nehta

Editorial Rules

Australian Medicines Terminology (Version 3 Model)

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Approved for external release

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Quality reviews

Revision	Version	Reviewer(s)	Role	Purpose
	0.2	AMT team	Peer review	To verify the accuracy and practicability of the editorial rules from an internal perspective.
	0.3	AMT support group	External stakeholder review	To verify the suitability of the editorial rules from an external perspective.
	005	Technical writer, CTI	Editorial review	General clarity and conformance to NCTIS guidelines.

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1 Executive summary

The National E-Health Transition Authority Limited (NEHTA) is a not-for-profit company established by the Australian Federal, State and Territory governments to develop better ways of electronically collecting and securely exchanging health information.

Electronic health information systems that are interoperable are essential for delivering high quality care across the health sector. By enabling the exchange of clinical and administrative information across the health sector, these systems have the potential to unlock substantially greater quality, safety and efficiency benefits.

Improved management of medication information is seen as one of the key areas for urgent reform. Benefits are particularly clear for eMedication management, where inconsistent or incomplete information not only results in inefficiency and unnecessary expense, but can also have an adverse impact on clinical care.

The Australian Medicines Terminology (AMT) uniquely and unambiguously codes and describes medicines, using a set of defining properties, and is intended to cover all commonly used medicines in Australia.

AMT version 3 is an upgrade to version 2 with changes to both content and structure. This document provides updated Editorial Rules that support Version 3 of the AMT model structure and content.

1.1 Opportunity for standardisation

Historically the lack of agreed standard medication identifiers has resulted in limited ability to share essential medicine information. There are numerous drug reference files in use, with similar essential data, but all require slightly different information and perform slightly different functions. These files are sourced from:

- the Therapeutic Goods Administration (TGA);
- the Australian Register of Therapeutic Goods (ARTG);
- the Pharmaceutical Benefits Scheme (PBS) Schedule; and
- state-wide and local hospital drug formularies and proprietary drug files, such as those used by the medical software and knowledge resource industry, which include decision support.

AMT is the agreed standard medication identifier for use within Australia. This enables sharing of essential information around medicines. NEHTA's aim is to ensure consistency and interoperability as required between these separate systems.

1.2 Aims and objectives of the AMT

The key aim of the Australian Medicines Terminology (AMT) is to provide a consistent and safe approach to the identification and naming of medicines, which can support medicines management and activity across the entire Australian health domain. The medicines terminology continues to be developed and made available for use in medication management in Australia.

AMT has been developed to be fit for the purpose of unambiguously identifying for clinicians and computer systems commonly used medicines (all PBS/RPBS, TGA AUSTR and a range of AUSTL items) in Australia and can be implemented in clinical information systems for the following activities:

- Prescribe
- Record
- Review
- Issue – including dispense
- Administer
- Transfer of information

The AMT continues to produce a medicines terminology, which will be accessible to all. To enable this to occur, the following objectives are of primary importance:

- consistent identification of branded and generically equivalent medicines; and
- consistent naming conventions and terminology used to describe and search for medications.

NEHTA continues to work with industry and international experts to further refine the specifications, standards and infrastructure necessary to achieve these aims and objectives.

2 Introduction

AMT terms are constructed based on syntax described by the Extended Backus-Naur Form (EBNF). For further details on EBNF, refer to Section 3.

2.1 Purpose

This document specifies the Editorial Rules for AMT v3 and focuses on the naming conventions and rules associated with all description types for concepts in the AMT Model.

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

2.2 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.

2.3 Scope of the AMT

2.3.1 In scope

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

- medicines registered with the TGA;
- medicines listed with the TGA; and
- other medicines and therapeutic products required to support AMT use cases.

AMT provides detailed descriptions at varying levels of specificity of both branded and generic medicines to support mapping (if required) with:

- items listed in the PBS;
- SNOMED CT-AU;
- international standard medicines classifications; and
- Australian Register of Therapeutic Goods (TGA).

