengthRefset.
BoSS_Strength	MPUU.StrengthRefset.value " " MPUU.StrengthRefset.unitId.PT ^{1 2 3} 1: If MPUU.StrengthRefset.denominator_unitId.PT = "each", only the MPUU.StrengthRefset.numerator_unitId.PT is used. 2: If: <ul style="list-style-type: none"> MPUU.UnitofUseSizeRefset.value is not "1"; and MPUU.StrengthRefset.denominator_unitId = MPUU.UnitofUseSizeRefset.unitId then $\text{BoSS_Strength} = (\text{MPUU.StrengthRefset.value} \times \text{MPUU.UnitofUseSizeRefset.value}) \text{ " " } \frac{\text{MPUU.StrengthRefset.numerator_unitId.PT}}{\text{MPUU.UnitofUseSizeRefset.value " " MPUU.UnitofUseSizeRefset.unitId.PT}}$ 3: If associated strength value > 1 then use plural units description for the associated strength units. Exceptions: For the units of measure of "microgram" the Preferred Term is used instead of the plural units.
Form	MPUU.has manufactured dose form.PT ¹ 1: Form is the Preferred Term of the Form concept that is the destination of the MPUU HAS MANUFACTURED DOSE FORM relationship.

Description Component	Definition
Unit_Of_Use_Details	<p>[" " Unit_Of_Use_Size] ¹ [" " Unit_Of_Use] ²</p> <p>1: Do not include Unit_Of_Use_Size if:</p> <ul style="list-style-type: none"> MPUU.UnitofUseSizeRefset.value = 1; and MPUU.UnitofUseSizeRefset.unitId.PT equals MPUU.has manufactured dose form (or one of its parents in the <i>Form</i> hierarchy). <p>2: Include Unit_Of_Use if:</p> <ul style="list-style-type: none"> MPUU.has unit of use.PT does not equal MPUU.has manufactured dose form.PT (or one of its parents in the <i>Form</i> hierarchy); and MPUU.has unit of use.PT does not equal MPUU.UnitofUseSizeRefset.unitId.PT; and MPUU.has unit of use.PT does not equal "Continuous".
Unit_Of_Use_Size	<p>MPUU.UnitofUseSizeRefset.value " "</p> <p>MPUU.UnitofUseSizeRefset.unitId.PT ¹</p> <p>1: The referenced component in the Unit of Use Size reference set is the HAS UNIT OF USE relationship with the same source MPUU concept as the focus concept of this MPUU FSN.</p>
Unit_Of_Use	<p>MPUU.has unit of use.PT ¹</p> <p>1: Unit_Of_Use is the Preferred Term of the Unit of Use concept that is the destination of the MPUU HAS UNIT OF USE relationship.</p>
(medicinal product unit of use)	The semantic tag used in the FSN of all Medicinal Product Unit of Use concepts.

L.2.2 Medicinal Product Unit of Use Preferred Term full definition

The Preferred Term of a Medicinal Product Unit of Use will, by default, follow the syntax:

```
MPUU PT := Ingredients_With_Strength " " Form
          [ " " Unit_Of_Use_Details]
```

The default PT of a Medicinal Product Unit of Use can be more fully defined as follows.

Table 112: MPUU PT description

Description Component	Definition
Medicinal Product Unit of Use FSN	<p>Ingredients_With_Strength " " Form [" " Unit_Of_Use_Details] ¹</p> <p>1: Unit_Of_Use_Details are included if they exist, based on the definition below.</p>

Description Component	Definition
Ingredients_With_Strength	<p>Ingredient_Strength { " + " Ingredient_Strength }^{1 2 3}</p> <p>1: One Ingredient_Strength is included for each MPUU HAS INTENDED ACTIVE INGREDIENT relationship that exists for the given MPUU.</p> <p>2: The strength component of Ingredient_Strength does not exist for certain MPUU PTs (that is, those MPUUs that do not have a HAS AUSTRALIAN BoSS relationship) for example, those representing inert substances, non-medicated dressings, diagnostic aids and nutritional supplements.</p> <p>3: The order of Ingredient_Strengths is derived from the order of the MPUU's parent MP.</p>
Ingredient_Strength	<p>IAI_Ingredient_Strength BoSS_Ingredient_Strength^{1 2}</p> <p>1: For each MPUU HAS INTENDED ACTIVE INGREDIENT relationship IAI_Ingredient_Strength BoSS_Ingredient_Strength must be included.</p> <p>2: Where the HAS INTENDED ACTIVE INGREDIENT relationship is ungrouped (that is, the relationshipGroup value is "0" because there is no associated BoSS_Ingredient), IAI_Ingredient_Strength is to be used. Otherwise use BoSS_Ingredient_Strength.</p>
IAI_Ingredient_Strength	<p>IAI_Ingredient [" " Other_Strength_Representation]¹</p> <p>1: Other_Strength_Representation is included if it exists for the given MPUU.</p>
IAI_Ingredient	<p>IAI_Ingredient is the Preferred Term of the Substance concept that is the destination of the HAS INTENDED ACTIVE INGREDIENT relationship from a given MPUU.</p>
Other_Strength_Representation	<p>Other_Strength_Representation is the exact string derived from the internal use field Other_Strength_Representation.</p>
BoSS_Ingredient_Strength	<p>BoSS_Ingredient " " BoSS_Strength^{1 2}</p> <p>1: BoSS_Ingredient is the Preferred Term of the Substance concept that is the destination of the HAS AUSTRALIAN BoSS relationship, within that (relationship) group.</p> <p>2: BoSS_Strength will be derived from the HAS AUSTRALIAN BoSS reference in StrengthRefset and/or include an alternative representation if Other_Strength_Representation exists.</p>

Description Component	Definition
BoSS_Strength	<p>MPUU.StrengthRefset.value " " MPUU.StrengthRefset.unitId.PT ^{1 2 3 4}</p> <p>1: If MPUU.StrengthRefset.denominator_unitId.PT = "each", only the MPUU.StrengthRefset.numerator_unitId.PT is used.</p> <p>2: If:</p> <ul style="list-style-type: none"> MPUU.UnitofUseSizeRefset.value is not "1"; and MPUU.StrengthRefset.denominator_unitId = MPUU.UnitofUseSizeRefset.unitId <p>then</p> <p>BoSS_Strength = (MPUU.StrengthRefset.value x MPUU.UnitofUseSizeRefset.value) " " MPUU.StrengthRefset.numerator_unitId.PT "/" MPUU.UnitofUseSizeRefset.value " " MPUU.UnitofUseSizeRefset.unitId.PT</p> <p>3: If associated strength value > 1 then use plural units description for the associated strength units.</p> <p>Exceptions:</p> <p>For the units of measure of "microgram" the Preferred Term is used instead of the plural units.</p> <p>4: There are 3 options of representing BoSS_Strength when Other_Strength_Representation is populated AND HAS AUSTRALIAN BoSS reference exists in StrengthRefset for this given MPUU:</p> <ul style="list-style-type: none"> Other_Strength_Representation only (that is, BoSS_Strength is excluded); or Other_Strength_Representation " (" BoSS_Strength ")"; or BoSS_Strength " (" Other_Strength_Representation ")"
Form	<p>MPUU.has manufactured dose form.PT ¹</p> <p>1: Form is the Preferred Term of the Form concept that is the destination of the MPUU HAS MANUFACTURED DOSE FORM relationship.</p>
Unit_Of_Use_Details	<p>[" " Unit_Of_Use_Size] ¹ [" " Unit_Of_Use] ²</p> <p>1: Do not include Unit_Of_Use_Size if either:</p> <ul style="list-style-type: none"> MPUU.UnitofUseSizeRefset.value = 1; and MPUU.UnitofUseSizeRefset.unitId.PT equals MPUU.has manufactured dose form (or one of its parents in the Form hierarchy); <p>OR</p> <ul style="list-style-type: none"> MPUU.UnitofUseSizeRefset.value equals MPUU.StrengthRefset.value; and MPUU.UnitofUseSizeRefset.unitId.PT equals MPUU.StrengthRefset.numerator_unitId.PT <p>2: Include Unit_Of_Use if:</p> <ul style="list-style-type: none"> MPUU.has unit of use.PT does not equal MPUU.has manufactured dose form.PT (or one of its parents in the Form hierarchy); and MPUU.has unit of use.PT does not equal MPUU.UnitofUseSizeRefset.unitId.PT; and Unit_Of_Use.PT ≠ "measure" and Unit of use.PT ≠ "Continuous".

Description Component	Definition
Unit_Of_Use_Size	MPUU.UnitofUseSizeRefset.value " " MPUU.UnitofUseSizeRefset.unitId.PT ¹ 1: The referenced component in the Unit of Use Size reference set is the HAS UNIT OF USE relationship with the same source MPUU concept as the focus concept of this MPUU PT.
Unit_Of_Use	MPUU.has unit of use.PT ¹ 1: Unit_Of_Use is the Preferred Term of the Unit of Use concept that is the destination of the MPUU HAS UNIT OF USE relationship.

L.3 Medicinal Product Pack

L.3.1 Medicinal Product Pack Fully Specified Name full definition

The Fully Specified Name of a Medicinal Product Pack will, by default, follow the syntax:

```
MPP_FSN :=      MPUU_Details { " (& " MPUU_Details} ", "
                  Total_Quantity_Size_Details " (medicinal product pack)"
```

The default FSN of a Medicinal Product Pack can be more fully defined as follows.

Table 113: MPP FSN description

Description Component	Definition
Medicinal Product Pack FSN	MPUU_Details { " (& " MPUU_Details} ^{1 2} ", " Total_Quantity_Size_Details " (medicinal product pack)" 1: One MPUU_Details is included for each MPUU associated with the given MPP that is, every MPUU that exists as the destination of MPP HAS MPUU relationship. 2: If multiple MPUU_Details exist, the MPUU_Details are ordered based on the alphabetical order of the first ingredient, followed by the descending order of the first ingredient strength, followed by the same for each subsequent component.
MPUU_Details	IF there exists more than one MPUU M ¹ such that MPP has MPUU M THEN MPUU_ISFO " [" MPUU_Qty_Size "]" ELSE MPUU_ISFO ENDIF 1: These relate to cases where the MPP represents a multi-component product.

Description Component	Definition
MPUU_ISFO	<p>Ingredient_Strength { " + " Ingredient_Strength }^{1 2 3 4} " " Form</p> <p>1: One Ingredient_Strength is included for each HAS INTENDED ACTIVE INGREDIENT relationship that exists for the given MPUU.</p> <p>2: The existence of multiple Ingredient_Strength relates to cases where the MPP represents a multi-ingredient product.</p> <p>3: The strength component of Ingredient_Strength does not exist for certain MPUU FSN, for example, those representing inert substances, non-medicated dressings, diagnostic aids and nutritional supplements.</p> <p>4: The Ingredient_Strengths are ordered alphabetically based on the Preferred Term of the MPUU's Basis of Strength Substance.</p>
Ingredient_Strength	Ingredient_Strength, as defined for the given MPUU's FSN.
Form	Form, as defined for the given MPUU's FSN.
MPUU_Qty_Size	<p>Unit of Use quantity reference set.value [" × " Unit of Use Size reference set.value " " Unit of Use Size reference set.unitId]^{1 2} " " Unit of Use quantity reference set.unitId^{3 4}</p> <p>1: Size value and size units are included when Unit of Use Size reference set.value exists</p> <p>2: The referenced component in the Unit of Use Size reference set is the HAS UNIT OF USE relationship with the same source MPUU concept as the target concept of this MPP has MPUU relationship.</p> <p>3: The referenced component in the Unit of Use quantity reference set is the HAS MPUU relationship with the same source MPP concept as the focus concept of this MPP FSN.</p> <p>4: If Unit of Use quantity reference set.value > 1 then use plural units for the associated Unit of Use quantity units.</p>

Description Component	Definition
Total_Quantity_Size_Details	<p>IF there exists only one MPUU M such that MPP has MPUU M THEN Quantity_Size ¹</p> <p>ELSEIF there exists more than one MPUU M such that MPP has MPUU M AND the given MPP is a source concept of MPP.has subpack relationship THEN Total_Subpack_Quantity " [" Subpack_Details "]" ²</p> <p>ELSEIF there exists more than one MPUU M such that MPP has MPUU M AND the given MPP is a destination concept of MPP.has subpack relationship THEN Total_Subpack_Quantity ³</p> <p>ELSEIF there exists more than one MPUU M such that MPP has MPUU M AND the given MPP is not a source or destination concept of MPP.has subpack relationship THEN Total_Quantity_Size ⁴</p> <p>ENDIF</p> <p>1: These relate to cases where the MPP represents a single-ingredient and single component product.</p> <p>2: These relate to cases where the MPP represents a multi-component product and the MPP has an associated subpack concept.</p> <p>3: These relate to cases where the MPP represents a multi-component product and the MPP is a subpack concept.</p> <p>4: These relate to cases where all of the following apply:</p> <ul style="list-style-type: none"> ◦ the MPP represents a multi-component product; and ◦ the MPP does not have an associated subpack; and ◦ the MPP is not a subpack concept. <p>These MPPs may or may not have MPP.has component pack relationships.</p>
Quantity_Size	<p>Unit of Use quantity reference set.value [" × " Unit of Use Size reference set.value " " Unit of Use Size reference set.unitId] ¹ " " Unit of Use quantity reference set.unitId</p> <p>1: Unit of Use Size reference set.value and Unit of Use Size reference set.unitId are included when Unit of Use Size reference set.value is not null.</p>
Total_Quantity_Size	" 1 pack"
Total_Subpack_Quantity	Total_Subpack_Quantity_Value " " Total_Subpack_Quantity_Units
Total_Subpack_Quantity_Value	<p>(Unit of Use quantity reference set.value + Unit of Use quantity reference set.value { + Unit of Use quantity reference set.value}) ¹</p> <p>1: This represents the sum of the multiple Unit of Use quantity reference set.value (by addition) for every MPP has MPUU relationship for a given MPP.</p>
Total_Subpack_Quantity_Units	<p>Unit of Use quantity reference set.unitId ^{1 2}</p> <p>1: Every Unit of Use quantity reference set.unitId associated with a Unit of Use quantity reference set.value references the same Unit of Measure concept. Therefore it is displayed only once in the FSN.</p> <p>2: If the sum of the multiple Unit of Use quantity reference set.value > 1 then use plural units.</p>
Subpack_Details	<p>MPP.Subpack quantity reference set.value " × "</p> <p>(Total_Subpack_Quantity_Value/MPP.Subpack quantity reference set.value) " " Total_Subpack_Quantity_Units</p>

Description Component	Definition
(medicinal product pack)	The semantic tag used in the FSN of all Medicinal Product Pack concepts.

L.3.2 Medicinal Product Pack Preferred Term full definition

The Preferred Term of a Medicinal Product Pack will, by default, follow the syntax:

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

The default PT of a Medicinal Product Pack can be more fully defined as follows.

Table 114: MPP PT description

Description Component	Definition
Medicinal Product Pack PT	MPUU_Details { " (&) " MPUU_Details } ^{1 2} " , " Total_Quantity_Size_Details 1: One MPUU_Details is included for each MPUU associated with the given MPP that is, every MPUU that exists as the destination of MPP HAS MPUU relationship. 2: If multiple MPUU_Details exist, the MPUU_Details are ordered based on the alphabetical order of the first ingredient, followed by the descending order of the first ingredient strength, followed by the same for each subsequent component (as per MPP.FSN).
MPUU_Details	IF there exists more than one MPUU M ¹ such that MPP has MPUU M THEN MPUU_ISFO " [" MPUU_Qty_Size "]" ELSE MPUU_ISFO ENDIF 1: These relate to cases where the MPP represents a multi-component product.
MPUU_ISFO	Ingredient_Strength { " + " Ingredient_Strength } ^{1 2 3 4} " " Form 1: One Ingredient_Strength is included for each HAS INTENDED ACTIVE INGREDIENT relationship that exists for the given MPUU. 2: The existence of multiple Ingredient_Strength relates to cases where the MPP represents a multi-ingredient product. 3: The strength component of Ingredient_Strength does not exist for certain MPUU FSN, for example, those representing inert substances, non-medicated dressings, diagnostic aids and nutritional supplements. 4: The Ingredient_Strengths are ordered alphabetically based on the Preferred Term of the MPUU's Basis of Strength Substance.
Ingredient_Strength	Ingredient_Strength as defined for the given MPUU's PT.
Form	Form as defined for the given MPUU's PT.

Description Component	Definition
MPUU_Qty_Size	<p>Unit of Use quantity reference set.value [" × " Unit of Use Size reference set.value " " Unit of Use Size reference set.unitId] ^{1 2} [" " Unit of Use quantity reference set.unitId] ^{3 4 5}</p> <p>1: Size value and size units are included when Unit of Use Size reference set.value exists.</p> <p>2: The referenced component in the <i>Unit of Use Size reference set</i> is the HAS UNIT OF USE relationship with the same source MPUU concept as the target concept of this MPP has MPUU relationship.</p> <p>3: Unit of Use quantity units is included when Unit of Use quantity reference set.unitId ≠ MPUU.has manufactured dose form.PT.</p> <p>4: The referenced component in the <i>Unit of Use quantity reference set</i> is the HAS MPUU relationship with the same source MPP concept as the focus concept of this MPP FSN.</p> <p>5: If Unit of Use quantity reference set.value > 1 then use plural units for the associated Unit of Use quantity units.</p>
Total_Quantity_Size_Details	<p>IF there exists only one MPUU M such that MPP has MPUU M THEN Quantity_Size ¹</p> <p>ELSEIF there exists more than one MPUU M such that MPP has MPUU M AND the given MPP is a source concept of MPP.has subpack relationship THEN Total_Subpack_Quantity " [" Subpack_Details "]" ²</p> <p>ELSEIF there exists more than one MPUU M such that MPP has MPUU M AND the given MPP is a destination concept of MPP.has subpack relationship THEN Total_Subpack_Quantity ³</p> <p>ELSEIF there exists more than one MPUU M such that MPP has MPUU M AND the given MPP is not a source or destination concept of MPP.has subpack relationship THEN Total_Quantity_Size ⁴</p> <p>ENDIF</p> <p>1: These relate to cases where the MPP represents a single-ingredient and single component product.</p> <p>2: These relate to cases where the MPP represents a multi-component product and the MPP has an associated subpack concept.</p> <p>3: These relate to cases where the MPP represents a multi-component product and the MPP is a subpack concept.</p> <p>4: These relate to cases where all of the following apply:</p> <ul style="list-style-type: none"> • the MPP represents a multi-component product; and • the MPP does not have an associated subpack; and • the MPP is not a subpack concept. <p>These MPPs may or may not have MPP.has component pack relationships.</p>

Description Component	Definition
Quantity_Size	Unit of Use quantity reference set.value [" × " Unit of Use Size reference set.value " " Unit of Use Size reference set.unitId] ¹ [" " Unit of Use quantity reference set.unitId] ² 1: Unit of Use Size reference set.value and Unit of Use Size reference set.unitId are included when Unit of Use Size reference set.value is not null. 2: Unit of Use quantity units is included when Unit of Use quantity reference set.unitId ≠ MPUU.has manufactured dose form.PT.
Total_Quantity_Size	" 1 pack"
Total_Subpack_Quantity	Total_Subpack_Quantity_Value " " Total_Subpack_Quantity_Units
Total_Subpack_Quantity_Value	(Unit of Use quantity reference set.value + Unit of Use quantity reference set.value { + Unit of Use quantity reference set.value }) ¹ 1: This represents the sum of the multiple Unit of Use quantity reference set.value (by addition) for every MPP has MPUU relationship for a given MPP.
Total_Subpack_Quantity_Units	Unit of Use quantity reference set.unitId ^{1 2} 1: Every Unit of Use quantity reference set.unitId associated with a Unit of Use quantity reference set.value references the same Unit of Measure concept. Therefore it is displayed only once in the FSN. 2: If the sum of the multiple Unit of Use quantity reference set.value > 1 then use plural units.
Subpack_Details	MPP.Subpack quantity reference set.value " × " (Total_Subpack_Quantity_Value/MPP.Subpack quantity reference set.value) " " Total_Subpack_Quantity_Units

L.4 Trade Product

L.4.1 Trade Product Fully Specified Name full definition

The Fully Specified Name of a Trade Product will, by default, follow the syntax:

TP FSN := TF_Name " (trade product)"

The FSN of a Trade Product can be more fully defined as follows.

Table 115: TP FSN description

Description Component	Definition
Trade Product FSN	TF_Name " (trade product)"
TF_Name	TP Where TP is TPUU.is a (TP).
(trade product)	The semantic tag used in the FSN of all Trade Product concepts.

L.4.2 Trade Product Preferred Term full definition

The Preferred Term of a Trade Product will, by default, follow the syntax:

TP PT := TF_Name

The default Preferred Term of a Trade Product can be more fully defined as follows.

Table 116: TP PT description

Description Component	Definition
Trade Product PT	TF_Name
TF_Name	TP Where TP is TPUU.is a (TP).PT

L.5 Trade Product Unit of Use

L.5.1 Trade Product Unit of Use Fully Specified Name full definition

The Fully Specified Name of a Trade Product Unit of Use will, by default, follow the syntax:

TPUU FSN := TF_Name [" " Other_Identifying_Information] " (" MPUU.Ingredients_With_Strength ") " Form [" , " MPUU.Unit_Of_Use_Details] " (trade product unit of use)"

The FSN of a Trade Product Unit of Use can be more fully defined as follows.

Table 117: TPUU FSN description

Description Component	Definition
Trade Product Unit of Use FSN	TF_Name ¹ [" " Other_Identifying_Information] ² " (" MPUU.Ingredients_With_Strength ") " ³ Form [" , " MPUU.Unit_Of_Use_Details] ⁴ " (trade product unit of use)" 1: TF_Name is the PT of the parent Trade product. 2: Other_Identifying_Information is included if it exists. 3: MPUU.Ingredients_With_Strength are determined based on the parent MPUU rules. 4: Unit_Of_Use_Details are included if they exist, based on the definition below.
Other_Identifying_Information	TPUU.other identifying information is the exact string derived from the internal use field Other_Identifying_Information
Ingredient_Strength	Ingredient_Strength, as derived from the associated MPUU FSN.
Form	If TPUU.has manufactured dose form.PT exists, this will be used Else use the MPUU.Form
Unit_Of_Use_Details	Unit_Of_Use_Details, as derived from the associated MPUU FSN.
(trade product unit of use)	The semantic tag used in the FSN of all Trade Product Unit of Use concepts.

L.5.2 Trade Product Unit of Use Preferred Term full definition

The Preferred Term of a Trade Product Unit of Use will, by default, follow the syntax:

```
TPUU PT := TF_Name [" " Other_Identifying_Information] [" ("
MPUU.Ingredients_With_Strength ")"] " " Form [" , "
MPUU.Unit_Of_Use_Details]
```

The default PT for a Trade Product Unit of Use can be more fully defined as follows.

Table 118: TPUU PT description

Description Component	Definition
Trade Product Unit of Use PT	<p>TF_Name¹ [" " Other_Identifying_Information]² [" (" MPUU.Ingredients_With_Strength ")"]³ " " Form [" , " MPUU.Unit_Of_Use_Details]⁴</p> <p>1: TF_Name is the PT of the parent Trade product. 2: Other_Identifying_Information is included if it exists. 3: MPUU.Ingredients_With_Strength are determined based on the parent MPUU rules. 4: Unit_Of_Use_Details are included if they exist, based on the definition below.</p>
Other_Identifying_Information	TPUU.other identifying information is the exact string derived from the internal use field Other_Identifying_Information
Ingredient_Strength	<p>Ingredient_Strength will be derived from the MPUU PT Ingredients_With_Strength.^{1 2 3}</p> <p>1: If there is only one IAI, THEN Other_Strength_Representation BoSS_Strength (That is, for single ingredient products, only strength details from the parent MPUU are retained. The ingredient name is not shown.) 2: If there is more than one IAI then Ingredient_Strength is not shown. (That is, for multi-ingredient products, neither ingredient nor strength details are shown.) 3: BoSS_Strength may be represented differently to the strength value (that is, value field) in the <i>Strength reference set</i>.</p>
Form	If TPUU.has manufactured dose form.PT exists, this will be used Else use the MPUU.Form
Unit_Of_Use_Details	Unit_Of_Use_Details, as derived from the associated MPUU FSN.