2.3.2 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 bases, (i.e. decision support) which can similarly be linked to product descriptions through the terminology.

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

- 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

AMT will not model excipients, or the absence thereof, unless presented with a clear use case, and agreed to by the relevant NEHTA governance body or bodies. A Medicinal Product will only define inactive (inert) ingredients where these are part of sequential multi-component products, or diluents provided for the preparation of the actual administrable form of a product.

2.4 Overview

2.4.1 Background

The AMT model was developed initially based on work previously undertaken.

The model has undergone modification in response to feedback from and consultation with software vendors, jurisdictions, clinicians currently working on implementing prescribing and dispensing software, 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.

2.4.2 Planned developments

NEHTA's next steps will include:

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

2.5 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 <terminologies@nehta.gov.au>.

3 Notation

3.1 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
:=	Definition	The symbol on the left can be replaced by the expression on the right.
;	Terminating character	This identifies the end of a rule (called a 'production rule').
|	Logical OR	A choice, with alternative items separated by this symbol.
[…]	Option	Encloses optional items.
{ … }	Optional repetition	Encloses optional items that can be repeated zero or more times.
(…)	Arrangement in groups	Encloses items that need to be grouped together.
" … "	Double quotation	A terminal expression (i.e. characters that appear exactly as shown).
(* … *)	Comment	Encloses a comment (i.e. the characters inside are not part of the expression).
? … ?	Special sequence	A special sequence.
-	Exception	An exception to the rule.

In the model when referring to EBNF definitions the "|" is used as the "logical OR" and in the given examples the "|" is used to show a separation of terms.

3.2 SNOMED CT

SNOMED CT relationships are sometimes represented as follows.

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

3.3 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 (e.g. rules tables are identified as such), so this document is entirely legible in greyscale print.

4 The AMT model

4.1 AMT components

4.1.1 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* [SUG2012] and *SNOMED CT Technical Implementation Guide* [STIG2012].

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 (i.e. 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". Refer to the *SNOMED CT Technical Implementation Guide* [STIG2012] for further details of the SctId format.	SNOMED CT
AU-COMP-4	ComponentUUID	All Components must have exactly one ComponentUUID. This is an alternate identifier for each component assigned during the terminology build process.	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 (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 (i.e. SctId of the module concept 'Australian Medicines Terminology module' in the *SNOMED CT Model Component* hierarchy).	SNOMED CT

4.1.2 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.

4.1.2.1 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 6.

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* [STIG2012] 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 *Australian Medicines Terminology Implementation Plan* [AMT2012].

4.1.2.2 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 (i.e. SctId of a definition status concept in the *SNOMED CT Model Component* hierarchy).	SNOMED CT

4.1.3 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 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.

4.1.3.1 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 (Fully Specified Name or Preferred Term), it has been noted that some vendors require this data atomically (i.e. datum). 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 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[1]
IS A	SNOMED CT	Yes
MAY BE A	SNOMED CT	Yes
MOVED FROM	SNOMED CT	Yes
MOVED TO	SNOMED CT	Yes
REPLACED BY	SNOMED CT	Yes
SAME AS	SNOMED CT	Yes
WAS A	SNOMED CT	Yes
HAS AUSTRALIAN BoSS	AMT	Yes
HAS BASE FORM STRENGTH DENOMINATOR UNITS	AMT	No
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

[1] 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[1]
HAS MANUFACTURED DOSE FORM	AMT	Yes
HAS INTENDED ACTIVE INGREDIENT	AMT	Yes
HAS MPUU	AMT	Yes
HAS NUMERATOR UNITS	AMT	Yes
HAS PHARMACEUTICAL INGREDIENT	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 *Australian Medicines Terminology Implementation Plan* [AMT2012].

4.1.3.2 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 (e.g. IS A relationships), only the closest relationships should be represented explicitly. Other relationships are subsumed[2] 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.