L.6 Trade Product Pack

L.6.1 Trade Product Pack Fully Specified Name full definition

The Fully Specified Name of a Trade Product Pack will, by default, follow the syntax:

```
TPP FSN := TF_Name " " MPP_FSN_Details " (trade product pack)"
```

The FSN of a Trade Product Pack can be more fully defined as follows.

Table 119: TPP FSN description

Description Component	Definition
Trade Product Pack FSN	TF_Name " " MPP_FSN_Details " (trade product pack)"
TF_Name	TF_Name is the Preferred Term of the Trade Product concept that is the destination of the HAS TP relationship from a given TPP.
MPP_FSN_Details	This is derived from the MPP FSN but without the semantic tag. (That is, " (medicinal product pack)" is not shown.)
(trade product pack)	The semantic tag used in the FSN of all Trade Product Pack concepts.

L.6.2 Trade Product Pack Preferred Term full definition

The Preferred Term of a Trade Product Pack will, by default, follow the syntax:

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

The default Preferred Term of a Trade Product Pack can be more fully defined as follows.

Table 120: TPP PT description

Description Component	Definition
Trade Product Pack PT	<p>TF_Name ¹ [" " Other_Identifying_Information] ² [" " Ingredient_Strength] ³ [" " Form] ⁴ [" (" Component_Details ")"] ⁵ ", " Total_Quantity_Size_Details</p> <p>1: TF_Name is the PT of the parent Trade Product. 2: Other_Identifying_Information is included if it exists. 3: Ingredient_Strength is not shown if the TPP has more than one HAS TPUU relationship. (That is, these are multicomponent products.) 4: Form is not shown if the TPP has more than one HAS TPUU relationship. (That is, these are multicomponent products.) 5: Component_Details is included if the TPP has more than one HAS TPUU relationship (that is, only for multicomponent products) and the following apply:</p> <ul style="list-style-type: none"> the TPP does not have an associated subpack; and the TPP is not a subpack concept; and the TPP does not have a Unit of Use quantity reference set.unitId.PT that contains "patch". <p>These TPPs may or may not have TPP.has component pack relationships.</p>
TF_Name	TF_Name is the Preferred Term of the Trade Product concept that is the destination of the HAS TP relationship from a given TPP.
Other_Identifying_Information	TPUU.other identifying information is the exact string derived from the internal use field Other_Identifying_Information
Ingredient_Strength	Ingredient_Strength will be derived from the TPUU PT.

Description Component	Definition
Form	Form will be derived from the TPUU PT.
Component_Details	<p>This component describes the details of each TPUU that is related to this TPP.</p> <p>IF the TPP.has TP relationship.PT contains "day" or "night" THEN Component_Details_Day_Night</p> <p>ELSEIF the TPP.IS A.MPP.PT contains "vaccine" THEN Component_Details_Vaccine</p> <p>ELSE Component_Qty_Size_Strength_Details</p>
Component_Details_Day_Night	<p>(TPP.UnitofUseQuantityRefset.value^{1 2} " x " "Day " TPP.UnitofUseQuantityRefset.unitId.PT³)⁴ ", "</p> <p>(TPP.UnitofUseQuantityRefset.value^{5 6} " x " "Night " TPP.UnitofUseQuantityRefset.unitId.PT)⁷</p> <p>1: This is the associated TPUU of the referenced component (TPP has TPUU) in which the PT contains "Day".</p> <p>2: This TPUU has an internal use field Preferred Component Order value of "1".</p> <p>3: Where plural units exist for any elements of this component, plural units are used instead.</p> <p>4: The individual elements comprising this component are derived from the same TPP. This represents the "Day" component of a Cold and Flu product.</p> <p>5: This is the associated TPUU of the referenced component (TPP has TPUU) in which the PT contains "Night".</p> <p>6: This TPUU has an internal use field Preferred Component Order value of "2".</p> <p>7: The individual elements comprising this component are derived from the same TPP. This represents the "Night" component of a Cold and Flu product.</p>

Description Component	Definition
Component_Details_Vaccine	<p>{ (TPP.UnitofUseQuantityRefset.value ¹ 2 " x "</p> <p>TPUU.UnitofUseSizeRefset.value ³ " "</p> <p>TPUU.UnitofUseSizeRefset.unitId.PT ⁴ " "</p> <p>"vaccine " ⁵</p> <p>TPUU.UnitofUseQuantityRefset.unitId.PT ", ") } ⁶</p> <p>(TPP.UnitofUseQuantityRefset.value ⁷ " x "</p> <p>TPUU.UnitofUseSizeRefset.value ⁸ " "</p> <p>TPUU.UnitofUseSizeRefset.unitId.PT " "</p> <p>"vaccine " "inert " ⁹</p> <p>TPUU.UnitofUseQuantityRefset.unitId.PT) ¹⁰</p> <p>1: This is the associated TPUU of the referenced component (TPP has TPUU) which PT contains "vaccine".</p> <p>2: This TPUU has an internal use field Preferred Component Order value of ≥"1" and < "n", where n represents the number of TPUUs for this TPP, for example, "2" if this TPP has two TPUUs.</p> <p>3: This is the referenced component (TPUU) which PT contains "vaccine" and the same TPUU as the component in (1) above.</p> <p>4: If plural units exist for any elements of this component, use plural units here.</p> <p>5: This is included if TPUU.has intended active ingredient.Substance.PT contains "vaccine".</p> <p>6: The individual elements comprising this optionally repeating component are derived from the same TPUU (which is associated with this TPP).</p> <p>7: This is the associated TPUU of the referenced component (TPP has TPUU) which PT contains "inert" or "vaccine". Its internal use field Preferred Component Order value is "n", where n represents the number of TPUUs for this TPP, for example, "2" if this TPP has two TPUUs.</p> <p>8: This is the same TPUU as the component in (7) above.</p> <p>9: IF the TPUU.has intended active ingredient.Substance.PT contains "vaccine" THEN "vaccine " is included</p> <p>ELSEIF the TPUU.has intended active ingredient.Substance.PT contains "inert" THEN "inert " is included.</p> <p>10: The individual elements comprising this mandatory component are derived from the same TPUU (which is associated with this TPP).</p>

Description Component	Definition
Component_Qty_Size_Strength_Details	<p>{ (TPP.UnitofUseQuantityRefset.value¹ " x "</p> <p>[BoSS_Strength]² ["enteric "]³</p> <p>[TPUU.UnitofUseSizeRefset.value⁴ " "</p> <p>TPUU.UnitofUseSizeRefset.unitId.PT⁵ " "]⁶</p> <p>TPP.UnitofUseQuantityRefset.unitId.PT⁷ ", ") }⁷</p> <p>(TPP.UnitofUseQuantityRefset.value⁸ " x "</p> <p>[BoSS_Strength]⁹</p> <p>[TPUU.UnitofUseSizeRefset.value¹⁰ " "</p> <p>TPUU.UnitofUseSizeRefset.unitId.PT¹¹ " "]¹¹</p> <p>["diluent "]¹²</p> <p>TPP.UnitofUseQuantityRefset.unitId.PT)¹³</p> <p>1: This is the associated TPUU of the referenced component (TPP has TPUU) that has an internal use field Preferred Component Order value of ≥ 1 and $< n$, where n represents the number of TPUUs for this TPP for example, "2" if this TPP has two TPUUs.</p> <p>2: This is included if the associated TPUU has a HAS AUSTRALIAN BoSS relationship and <i>Strength reference set</i> entry.</p> <p>3: This is included if TPUU.has manufactured dose form.Form.PT contains "enteric".</p> <p>4: This is the same TPUU as the component in (1) above.</p> <p>5: Where plural units exist for any elements of this component, plural units is used instead.</p> <p>6: Unit of use size value/units are included if:</p> <ul style="list-style-type: none"> • Unit of use size units \neq Unit of use quantity units; • Unit of use size value \neq Strength reference set.value; AND • Unit of use quantity units \neq "each". <p>7: The individual elements comprising this optionally repeating component are derived from the same TPUU (that is associated with this TPP).</p> <p>8: This is the associated TPUU of the referenced component (TPP has TPUU) with an internal use field Preferred Component Order value of "n" where n represents the number of TPUUs for this TPP, for example, "2" if this TPP has two TPUUs.</p> <p>9: This is included if the associated TPUU has a HAS AUSTRALIAN BoSS relationship and Strength reference set entry.</p> <p>10: This is the same TPUU as the component in (8) above.</p> <p>11: Unit of use size value/units are included if:</p> <ul style="list-style-type: none"> • Unit of use size units \neq Unit of use quantity units; • Unit of use size value \neq Strength reference set.value; AND • Unit of use quantity units \neq "each". <p>12: This is included if TPUU.has manufactured dose form.Form.PT is "diluent".</p> <p>13: The individual elements comprising this component are derived from the same TPUU (that is associated with this TPP).</p>
BoSS_Strength	<p>This is derived from the BoSS_Strength of the related MPUU PT.</p> <p>If an internal use non-normalised strength exists (that is, pre-unit conversion), this is used instead, for example, 500 mg, not 500000 micrograms.</p>

Description Component	Definition
Total_Quantity_Size_Details	This is derived from the Total_Quantity_Size_Details of the related MPP PT.

L.7 Containered Trade Product Pack

L.7.1 Containered Trade Product Pack Fully Specified Name full definition

The Fully Specified Name of a Containered Trade Product Pack will, by default, follow the syntax:

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

The FSN of a Containered Trade Product Pack can be more fully defined as follows.

Table 121: CTPP FSN description

Description Component	Definition
Containered Trade Product Pack FSN	TPP_FSN_Details [", " Container] ¹ " (containered trade product pack)" 1: If the MPUU.UnitofUseQuantityRefset.unitId.PT is the same as the CTPP.hasContainerType.PT then the container is not shown.
TPP_FSN_Details	This is derived from the TPP FSN but without the semantic tag. (That is, " (trade product pack)" is not shown.)
Container	CTPP.has container type.PT
(containered trade product pack)	The semantic tag used in the FSN of all Containered Trade Product Pack concepts.

L.7.2 Containered Trade Product Pack Preferred Term full definition

The Preferred Term of a Containered Trade Product Pack will, by default, follow the syntax:

```
CTPP PT :=   TPP_PT_Details [", " Container]
```

The default PT of a Containered Trade Product Pack can be more fully defined as follows.