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.

[2] Further details on subsumption may be found in the *SNOMED CT User Guide* [SUG2012].

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 *SNOMED CT Model Component* 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 *SNOMED CT Model Component* hierarchy.	AMT
AU-REL-11	modifierId	The modifierId must equal the SctId of the modifier concept 'Some' in the *SNOMED CT Model Component* hierarchy.	AMT

4.1.4 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 Fully Specified Names, Preferred Terms and Synonyms.

4.1.4.1 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 is an additional term 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

Concept	Australian Additional Description Type Name	Included in AMT release files	Reference
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
	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
Containered Trade Product Pack (CTPP)	Manufacturer's code	No	See Section 5.8.2.5
	Other containered 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

4.1.4.2 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

Rule ID	Data Element	Constraint/Data Definition	Constraint Source
AU-DES-7	typeId	The typeId must equal the SctId of a description type concept in the *SNOMED CT Model Component* hierarchy.	SNOMED CT
AU-DES-8	typeId	The valid values for typeId are the SctId of the following description type concepts: Fully specified name (FSN) • Synonym • Definition	SNOMED CT
AU-DES-9	typeId	The typeId for all AMT descriptions are the SctId for Fully specified name or Synonym.	AMT
AU-DES-10	term	Each description must have exactly one term, which is valid per 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 32Kb.	AMT
AU-DES-13	caseSignificanceId	The caseSignificanceId must equal the SctId of a case significance concept in the *SNOMED CT Model Component* 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

4.1.4.3 Specific description constraints/data definitions for the description terms

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

4.1.4.3.1 *Fully Specified Name definition and rules*

Each concept has one unique Fully Specified Name (FSN) intended to provide an unambiguous way to name that concept. The purpose of the FSN is to uniquely identify a concept and clarify its meaning. 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 (e.g. medicinal product, trade product pack, AU qualifier, AU substance, etc).

For example, 'amoxycillin (medicinal product)' is a FSN that describes a product that a clinician may choose to prescribe, whereas 'amoxycillin (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 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, i.e. it will include the semantic tag of its appropriate parent e.g. '(medicinal product)'.	SNOMED CT

4.1.4.3.2 *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 concept 'amoxicillin (medicinal product)' has been created based on the International Non-Proprietary 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 Fully Specified Name and Preferred Term are based on Australian Approved Names. Using the same example 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

4.1.4.3.3 Synonym definition and rules

Synonyms represent any additional terms that are used to refer to the same concept as the FSN. Synonyms are optional, i.e. not all concepts will have associated Synonyms.

Synonyms, like PTs, are not required to be unique across concepts. A Synonym is a description type with an acceptability value of "acceptable" defined in the *Australian English language reference set*.

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

Table 9: Synonym constraint/data definition rules

Rule ID	Constraints/Data Definition	Constraint Source
AMT-SYN-1	There may be more than one Synonym with acceptability value of "acceptable" for each concept.	SNOMED CT
AMT-SYN-2	A Synonym cannot be the same as the FSN.	SNOMED CT
AMT-SYN-3	Synonyms are optional and will only be populated when deemed clinically relevant for a concept.	SNOMED CT

4.2 Reference sets and History

Information on reference sets and history mechanisms may be found in the *SNOMED CT Technical Implementation Guide* [STIG2012].

5 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);
- Containered Trade Product Pack (CTPP); and
- Trade Product Pack (TPP).

These concepts and their principal relationships are diagrammatically represented below.