Table 122: CTPP PT description

Description Component	Definition
Containerized Trade Product Pack PT	TPP_PT_Details ["", " Container"] ¹ 1: If the MPUU.UnitofUseQuantityRefset.unitId.PT is the same as the CTPP.hasContainerType.PT then the container is not shown.
TPP_PT_Details	This is derived from the TPP PT.
Container	CTPP.has container type.PT ¹

Appendix M Fully Specified Name (FSN) examples

Table 123: Fully Specified Name examples

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
amorolfine (medicinal product)	amorolfine 50 mg / 1 mL application (medicinal product unit of use)	amorolfine 50 mg / 1 mL application, 5 mL (medicinal product pack)	Loceryl Nail Lacquer (trade product)	Loceryl Nail Lacquer (amorolfine) 50 mg / 1 mL application (trade product unit of use)	Loceryl Nail Lacquer 5% (amorolfine) 50 mg / 1 mL application, 5 mL (trade product pack)	Loceryl Nail Lacquer (amorolfine) 50 mg / 1 mL application, 5 mL, bottle (containerised trade product pack)
oestradiol (medicinal product)	oestradiol 100 microgram / 24 hours patch (medicinal product unit of use)	oestradiol 100 microgram / 24 hours patch, 8 patches (medicinal product pack)	Estraderm (trade product)	Estraderm (oestradiol) 100 microgram / 24 hours) patch (trade product unit of use)	Estraderm 100 (oestradiol) 100 microgram / 24 hours) patch, 8 patches (trade product pack)	Estraderm (oestradiol) 100 microgram / 24 hours) patch, 8 patches, sachet (containerised trade product pack)
mesalazine (medicinal product)	mesalazine 500 mg granules, 500 mg sachet (medicinal product unit of use)	mesalazine 500 mg granules, 100 x 500 mg sachets (medicinal product pack)	Salofalk (trade product)	Salofalk (mesalazine 500 mg) granules, 500 mg sachet (trade product unit of use)	Salofalk (mesalazine 500 mg) granules, 100 x 500 mg sachets (trade product pack)	Salofalk (mesalazine 500 mg) granules, 100 x 500 mg sachets (containerised trade product pack)
ganciclovir (medicinal product)	ganciclovir 4.5 mg implant (medicinal product unit of use)	ganciclovir 4.5 mg implant, 1 implant (medicinal product pack)	Vitrasert (trade product)	Vitrasert (ganciclovir 4.5 mg) implant (trade product unit of use)	Vitrasert (ganciclovir 4.5 mg) implant, 1 implant (trade product pack)	Vitrasert (ganciclovir 4.5 mg) implant, 1 implant, sachet (containerised trade product pack)
carboplatin (medicinal product)	carboplatin 150 mg / 15 mL injection, 15 mL vial (medicinal product unit of use)	carboplatin 150 mg / 15 mL injection, 1 x 15 mL vial (medicinal product pack)	Carboplatin (Ebewe) (trade product)	Carboplatin (Ebewe) (carboplatin 150 mg / 15 mL) injection, 15 mL vial (trade product unit of use)	Carboplatin (Ebewe) (carboplatin 150 mg / 15 mL) injection, 1 x 15 mL vial (trade product pack)	Carboplatin (Ebewe) (carboplatin 150 mg / 15 mL) injection, 1 x 15 mL vial (containerised trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
frusemide (medicinal product)	frusemide 10 mg / 1 mL oral liquid, 1 mL measure (medicinal product unit of use)	frusemide 10 mg / 1 mL oral liquid, 30 mL (medicinal product pack)	Lasix (trade product)	Lasix (frusemide 10 mg / 1 mL) oral liquid: solution, 1 mL measure (trade product unit of use)	Lasix (frusemide 10 mg / 1 mL) oral liquid: solution, 30 mL (trade product pack)	Lasix (frusemide 10 mg / 1 mL) oral liquid: solution, 30 mL, bottle (containerised trade product pack)
nystatin (medicinal product)	nystatin 100000 international units pessary (medicinal product unit of use)	nystatin 100000 international units pessary, 15 pessaries (medicinal product pack)	Nilstat Cream Pessary (trade product)	Nilstat Cream Pessary (nystatin 100000 international units) pessary: shell (trade product unit of use)	Nilstat Cream Pessary (nystatin 100000 international units) pessary: shell, 15 pessaries (trade product pack)	Nilstat Cream Pessary (nystatin 100000 international units) pessary: shell, 15 pessaries, bottle (containerised trade product pack)
ondansetron (medicinal product)	ondansetron 4 mg wafer (medicinal product unit of use)	ondansetron 4 mg wafer, 10 wafers (medicinal product pack)	Zofran Zydis (trade product)	Zofran Zydis (ondansetron 4 mg) wafer (trade product unit of use)	Zofran Zydis (ondansetron 4 mg) wafer, 10 wafers (trade product pack)	Zofran Zydis (ondansetron 4 mg) wafer, 10 wafers, blister pack (containerised trade product pack)
amoxycillin (medicinal product)	amoxycillin 500 mg capsule (medicinal product unit of use)	amoxycillin 500 mg capsule, 20 capsules (medicinal product pack)	Amoxil (trade product)	Amoxil (amoxycillin 500 mg) capsule: hard (trade product unit of use)	Amoxil (amoxycillin 500 mg) capsule: hard, 20 capsules (trade product pack)	Amoxil (amoxycillin 500 mg) capsule: hard, 20 capsules, blister pack (containerised trade product pack)
salbutamol (medicinal product)	salbutamol 100 microgram / 1 actuation inhalation: pressurised, actuation (medicinal product unit of use)	salbutamol 100 microgram / 1 actuation inhalation: pressurised, 200 actuations (medicinal product pack)	Airomir (trade product)	Airomir (salbutamol 100 microgram / 1 actuation) inhalation: pressurised, actuation (trade product unit of use)	Airomir Inhaler (salbutamol 100 microgram / 1 actuation) inhalation: pressurised, 200 actuations (trade product pack)	Airomir (salbutamol 100 microgram / 1 actuation) inhalation: pressurised, 200 actuations, aerosol can: metered dose (containerised trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
ampicillin (medicinal product)	ampicillin 500 mg injection, 500 mg vial (medicinal product unit of use)	ampicillin 500 mg injection, 5 x 500 mg vials (medicinal product pack)	Austrapen (trade product)	Austrapen (ampicillin 500 mg) injection: powder for, 500 mg vial (trade product unit of use)	Austrapen (ampicillin 500 mg) injection: powder for, 5 x 500 mg vials (trade product pack)	Austrapen (ampicillin 500 mg) injection: powder for, 5 x 500 mg vials (containerised trade product pack)
cefaclor (medicinal product)	cefaclor 125 mg / 5 mL oral liquid: powder for, 5 mL measure (medicinal product unit of use)	cefaclor 125 mg / 5 mL oral liquid: powder for, 100 mL (medicinal product pack)	Ceclor (trade product)	Ceclor (cefaclor 125 mg / 5 mL) oral liquid: powder for, 5 mL measure (trade product unit of use)	Ceclor (cefaclor 125 mg / 5 mL) oral liquid: powder for, 100 mL (trade product pack)	Ceclor (cefaclor 125 mg / 5 mL) oral liquid: powder for, 100 mL, bottle (containerised trade product pack)
diclofenac (medicinal product)	diclofenac sodium 50 mg tablet: enteric (medicinal product unit of use)	diclofenac sodium 50 mg tablet: enteric, 50 tablets (medicinal product pack)	Voltaren (trade product)	Voltaren (diclofenac sodium 50 mg) tablet: enteric (trade product unit of use)	Voltaren (diclofenac sodium 50 mg) tablet: enteric, 50 tablets (trade product pack)	Voltaren (diclofenac sodium 50 mg) tablet: enteric, 50 tablets, bottle (containerised trade product pack)
terbinafine (medicinal product)	terbinafine hydrochloride 10 mg / 1 g cream (medicinal product unit of use)	terbinafine hydrochloride 10 mg / 1 g cream, 15 g (medicinal product pack)	Lamisil (trade product)	Lamisil (terbinafine hydrochloride 10 mg / 1 g) cream (trade product unit of use)	Lamisil (terbinafine hydrochloride 10 mg / 1 g) cream, 15 g (trade product pack)	Lamisil (terbinafine hydrochloride 10 mg / 1 g) cream, 15 g, tube (containerised trade product pack)
budesonide + eformoterol (medicinal product)	budesonide 100 microgram / 1 actuation + eformoterol fumarate dihydrate 6 microgram / 1 actuation inhalation: powder for, actuation (medicinal product unit of use)	budesonide 100 microgram / 1 actuation + eformoterol fumarate dihydrate 6 microgram / 1 actuation inhalation: powder for, 120 actuations (medicinal product pack)	Symbicort Turbuhaler 100 / 6 (trade product)	Symbicort Turbuhaler 100 / 6 (budesonide 100 microgram / 1 actuation + eformoterol fumarate dihydrate 6 microgram / 1 actuation) inhalation: powder for, actuation (trade product unit of use)	Symbicort Turbuhaler 100 / 6 (budesonide 100 microgram / 1 actuation + eformoterol fumarate dihydrate 6 microgram / 1 actuation) inhalation: powder for, 120 actuations (trade product pack)	Symbicort Turbuhaler 100 / 6 (budesonide 100 microgram / 1 actuation + eformoterol fumarate dihydrate 6 microgram / 1 actuation) inhalation: powder for, 120 actuations, inhaler: dry powder (containerised trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
fluphenazine decanoate (medicinal product)	fluphenazine decanoate 12.5 mg / 0.5 mL injection, 0.5 mL ampoule (medicinal product unit of use)	fluphenazine decanoate 12.5 mg / 0.5 mL injection, 5 x 0.5 mL ampoules (medicinal product pack)	Modecate (trade product)	Modecate (fluphenazine decanoate 12.5 mg / 0.5 mL) injection: solution, 0.5 mL ampoule (trade product unit of use)	Modecate (fluphenazine decanoate 12.5 mg / 0.5 mL) injection: solution, 5 x 0.5 mL ampoules (trade product pack)	Modecate (fluphenazine decanoate 12.5 mg / 0.5 mL) injection: solution, 5 x 0.5 mL ampoules (containerized trade product pack)
sodium chloride (medicinal product)	sodium chloride 9 g / 1 L injection, 1 L bag (medicinal product unit of use)	sodium chloride 9 g / 1 L injection, 1 x 1 L bag (medicinal product pack)	Sodium Chloride (Baxter) (trade product)	Sodium Chloride (Baxter) (sodium chloride 9 g / 1 L) injection: solution, 1 L bag (trade product unit of use)	Sodium Chloride (Baxter) (sodium chloride 9 g / 1 L) injection: solution, 1 x 1 L bag (trade product pack)	Sodium Chloride (Baxter) (sodium chloride 9 g / 1 L) injection: solution, 1 x 1 L bag (containerized trade product pack)
ipratropium (medicinal product)	ipratropium bromide 500 microgram / 1 mL inhalation: solution, 1 mL ampoule (medicinal product unit of use)	ipratropium bromide 500 microgram / 1 mL inhalation: solution, 30 x 1 mL ampoules (medicinal product pack)	Atrovent Adult UDV (trade product)	Atrovent Adult UDV (ipratropium bromide 500 microgram / 1 mL) inhalation: solution, 1 mL ampoule (trade product unit of use)	Atrovent Adult UDV (ipratropium bromide 500 microgram / 1 mL) inhalation: solution for, 30 x 1 mL ampoules (trade product pack)	Atrovent Adult UDV (ipratropium bromide 500 microgram / 1 mL) inhalation: solution, 30 x 1 mL ampoules (containerized trade product pack)
lamivudine + zidovudine (medicinal product)	lamivudine 150 mg + zidovudine 300 mg tablet (medicinal product unit of use)	lamivudine 150 mg + zidovudine 300 mg tablet, 60 tablets (medicinal product pack)	Combivir (trade product)	Combivir (lamivudine 150 mg + zidovudine 300 mg) tablet: film-coated (trade product unit of use)	Combivir (lamivudine 150 mg + zidovudine 300 mg) tablet: film-coated, 60 tablets (trade product pack)	Combivir (lamivudine 150 mg + zidovudine 300 mg) tablet: film-coated, 60 tablets, bottle (containerized trade product pack)
amlodipine + atorvastatin (medicinal product)	amlodipine 10 mg + atorvastatin 20 mg tablet (medicinal product unit of use)	amlodipine 10 mg + atorvastatin 20 mg tablet, 30 tablets (medicinal product pack)	Caduet 10 / 20 (trade product)	Caduet 10 / 20 (amlodipine 10 mg + atorvastatin 20 mg) tablet: film-coated (trade product unit of use)	Caduet 10 / 20 (amlodipine 10 mg + atorvastatin 20 mg) tablet: film-coated, 30 tablets (trade product pack)	Caduet 10 / 20 (amlodipine 10 mg + atorvastatin 20 mg) tablet: film-coated, 30 tablets, blister pack (containerized trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
antazoline + naphazoline (medicinal product)	antazoline phosphate 5 mg / 1 mL + naphazoline hydrochloride 500 microgram / 1 mL eye drops (medicinal product unit of use)	antazoline phosphate 5 mg / 1 mL + naphazoline hydrochloride 500 microgram / 1 mL eye drops, 15 mL (medicinal product pack)	Albalon-A Liquifilm 0.5% / 0.05% (trade product)	Albalon-A Liquifilm 0.5% / 0.05% (antazoline phosphate 5 mg / 1 mL + naphazoline hydrochloride 500 microgram / 1 mL) eye drops: solution (trade product unit of use)	Albalon-A Liquifilm 0.5% / 0.05% (antazoline phosphate 5 mg / 1 mL + naphazoline hydrochloride 500 microgram / 1 mL) eye drops: solution, 15 mL (trade product pack)	Albalon-A Liquifilm 0.5% 0.05% (antazoline phosphate 5 mg / 1 mL + naphazoline hydrochloride 500 microgram / 1 mL) eye drops: solution, 15 mL, bottle (containered trade product pack)
codeine + paracetamol (medicinal product)	codeine phosphate 30 mg + paracetamol 500 mg tablet (medicinal product unit of use)	codeine phosphate 30 mg + paracetamol 500 mg tablet, 20 tablets (medicinal product pack)	Panadeine Forte (trade product)	Panadeine Forte (codeine phosphate 30 mg + paracetamol 500 mg) tablet: uncoated (trade product unit of use)	Panadeine Forte (codeine phosphate 30 mg + paracetamol 500 mg) tablet: uncoated, 20 tablets (trade product pack)	Panadeine Forte (codeine phosphate 30 mg + paracetamol 500 mg) tablet: uncoated, 20 tablets, blister pack (containered trade product pack)
<ul style="list-style-type: none"> ethinyloestradiol + levonorgestrel (medicinal product) inert substance (medicinal product) 	<ul style="list-style-type: none"> ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet (medicinal product unit of use) ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet (medicinal product unit of use) ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet (medicinal product unit of use) 	<ul style="list-style-type: none"> ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet [40 tablets] (& ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [24 tablets] (& ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [20 tablets] (& inert substance 	<ul style="list-style-type: none"> Triphasil (trade product) 	<ul style="list-style-type: none"> Triphasil (ethinyloestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated (trade product unit of use) Triphasil (ethinyloestradiol 40 microgram + levonorgestrel 75 microgram) tablet: sugar-coated (trade product unit of use) Triphasil 	<ul style="list-style-type: none"> Triphasil (ethinyloestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated [40 tablets] (& ethinyloestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated [24 tablets] (& ethinyloestradiol 40 microgram + levonorgestrel 75 microgram) 	<ul style="list-style-type: none"> Triphasil (ethinyloestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated [40 tablets] (& ethinyloestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated [24 tablets] (& ethinyloestradiol 40 microgram + levonorgestrel 75 microgram)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
	product unit of use) • inert substance tablet (medicinal product unit of use)	tablet [28 tablets], 112 tablets [4 x 28 tablets] (medicinal product pack) • ethinylloestradiol 30 microgram + levonorgestrel 125 microgram tablet [10 tablets] (& ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet [6 tablets] (& ethinylloestradiol 40 microgram + levonorgestrel 75 microgram tablet [5 tablets] (& inert substance tablet [7 tablets], 28 tablets (medicinal product pack)		(ethinylloestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated (trade product unit of use) • Triphasil (inert substance) tablet: sugar-coated (trade product unit of use)	tablet: sugar-coated [20 tablets] (& (inert substance) tablet: sugar-coated [28 tablets], 112 tablets [4 x 28 tablets] (trade product pack) • Triphasil (ethinylloestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated [10 tablets] (& (ethinylloestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated [6 tablets] (& (ethinylloestradiol 40 microgram + levonorgestrel 75 microgram) tablet: sugar-coated [5 tablets] (& (inert substance) tablet: sugar-coated [7 tablets], 28 tablets (trade product pack)	tablet: sugar-coated [20 tablets] (& (inert substance) tablet: sugar-coated [28 tablets], 112 tablets [4 x 28 tablets], blister pack (containerized trade product pack) • Triphasil (ethinylloestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated [10 tablets] (& (ethinylloestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated [6 tablets] (& (ethinylloestradiol 40 microgram + levonorgestrel 75 microgram) tablet: sugar-coated [5 tablets] (& (inert substance) tablet: sugar-coated [7 tablets], 28 tablets, blister pack (containerized trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
<ul style="list-style-type: none"> ethinyloestradiol + norethisterone (medicinal product) 	<ul style="list-style-type: none"> ethinyloestradiol 35 microgram + norethisterone 500 microgram tablet (medicinal product unit of use) 	<ul style="list-style-type: none"> ethinyloestradiol 35 microgram + norethisterone 500 microgram tablet, 84 tablets [4 x 21 tablets] (medicinal product pack) ethinyloestradiol 35 microgram + norethisterone 500 microgram tablet, 21 tablets (medicinal product pack) 	<ul style="list-style-type: none"> Brevinor 21 Day (trade product) 	<ul style="list-style-type: none"> Brevinor 21 Day (ethinyloestradiol 35 microgram + norethisterone 500 microgram) tablet: uncoated (trade product unit of use) 	<ul style="list-style-type: none"> Brevinor 21 Day (ethinyloestradiol 35 microgram + norethisterone 500 microgram) tablet: uncoated, 84 tablets [4 x 21 tablets] (trade product pack) Brevinor 21 Day (ethinyloestradiol 35 microgram + norethisterone 500 microgram) tablet: uncoated, 21 tablets (trade product pack) 	<ul style="list-style-type: none"> Brevinor 21 Day (ethinyloestradiol 35 microgram + norethisterone 500 microgram) tablet: uncoated, 84 tablets [4 x 21 tablets], blister pack (containerised trade product pack) Brevinor 21 Day (ethinyloestradiol 35 microgram + norethisterone 500 microgram) tablet: uncoated, 21 tablets, blister pack (containerised trade product pack)
<ul style="list-style-type: none"> norethisterone acetate + oestradiol (medicinal product) oestradiol (medicinal product) 	<ul style="list-style-type: none"> oestradiol 2 mg tablet (medicinal product unit of use) norethisterone acetate 1 mg + oestradiol 2 mg tablet (medicinal product unit of use) oestradiol 1 mg tablet (medicinal product unit of use) 	<ul style="list-style-type: none"> norethisterone acetate 1 mg + oestradiol 2 mg tablet [10 tablets] (& oestradiol 1 mg tablet [6 tablets] (& oestradiol 2 mg tablet [12 tablets], 1 pack (medicinal product pack) 	<ul style="list-style-type: none"> Trisequens (trade product) 	<ul style="list-style-type: none"> Trisequens (oestradiol 2 mg) tablet: film-coated (trade product unit of use) Trisequens (norethisterone acetate 1 mg + oestradiol 2 mg) tablet: film-coated (trade product unit of use) Trisequens (oestradiol 1 mg) tablet: film-coated (trade product unit of use) 	<ul style="list-style-type: none"> Trisequens (norethisterone acetate 1 mg + oestradiol 2 mg) tablet: film-coated [10 tablets] (& oestradiol 1 mg) tablet: film-coated [6 tablets] (& oestradiol 2 mg) tablet: film-coated [12 tablets], 1 pack (trade product pack) 	<ul style="list-style-type: none"> Trisequens (norethisterone acetate 1 mg + oestradiol 2 mg) tablet: film-coated [10 tablets] (& oestradiol 1 mg) tablet: film-coated [6 tablets] (& oestradiol 2 mg) tablet: film-coated [12 tablets], 1 pack, dial dispenser pack (containerised trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
<ul style="list-style-type: none"> calcium carbonate (medicinal product) risedronate (medicinal product) 	<ul style="list-style-type: none"> risedronate sodium 35 mg tablet: enteric (medicinal product unit of use) calcium (as carbonate) 500 mg tablet (medicinal product unit of use) 	<ul style="list-style-type: none"> calcium (as carbonate) 500 mg tablet [24 tablets] (&) risedronate sodium 35 mg tablet: enteric [4 tablets], 1 pack (medicinal product pack) 	<ul style="list-style-type: none"> Actonel EC Combi (trade product) Actonel EC Once-a-Week (trade product) Calcium Carbonate (Sanofi-Aventis) (trade product) 	<ul style="list-style-type: none"> Actonel EC Once-a-Week (risedronate sodium 35 mg) tablet: enteric (trade product unit of use) Calcium Carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg) tablet: film-coated (trade product unit of use) 	<ul style="list-style-type: none"> Actonel EC Combi (calcium (as carbonate) 500 mg) tablet: film-coated [24 tablets] (&) (risedronate sodium 35 mg) tablet: enteric [4 tablets], 1 pack (trade product pack) Calcium Carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg) tablet: film-coated, 24 tablets (trade product pack) Actonel EC Once-a-Week (risedronate sodium 35 mg) tablet: enteric, 4 tablets (trade product pack) 	<ul style="list-style-type: none"> Actonel EC Combi (calcium (as carbonate) 500 mg) tablet: film-coated [24 tablets] (&) (risedronate sodium 35 mg) tablet: enteric [4 tablets], 1 pack, blister pack (containered trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
<ul style="list-style-type: none"> risperidone (medicinal product) inert substance (medicinal product) 	<ul style="list-style-type: none"> risperidone 25 mg injection: modified release, 25 mg vial (medicinal product unit of use) inert substance diluent, 2 mL syringe (medicinal product unit of use) 	<ul style="list-style-type: none"> inert substance diluent [1 x 2 mL syringe] (& risperidone 25 mg injection: modified release [1 x 25 mg vial], 1 pack (medicinal product pack) 	<ul style="list-style-type: none"> Risperdal I Consta (trade product) 	<ul style="list-style-type: none"> Risperdal Consta (risperidone 25 mg) injection: modified release, 25 mg vial (trade product unit of use) Risperdal Consta (inert substance) diluent, 2 mL syringe (trade product unit of use) 	<ul style="list-style-type: none"> Risperdal Consta (inert substance) diluent [1 x 2 mL syringe] (& (risperidone 25 mg) injection: modified release [1 x 25 mg vial], 1 pack (trade product pack) 	<ul style="list-style-type: none"> Risperdal Consta (inert substance) diluent [1 x 2 mL syringe] (& (risperidone 25 mg) injection: modified release [1 x 25 mg vial], 1 pack, composite pack (containerised trade product pack)
<ul style="list-style-type: none"> lanreotide (medicinal product) inert substance (medicinal product) 	<ul style="list-style-type: none"> lanreotide 30 mg injection: modified release, 30 mg vial (medicinal product unit of use) inert substance diluent, 2 mL ampoule (medicinal product unit of use) 	<ul style="list-style-type: none"> inert substance diluent [1 x 2 mL ampoule] (& lanreotide 30 mg injection: modified release [1 x 30 mg vial], 1 pack (medicinal product pack) 	<ul style="list-style-type: none"> Somatuline LA (trade product) 	<ul style="list-style-type: none"> Somatuline LA (lanreotide 30 mg) injection: modified release, 30 mg vial (trade product unit of use) Somatuline LA (inert substance) diluent, 2 mL ampoule (trade product unit of use) 	<ul style="list-style-type: none"> Somatuline LA (inert substance) diluent [1 x 2 mL ampoule] (& (lanreotide 30 mg) injection: modified release [1 x 30 mg vial], 1 pack (trade product pack) 	<ul style="list-style-type: none"> Somatuline LA (inert substance) diluent [1 x 2 mL ampoule] (& (lanreotide 30 mg) injection: modified release [1 x 30 mg vial], 1 pack, composite pack (containerised trade product pack)
<ul style="list-style-type: none"> epoprostenol (medicinal product) inert substance (medicinal product) 	<ul style="list-style-type: none"> epoprostenol 500 microgram injection, 500 microgram vial (medicinal product unit of use) inert substance diluent, 50 mL vial (medicinal product unit of use) 	<ul style="list-style-type: none"> epoprostenol 500 microgram injection [1 x 500 microgram vial] (& inert substance diluent [1 x 50 mL vial], 1 pack (medicinal product pack) 	<ul style="list-style-type: none"> Flolan (trade product) 	<ul style="list-style-type: none"> Flolan (epoprostenol 500 microgram) injection: powder for, 500 microgram vial (trade product unit of use) Flolan (inert substance) diluent, 50 mL vial (trade product unit of use) 	<ul style="list-style-type: none"> Flolan (epoprostenol 500 microgram) injection: powder for [1 x 500 microgram vial] (& (inert substance) diluent [1 x 50 mL vial], 1 pack (trade product pack) 	<ul style="list-style-type: none"> Flolan (epoprostenol 500 microgram) injection: powder for [1 x 500 microgram vial] (& (inert substance) diluent [1 x 50 mL vial], 1 pack, composite pack (containerised trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
calcium + chloride + polygeline + potassium + sodium (medicinal product)	calcium 125 mg / 500 mL + chloride 2.574 g / 500 mL + polygeline 17.5 g / 500 mL + potassium 99.71 mg / 500 mL + sodium 1.67 g / 500 mL injection, 500 mL bottle (medicinal product unit of use)	calcium 125 mg / 500 mL + chloride 2.574 g / 500 mL + polygeline 17.5 g / 500 mL + potassium 99.71 mg / 500 mL + sodium 1.67 g / 500 mL injection, 1 x 500 mL bottle (medicinal product pack)	Haemacel (trade product)	Haemacel (calcium 125 mg / 500 mL + chloride 2.574 g / 500 mL + polygeline 17.5 g / 500 mL + potassium 99.71 mg / 500 mL + sodium 1.67 g / 500 mL) injection: solution, 500 mL bottle (trade product unit of use)	Haemacel (calcium 125 mg / 500 mL + chloride 2.574 g / 500 mL + polygeline 17.5 g / 500 mL + potassium 99.71 mg / 500 mL + sodium 1.67 g / 500 mL) injection: solution, 1 x 500 mL bottle (trade product pack)	Haemacel (calcium 125 mg / 500 mL + chloride 2.574 g / 500 mL + polygeline 17.5 g / 500 mL + potassium 99.71 mg / 500 mL + sodium 1.67 g / 500 mL) injection: solution, 1 x 500 mL bottle (contained trade product pack)
<ul style="list-style-type: none"> peginterferon alfa-2b (medicinal product) ribavirin (medicinal product) inert substance (medicinal product) 	<ul style="list-style-type: none"> peginterferon alfa-2b 100 microgram injection, 100 microgram cartridge (medicinal product unit of use) ribavirin 200 mg capsule (medicinal product unit of use) inert substance diluent, 0.5 mL cartridge (medicinal product unit of use) 	<ul style="list-style-type: none"> inert substance diluent [4 x 0.5 mL cartridges] (& peginterferon alfa-2b 100 microgram injection [4 x 100 microgram cartridges] (& ribavirin 200 mg capsule [112 capsules], 1 pack (medicinal product pack) 	<ul style="list-style-type: none"> Rebetrol (trade product) Peg-Intron Redipen Injector (trade product) Pegatron Combination Therapy with Redipen Injector (trade product) 	<ul style="list-style-type: none"> Peg-Intron Redipen Injector (peginterferon alfa-2b 100 microgram) injection: powder for, 100 microgram cartridge (trade product unit of use) Rebetol (ribavirin 200 mg) capsule: hard (trade product unit of use) Peg-Intron Redipen Injector (inert substance) diluent, 0.5 mL cartridge (trade product unit of use) 	<ul style="list-style-type: none"> Pegatron Combination Therapy with Redipen Injector (inert substance) diluent [4 x 0.5 mL cartridges] (& (peginterferon alfa-2b 100 microgram) injection: powder for [4 x 100 microgram cartridges] (& (ribavirin 200 mg) capsule: hard [112 capsules], 1 pack (trade product pack) Peg-Intron Redipen Injector (inert substance) diluent [4 x 0.5 mL 	<ul style="list-style-type: none"> Pegatron Combination Therapy with Redipen Injector (inert substance) diluent [4 x 0.5 mL cartridges] (& (peginterferon alfa-2b 100 microgram) injection: powder for [4 x 100 microgram cartridges] (& (ribavirin 200 mg) capsule: hard [112 capsules], 1 pack, composite pack (contained trade product pack) Peg-Intron Redipen Injector (inert substance) diluent [4 x 0.5 mL

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
					cartridges] (& (peginterferon alfa-2b 100 microgram) injection: powder for [4 x 100 microgram cartridges], 1 pack (trade product pack) <ul style="list-style-type: none"> Rebetol (ribavirin 200 mg) capsule: hard, 112 capsules (trade product pack) 	cartridges] (& (peginterferon alfa-2b 100 microgram) injection: powder for [4 x 100 microgram cartridges], 1 pack, dual chamber composite pack (containered trade product pack)
calcium chloride dihydrate + potassium chloride + sodium chloride (medicinal product)	calcium chloride dihydrate 330 mg / 1 L + potassium chloride 300 mg / 1 L + sodium chloride 8.6 g / 1 L injection, 1 L bag (medicinal product unit of use)	calcium chloride dihydrate 330 mg / 1 L + potassium chloride 300 mg / 1 L + sodium chloride 8.6 g / 1 L injection, 1 x 1 L bag (medicinal product pack)	Ringer's (Fresenius Kabi) (trade product)	Ringer's (Fresenius Kabi) (calcium chloride dihydrate 330 mg / 1 L + potassium chloride 300 mg / 1 L + sodium chloride 8.6 g / 1 L) injection: solution, 1 L bag (trade product unit of use)	Ringer's (Fresenius Kabi) (calcium chloride dihydrate 330 mg / 1 L + potassium chloride 300 mg / 1 L + sodium chloride 8.6 g / 1 L) injection: solution, 1 x 1 L bag (trade product pack)	Ringer's (Fresenius Kabi) (calcium chloride dihydrate 330 mg / 1 L + potassium chloride 300 mg / 1 L + sodium chloride 8.6 g / 1 L) injection: solution, 1 x 1 L bag (containered trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
<ul style="list-style-type: none"> esomeprazole (medicinal product) clarithromycin (medicinal product) amoxicillin (medicinal product) 	<ul style="list-style-type: none"> esomeprazole 20 mg tablet: enteric (medicinal product unit of use) clarithromycin 500 mg tablet (medicinal product unit of use) amoxicillin 500 mg capsule (medicinal product unit of use) 	<ul style="list-style-type: none"> amoxicillin 500 mg capsule [28 capsules] (& clarithromycin 500 mg tablet [14 tablets] (& esomeprazole 20 mg tablet: enteric [14 tablets], 1 pack (medicinal product pack) esomeprazole 20 mg tablet: enteric, 14 tablets (medicinal product pack) clarithromycin 500 mg tablet, 14 tablets (medicinal product pack) amoxicillin 500 mg capsule, 28 capsules (medicinal product pack) 	<ul style="list-style-type: none"> Nexium Hp7 (trade product) Nexium (trade product) Klacid (trade product) Amoxil (trade product) 	<ul style="list-style-type: none"> Nexium (esomeprazole 20 mg) tablet: enteric (trade product unit of use) Klacid (clarithromycin 500 mg) tablet: film-coated (trade product unit of use) Amoxil (amoxicillin 500 mg) capsule: hard (trade product unit of use) 	<ul style="list-style-type: none"> Nexium Hp7 (amoxicillin 500 mg) capsule: hard [28 capsules] (& clarithromycin 500 mg) tablet: film-coated [14 tablets] (& esomeprazole 20 mg) tablet: enteric [14 tablets], 1 pack (trade product pack) Klacid (clarithromycin 500 mg) tablet: film-coated, 14 tablets (trade product pack) Amoxil (amoxicillin 500 mg) capsule: hard, 28 capsules (trade product pack) Nexium (esomeprazole 20 mg) tablet: enteric, 14 tablets (trade product pack) 	<ul style="list-style-type: none"> Nexium Hp7 (amoxicillin 500 mg) capsule: hard [28 capsules] (& clarithromycin 500 mg) tablet: film-coated [14 tablets] (& esomeprazole 20 mg) tablet: enteric [14 tablets], 1 pack, composite pack (containerized trade product pack) Amoxil (amoxicillin 500 mg) capsule: hard, 28 capsules, blister pack (containerized trade product pack) Klacid (clarithromycin 500 mg) tablet: film-coated, 14 tablets, blister pack (containerized trade product pack) Nexium (esomeprazole 20 mg) tablet: enteric, 14 tablets, blister pack (containerized trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
mirtazapine (medicinal product)	mirtazapine 15 mg tablet: orally disintegrating (medicinal product unit of use)	mirtazapine 15 mg tablet: orally disintegrating, 30 tablets (medicinal product pack)	Avanza Soltab (trade product)	Avanza Soltab (mirtazapine 15 mg) tablet: orally disintegrating (trade product unit of use)	Avanza Soltab (mirtazapine 15 mg) tablet: orally disintegrating, 30 tablets (trade product pack)	Avanza Soltab (mirtazapine 15 mg) tablet: orally disintegrating, 30 tablets, blister pack (containerised trade product pack)
vinblastine (medicinal product)	vinblastine sulfate 10 mg / 10 mL injection, 10 mL vial (medicinal product unit of use)	vinblastine sulfate 10 mg / 10 mL injection, 5 x 10 mL vials (medicinal product pack)	Vinblastine Sulfate (DBL) (trade product)	Vinblastine Sulfate (DBL) (vinblastine sulfate 10 mg / 10 mL) injection: solution, 10 mL vial (trade product unit of use)	Vinblastine Sulfate (DBL) (vinblastine sulfate 10 mg / 10 mL) injection: solution, 5 x 10 mL vials (trade product pack)	Vinblastine Sulfate (DBL) (vinblastine sulfate 10 mg / 10 mL) injection: solution, 5 x 10 mL vials (containerised trade product pack)
insulin isophane human + insulin neutral human (medicinal product)	insulin isophane human 70 international units / 1 mL + insulin neutral human 30 international units / 1 mL injection, cartridge (medicinal product unit of use)	insulin isophane human 70 international units / 1 mL + insulin neutral human 30 international units / 1 mL injection, 5 x 3 mL cartridges (medicinal product pack)	Mixtard 30 / 70 Innolet	Mixtard 30 / 70 Innolet (insulin isophane human 70 international units / 1 mL + insulin neutral human 30 international units / 1 mL) injection: suspension, cartridge (trade product unit of use)	Mixtard 30 / 70 Innolet (insulin isophane human 70 international units / 1 mL + insulin neutral human 30 international units / 1 mL) injection: suspension, 5 x 3 mL cartridges, cartridge (containerised trade product pack)	Mixtard 30 / 70 Innolet (insulin isophane human 70 international units / 1 mL + insulin neutral human 30 international units / 1 mL) injection: suspension, 5 x 3 mL cartridges (containerised trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
atropine sulfate monohydrate + hyoscine hydrobromide trihydrate + hyoscyamine + kaolin + pectin (medicinal product)	atropine sulfate monohydrate 19.4 microgram / 30 mL + hyoscine hydrobromide trihydrate 6.5 microgram / 30 mL + hyoscyamine sulfate dihydrate 103.7 microgram / 30 mL + kaolin 6 g / 30 mL + pectin 142.8 mg / 30 mL oral liquid, 30 mL measure (medicinal product unit of use)	atropine sulfate monohydrate 19.4 microgram / 30 mL + hyoscine hydrobromide trihydrate 6.5 microgram / 30 mL + hyoscyamine sulfate dihydrate 103.7 microgram / 30 mL + kaolin 6 g / 30 mL + pectin 142.8 mg / 30 mL oral liquid, 200 mL (medicinal product pack)	Donnagel	Donnagel (atropine sulfate monohydrate 19.4 microgram / 30 mL + hyoscine hydrobromide trihydrate 6.5 microgram / 30 mL + hyoscyamine sulfate dihydrate 103.7 microgram / 30 mL + kaolin 6 g / 30 mL + pectin 142.8 mg / 30 mL) oral liquid: suspension, 30 mL	Donnagel (atropine sulfate monohydrate 19.4 microgram / 30 mL + hyoscine hydrobromide trihydrate 6.5 microgram / 30 mL + hyoscyamine sulfate dihydrate 103.7 microgram / 30 mL + kaolin 6 g / 30 mL + pectin 142.8 mg / 30 mL) oral liquid: suspension, 200 mL, bottle (containerized trade product pack)	Donnagel (atropine sulfate monohydrate 19.4 microgram / 30 mL + hyoscine hydrobromide trihydrate 6.5 microgram / 30 mL + hyoscyamine sulfate dihydrate 103.7 microgram / 30 mL + kaolin 6 g / 30 mL + pectin 142.8 mg / 30 mL) oral liquid: suspension, 200 mL, bottle (containerized trade product pack)

Appendix N Preferred Term (PT) examples

Table 124: Preferred Term examples

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
amorolfine	amorolfine 5% application	amorolfine 5% application, 5 mL	Loceryl Nail Lacquer	Loceryl Nail Lacquer 5% application	Loceryl Nail Lacquer 5% application, 5 mL	Loceryl Nail Lacquer 5% application, 5 mL, bottle
oestradiol	oestradiol 100 microgram/ 24 hours patch	oestradiol 100 microgram/ 24 hours patch, 8	Estraderm	Estraderm 100 microgram/ 24 hour patch	Estraderm 100 microgram/ 24 hours patch, 8	Estraderm 100 microgram/ 24 hours patch, 8, sachet
mesalazine	mesalazine 500 mg granules, sachet	mesalazine 500 mg granules, 100 sachets	Salofalk	Salofalk 500 mg granules, 500 mg sachet	Salofalk 500 mg granules, 100 sachets	Salofalk 500 mg granules, 100 sachets
ganciclovir	ganciclovir 4.5 mg implant	ganciclovir 4.5 mg implant, 1	Vitrasert	Vitrasert 4.5 mg implant	Vitrasert 4.5 mg implant, 1	Vitrasert 4.5 mg implant, 1, sachet
carboplatin	carboplatin 150 mg/15 mL injection, vial	carboplatin 150 mg/15 mL injection, 15 mL vial	Carboplatin (Ebewe)	Carboplatin (Ebewe) 150 mg/15 mL injection, 15 mL vial	Carboplatin (Ebewe) 150 mg/15 mL injection, 15 mL vial	Carboplatin (Ebewe) 150 mg/15 mL injection, 15 mL vial
frusemide	frusemide 10 mg/mL oral liquid	frusemide 10 mg/mL oral liquid, 30 mL	Lasix	Lasix 10 mg/mL oral liquid: solution	Lasix 10 mg/mL oral liquid: solution, 30 mL	Lasix 10 mg/mL oral liquid: solution, 30 mL, bottle
nystatin	nystatin 100 000 units pessary	nystatin 100 000 units pessary, 15	Nilstat Cream Pessary	Nilstat Cream Pessary 100 000 units pessary: shell	Nilstat Cream Pessary 100 000 units pessary: shell, 15	Nilstat Cream Pessary 100 000 units pessary: shell, 15, bottle
ondansetron	ondansetron 4 mg wafer	ondansetron 4 mg wafer, 10	Zofran Zydis	Zofran Zydis 4 mg wafer	Zofran Zydis 4 mg wafer, 10	Zofran Zydis 4 mg wafer, 10, blister pack
amoxycillin	amoxycillin 500 mg capsule	amoxycillin 500 mg capsule, 20	Amoxil	Amoxil 500 mg capsule: hard	Amoxil 500 mg capsule: hard, 20	Amoxil 500 mg capsule: hard, 20, blister pack

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
salbutamol	salbutamol 100 microgram/actuation on inhalation: pressurised, actuation	salbutamol 100 microgram/actuation on inhalation: pressurised, 200 actuations	Airomir	Airomir 100 microgram/actuation on inhalation: pressurised, actuation	Airomir Inhaler 100 microgram/actuation on inhalation: pressurised, 200 actuations	Airomir 100 microgram/actuation on inhalation: pressurised, 200 actuations, metered dose aerosol can
ampicillin	ampicillin 500 mg injection, vial	ampicillin 500 mg injection, 5 mg vials	Austrapen	Austrapen 500 mg injection: powder for, 500 mg vial	Austrapen 500 mg injection: powder for, 5 x 500 mg vials	Austrapen 500 mg injection: powder for, 5 vials
cefaclor	cefaclor 125 mg/5 mL oral liquid: powder for	cefaclor 125 mg/5 mL oral liquid: powder for, 100 mL	Ceclor	Ceclor 125 mg/5 mL oral liquid: powder for, 5 mL	Ceclor 125 mg/5 mL oral liquid: powder for, 100 mL	Ceclor 125 mg/5 mL oral liquid: powder for, 100 mL, bottle
diclofenac	diclofenac sodium 50 mg tablet: enteric	diclofenac sodium 50 mg tablet: enteric, 50	Voltaren	Voltaren 50 mg tablet: enteric	Voltaren 50 mg tablet: enteric, 50	Voltaren 50 mg tablet: enteric, 50, bottle
terbinafine	terbinafine hydrochloride 1% cream	terbinafine hydrochloride 1% cream, 15 g	Lamisil	Lamisil 1% cream	Lamisil 1% cream, 15 g	Lamisil 1% cream, 15 g, tube
budesonide + eformoterol	budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, actuation	budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 120 actuations	Symbicort Turbuhaler 100/6	Symbicort Turbuhaler 100/6 inhalation: powder for, actuation	Symbicort Turbuhaler 100/6 inhalation: powder for, 120 actuations	Symbicort Turbuhaler 100/6 inhalation: powder for, 120 actuations, dry powder inhaler
fluphenazine decanoate	fluphenazine decanoate 12.5 mg/0.5 mL injection, ampoule	fluphenazine decanoate 12.5 mg/0.5 mL injection, 5 x 0.5 mL ampoules	Modecate	Modecate 12.5 mg/0.5 mL injection: solution, 0.5 mL ampoule	Modecate 12.5 mg/0.5 mL injection: solution, 5 x 0.5 mL ampoules	Modecate 12.5 mg/0.5 mL injection: solution, 5 x 0.5 mL ampoules

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
sodium chloride	sodium chloride 0.9% (9 g/1 L) injection, bag	sodium chloride 0.9% (9 g/1 L) injection, 1 L bag	Sodium Chloride (Baxter)	Sodium Chloride (Baxter) 0.9% (9 g/1 L) injection: solution, 1 L bag	Sodium Chloride (Baxter) 0.9% (9 g/1 L) injection: solution, 1 L bag	Sodium Chloride (Baxter) 0.9% (9 g/1 L) injection: solution, 1 L bag (AHB1324)
ipratropium	ipratropium bromide 500 microgram/mL inhalation: solution, ampoule	ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules	Atrovent Adult UDV	Atrovent Adult UDV 500 microgram/mL inhalation: solution, ampoule	Atrovent Adult UDV 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules	Atrovent Adult UDV 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules
lamivudine + zidovudine	lamivudine 150 mg + zidovudine 300 mg tablet	lamivudine 150 mg + zidovudine 300 mg tablet, 60	Combivir	Combivir tablet; film-coated	Combivir tablet: film-coated, 60	Combivir tablet: film-coated, 60, bottle
amlodipine + atorvastatin	amlodipine 10 mg + atorvastatin 20 mg tablet	amlodipine 10 mg + atorvastatin 20 mg tablet, 30	Caduet 10/20	Caduet 10/20 tablet: film-coated	Caduet 10/20 tablet: film-coated, 30	Caduet 10/20 tablet: film-coated, 30, blister pack
antazoline + naphazoline	antazoline phosphate 0.5% + naphazoline hydrochloride 0.05% eye drops	antazoline phosphate 0.5% + naphazoline hydrochloride 0.05% eye drops, 15 mL	Albalon-A Liquifilm 0.5%/0.05%	Albalon-A Liquifilm 0.5%/0.05% eye drops: solution	Albalon-A Liquifilm 0.5%/0.05% eye drops: solution, 15 mL	Albalon-A Liquifilm 0.5%/0.05% eye drops: solution, 15 mL, bottle
paracetamol + codeine	paracetamol 500 mg + codeine phosphate 30 mg tablet	paracetamol 500 mg + codeine phosphate 30 mg tablet, 20	Panadeine Forte	Panadeine Forte tablet: uncoated	Panadeine Forte tablet: uncoated, 20	Panadeine Forte tablet: uncoated, 20, blister pack

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
<ul style="list-style-type: none"> ethinyloestradiol + levonorgestrel inert substance 	<ul style="list-style-type: none"> ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet inert substance tablet 	<ul style="list-style-type: none"> ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [24] (& ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [20] (& ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet [40] (& inert substance tablet [28], 112 [4 x 28]) ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [6] (& ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [5] (& ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet [10] (& inert substance tablet [7], 28 	<ul style="list-style-type: none"> Triphasil 	<ul style="list-style-type: none"> Triphasil (ethinyloestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated Triphasil (ethinyloestradiol 40 microgram + levonorgestrel 75 microgram) tablet: sugar-coated Triphasil (ethinyloestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated Triphasil (inert substance) tablet: sugar-coated 	<ul style="list-style-type: none"> Triphasil, 112 tablets [4 x 28] Triphasil, 28 tablets 	<ul style="list-style-type: none"> Triphasil, 112 tablets [4 x 28], blister pack Triphasil, 28 tablets, blister pack

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
<ul style="list-style-type: none"> ethinyloestradiol + norethisterone 	<ul style="list-style-type: none"> ethinyloestradiol 35 microgram + norethisterone 500 microgram tablet 	<ul style="list-style-type: none"> ethinyloestradiol 35 microgram + norethisterone 500 microgram tablet, 84 [4 x 21] ethinyloestradiol 35 microgram + norethisterone 500 microgram tablet, 21 	<ul style="list-style-type: none"> Brevinor 21 Day 	<ul style="list-style-type: none"> Brevinor 21 Day tablet: uncoated 	<ul style="list-style-type: none"> Brevinor 21 Day tablet: uncoated, 84 [4 x 21] Brevinor 21 Day tablet: uncoated, 21 	<ul style="list-style-type: none"> Brevinor 21 Day tablet: uncoated, 84 [4 x 21], blister pack Brevinor 21 Day tablet: uncoated, 21, blister pack
<ul style="list-style-type: none"> norethisterone acetate + oestradiol oestradiol 	<ul style="list-style-type: none"> oestradiol 2 mg tablet norethisterone acetate 1 mg + oestradiol 2 mg tablet oestradiol 1 mg tablet 	<ul style="list-style-type: none"> oestradiol 2 mg tablet [12] (& norethisterone acetate 1 mg + oestradiol 2 mg tablet [10] (& oestradiol 1 mg tablet [6], 1 pack 	<ul style="list-style-type: none"> Trisequens 	<ul style="list-style-type: none"> Trisequens 2 mg tablet: film-coated Trisequens tablet: film-coated Trisequens 1 mg tablet: film-coated 	<ul style="list-style-type: none"> Trisequens, 1 pack 	<ul style="list-style-type: none"> Trisequens, 1 pack, dial dispenser pack
<ul style="list-style-type: none"> calcium carbonate risedronate 	<ul style="list-style-type: none"> risedronate sodium 35 mg tablet: enteric calcium (as carbonate) 500 mg tablet 	<ul style="list-style-type: none"> risedronate sodium 35 mg tablet: enteric [4] (& calcium (as carbonate) 500 mg tablet [24], 1 pack 	<ul style="list-style-type: none"> Actonel EC Combi Actonel EC Once-a-Week Calcium Carbonate (Sanofi-Aventis) 	<ul style="list-style-type: none"> Actonel EC Once-a-Week 35 mg tablet: enteric Calcium Carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg) tablet: film-coated 	<ul style="list-style-type: none"> Actonel EC Combi, 1 pack Calcium Carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg), tablet: film coated, 24 Actonel EC Once-a-Week tablet: enteric, 4 	<ul style="list-style-type: none"> Actonel EC Combi (4 x 35 mg enteric tablets, 24 x 500 mg tablets), 1 pack, blister pack

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
<ul style="list-style-type: none"> risperidone inert substance 	<ul style="list-style-type: none"> risperidone 25 mg injection: modified release, vial inert substance diluent, 2 mL syringe 	<ul style="list-style-type: none"> risperidone 25 mg injection: modified release [25 mg vial] (&) inert substance diluent [2 mL syringe], 1 pack 	<ul style="list-style-type: none"> Risperdal Consta 	<ul style="list-style-type: none"> Risperdal Consta (risperidone 25 mg) injection: modified release, 25 mg vial Risperdal Consta (inert substance) diluent, 2 mL syringe 	<ul style="list-style-type: none"> Risperdal Consta (1 x 25 mg vial, 1 x 2 mL diluent syringe), 1 pack 	<ul style="list-style-type: none"> Risperdal Consta (1 x 25 mg vial, 1 x 2 mL diluent syringe), 1 pack, composite pack
<ul style="list-style-type: none"> lanreotide inert substance 	<ul style="list-style-type: none"> lanreotide 30 mg injection: modified release, vial inert substance diluent, 2 mL ampoule 	<ul style="list-style-type: none"> lanreotide 30 mg injection; modified release [30 mg vial] (&) inert substance diluent [2 mL ampoule], 1 pack 	<ul style="list-style-type: none"> Somatuline LA 	<ul style="list-style-type: none"> Somatuline LA (lanreotide 30 mg) injection: modified release, 30 mg vial Somatuline LA (inert substance) diluent, 2 mL ampoule 	<ul style="list-style-type: none"> Somatuline LA (1 x 30 mg vial, 1 x 2 mL diluent ampoule), 1 pack 	<ul style="list-style-type: none"> Somatuline LA (1 x 30 mg vial, 1 x 2 mL diluent ampoule), 1 pack, composite pack
<ul style="list-style-type: none"> epoprostenol inert substance 	<ul style="list-style-type: none"> epoprostenol 500 microgram injection, vial inert substance diluent, 50 mL vial 	<ul style="list-style-type: none"> epoprostenol 500 microgram injection [500 microgram vial] (&) inert substance diluent [50 mL vial], 1 pack 	<ul style="list-style-type: none"> Flolan 	<ul style="list-style-type: none"> Flolan (epoprostenol 500 microgram) injection: powder for, 500 microgram vial Flolan (inert substance) diluent, 50 mL vial 	<ul style="list-style-type: none"> Flolan (1 x 500 microgram vial, 1 x 50 mL diluent), 1 pack 	<ul style="list-style-type: none"> Flolan (1 x 500 microgram vial, 1 x 50 mL diluent vial), 1 pack, composite pack

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
polygeline + potassium + sodium + calcium + chloride	polygeline 17.5 g/500 mL + potassium 99.71 mg/500 mL + sodium 1.67 g/500 mL + calcium 125 mg/500 mL + chloride 2.574 g/500 mL injection, bottle	polygeline 17.5 g/500 mL + potassium 99.71 mg/500 mL + sodium 1.67 g/500 mL + calcium 125 mg/500 mL + chloride 2.574 g/500 mL injection, 500 mL bottle	Haemaccel	Haemaccel injection: solution, 500 mL bottle	Haemaccel injection: solution, 500 mL bottle	Haemaccel injection: solution, 500 mL bottle
<ul style="list-style-type: none"> • peginterferon alfa-2b • ribavirin • inert substance 	<ul style="list-style-type: none"> • peginterferon alfa-2b 100 microgram injection, cartridge • ribavirin 200 mg capsule • inert substance diluent, 0.5 mL cartridge 	<ul style="list-style-type: none"> • peginterferon alfa-2b 100 microgram injection [4 x 100 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack 	<ul style="list-style-type: none"> • Rebetol • Peg-Intron Redipen Injector • Pegatron Combination Therapy with Redipen Injector 	<ul style="list-style-type: none"> • Peg-Intron Redipen Injector (peginterferon alfa-2b 100 microgram) injection: powder for, 100 microgram cartridge • Rebetol 200 mg capsule: hard • Peg-Intron Redipen Injector (inert substance) diluent, 0.5 mL cartridge 	<ul style="list-style-type: none"> • Pegatron Combination Therapy with Redipen Injector (4 x 100 microgram cartridges, 112 x 200 mg capsules), 1 pack • Peg-Intron Redipen Injector (4 x 100 microgram cartridges, 4 x 0.5 mL diluent cartridges), 1 pack • Rebetol 200mg capsule: hard, 112 	<ul style="list-style-type: none"> • Pegatron Combination Therapy with Redipen Injector (4 x 100 microgram cartridges, 112 x 200 mg capsules, 4 x 0.5 mL diluent cartridges), 1 pack, composite pack • Peg-Intron Redipen Injector (4 x 100 microgram cartridges, 4 x 0.5 mL diluent cartridges), 1 pack, dual chamber composite pack • Rebetol 200 mg capsule: hard, 112, blister pack

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
sodium chloride + potassium chloride + calcium chloride	sodium chloride 8.6 g/1 L + potassium chloride 300 mg/1 L + calcium chloride 330 mg/1 L injection, bag	sodium chloride 8.6 g/1 L + potassium chloride 300 mg/1 L + calcium chloride 330 mg/1 L injection, 1 L bag	Ringer's (Fresenius Kabi)	Ringer's (Fresenius Kabi) injection: solution, 1 L bag	Ringer's (Fresenius Kabi) injection: solution, 1 L bag	Ringer's (Fresenius Kabi) injection: solution, 1 L bag
<ul style="list-style-type: none"> esomeprazole clarithromycin amoxicillin 	<ul style="list-style-type: none"> esomeprazole 20 mg tablet clarithromycin 500 mg tablet amoxicillin 500 mg capsule 	<ul style="list-style-type: none"> esomeprazole 20 mg tablet [14 tablets] (& clarithromycin 500 mg tablet [14 tablets] (& amoxicillin 500 mg capsule [28 capsules], 1 pack clarithromycin 550 mg tablet, 14 esomeprazole 20 mg tablet, 14 amoxicillin 500 mg capsule, 28 	<ul style="list-style-type: none"> Nexium Klacid Amoxil Nexium Hp7 	<ul style="list-style-type: none"> Nexium 20 mg tablet: enteric Klacid 500 mg tablet: film-coated Amoxil 500 mg capsule: hard 	<ul style="list-style-type: none"> Nexium Hp7, 1 pack Klacid 500 mg tablet: film-coated, 14 Klacid 500 mg tablet: film-coated, 14 Nexium 20 mg tablet: enteric, 14 	<ul style="list-style-type: none"> Nexium Hp7 (14 x 20 mg enteric tablets, 14 x 500 mg tablets, 28 x 500 mg capsules), 1 pack, composite pack Amoxil 500 mg capsule: hard, 28, blister pack Klacid 500 mg tablet: film-coated, 14, blister pack Nexium 20 mg tablet: enteric, 14, blister pack
mirtazapine	mirtazapine 15 mg tablet: orally disintegrating	mirtazapine 15 mg tablet: orally disintegrating, 30	Avanza Soltab	Avanza Soltab 15 mg tablet: orally disintegrating	Avanza Soltab 15 mg tablet: orally disintegrating, 30	Avanza Soltab 15 mg tablet: orally disintegrating, 30, blister pack
vinblastine	vinblastine sulfate 10 mg/10 mL injection, vial	vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials	Vinblastine Sulfate (DBL)	Vinblastine Sulfate (DBL) 10 mg/10 mL injection: solution, 10 mL vial	Vinblastine Sulfate (DBL) 10 mg/10 mL injection: solution, 5 x 10 mL vials	Vinblastine Sulfate (DBL) 10 mg/10 mL injection: solution, 5 x 10 mL vials

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
insulin isophane human + insulin neutral human	insulin isophane human 70 international units/mL + insulin neutral human 30 international units/mL injection, cartridge	insulin isophane human 70 international units/mL + insulin neutral human 30 international units/mL injection, 5 x 3 mL cartridges	Mixtard 30/70 Innolet	Mixtard 30/70 Innolet injection: suspension, cartridge	Mixtard 30/70 Innolet injection: suspension, 5 x 3 mL cartridges	Mixtard 30/70 Innolet injection: suspension, 5 x 3 mL cartridges
atropine sulfate + hyoscine hydrobromide + hyoscyamine + kaolin + pectin	atropine sulfate 19.4 microgram/30 mL + hyoscine hydrobromide 6.5 microgram/30 mL + hyoscyamine sulfate 103.7 microgram/30 mL + kaolin 6 g/30 mL + pectin 142.8 mg/30 mL oral liquid	atropine sulfate 19.4 microgram/30 mL + hyoscine hydrobromide 6.5 microgram/30 mL + hyoscyamine sulfate 103.7 microgram/30 mL + kaolin 6 g/30 mL + pectin 142.8 mg/30 mL oral liquid, 200 mL	Donnagel	Donnagel oral liquid: suspension, 30 mL	Donnagel oral liquid: suspension, 200 mL, bottle	Donnagel oral liquid: suspension, 200 mL

Appendix O Change summary

This section summarises the changes that have been made to this document since the v1.0 release (published 29 June 2012).

Section/Appendix	Changes
1 Executive summary	No longer a separate section, merged with introduction.
2 Introduction	Reorganised to accommodate Executive Summary content. Added documentation map.
3 Notation	Unchanged
4 The AMT Model	General constraints and data definitions amended Old relationship types removed according to model changes Term field length corrected
5 Product concepts	Full review of all rules to ensure compliance with the v3 model
6 Substance concepts	Added exceptions to rules
7 Australian Qualifier concepts	Unchanged
8 SNOMED CT Model Component hierarchy	Unchanged
9 References	All references reviewed and updated to current documents. Reference section moved to end matter (that is, no longer a numbered section).
A Capitalisation	Addition of rules AMT-APP-CAP-9 and AMT-APP-CAP-10
B Exception examples for MP and MPUU	Unchanged
C Ingredient naming conventions	Reviewed and amended to reflect AMT Support Group decisions: D.1, D.2, D.3, D.6
D Examples of products with more than three ingredients	Unchanged
E General strength formats	Major changes to rules: AMT-APP-STR-4, AMT-APP-STR-9 Minor changes to rules: AMT-APP-STR-6 Addition of new rule: AMT-APP-STR-12 F.1 – changed to reflect AMT Support Group decision on representation of strengths for topical products
F Units of measure	G.1 – changed to reflect v3 model
G Form	Added source of form description New forms added Minor changes to make some descriptions more explicit
H Dose form and associated proprietary	Minor changes to correct casing

Section/Appendix	Changes
form	
I Pack Quantity Unit of Measure	New units of measure added
J Container Types	Added source of container type description Removed abbreviation (redundant) New container types added Minor changes to make some descriptions more explicit
K Special classes of products	Unchanged
L Product Concepts – Full Definitions	Full review of all rules to ensure compliance with the v3 model Order of concept sections changed to align with v3
M Fully Specified Name (FSN) examples	All examples reviewed and amended to comply with v3 rules
N Preferred Term (PT) examples	All examples reviewed and amended to comply with v3 rules
Glossary	Reviewed and expanded; moved to end matter (that is, no longer an appendix). As a result the following appendices now have different index letters.
General	“salt” changed to “primary modified base” “modified salt” changed to “secondary modified base” All references reviewed and updated.

Glossary

Acronym	Term	Meaning
ATC	Anatomical Therapeutic Chemical Classification	
AAN	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.
AMT	Australian Medicines Terminology	
ARTG	Australian Register of Therapeutic Goods	
	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).
BoSS	Basis of Strength Substance	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.
CT	Container Type	
CTPP	Containerised Trade Product Pack	
dm+d	Dictionary of Medicines and Devices	
	Diluent	A single substance or preparation usually in liquid form, supplied individually or as part of a composite 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.
EBNF	Extended Backus-Naur Form	
F	Form	
FSN	Fully Specified Name	The FSN represents 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. ¹²
	Generic	A generic product is one in which the name of the product is a substance name or an indication for treatment.
ID	Identifier	
ING	Ingredient	

¹² Source: *SNOMED CT Starter Guide* [19].

Acronym	Term	Meaning
IHTSDO	International Health Terminology Standards Development Organization	
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	
NEHTA	National E-Health Transition Authority	
NHS	National Health Service (UK)	
PBS	Pharmaceutical Benefits Scheme	
PT	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”. ¹³
	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.
PF	Proprietary Form	
RPBS	Repatriation Pharmaceutical Benefits Scheme	
R	Route	The route of administration for a medicine.
	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.

¹³ Source: *SNOMED CT Starter Guide* [19].

Acronym	Term	Meaning
SCTID	SNOMED Clinical Terms Identifier	
SNOMED CT-AU	SNOMED CT Australian Release	
SPO	Sponsor	
	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. ¹⁴
SNOMED	Systematized Nomenclature of Medicine	
SNOMED CT	Systematized Nomenclature of Medicine, Clinical Terms	
TGA	Therapeutic Goods Administration	Australia's regulatory agency for medical drugs and devices.
TBC	To be created	
TF	Trade Family	
TP	Trade Product	
TPP	Trade Product Pack	
TPUU	Trade Product Unit of Use	
UTF-8	Unicode Transformation Format (8-bit)	
UOM	Unit of Measure	
UOU	Unit of Use	
UOUS	Unit of Use Size	
UUID	Universally Unique Identifier	
WHO	World Health Organisation	

¹⁴ Source: *SNOMED CT Starter Guide* [19].

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