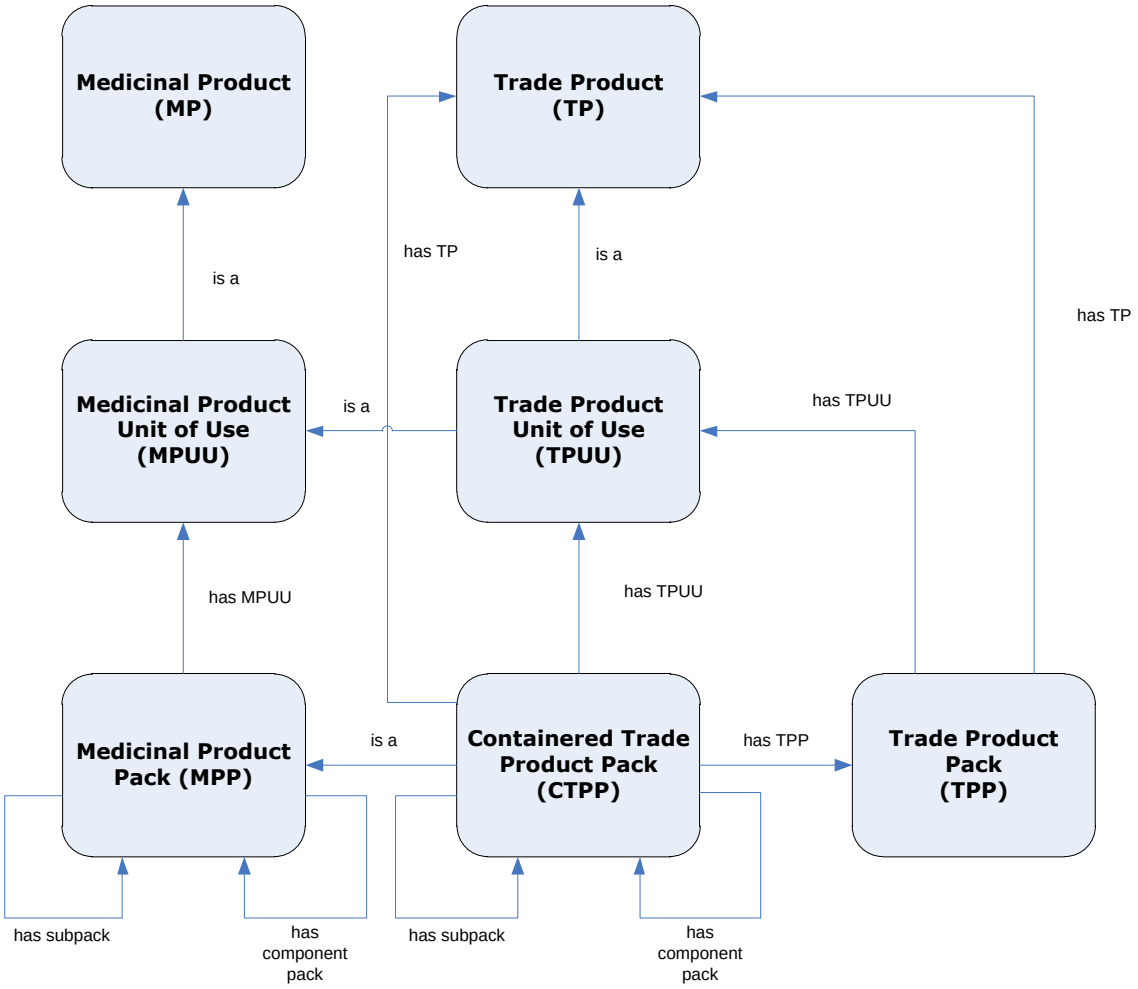

Figure 1: The AMT model (Product concepts)

5.1 Product types

For inclusion in the AMT, a product is defined as a medicinal preparation that can be attributed to a specific sponsor as defined by a trade product name, active ingredient(s)[3], 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. This includes PBS extemporaneous products which may not be attributable to a specific sponsor.

The model handles the following types of products:

- Single ingredient
- Multi-ingredient
- Single component
- Multi-component
- Subpacks

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)					
Trade Product Unit of Use (TPUU)	Yes	Yes	Yes		
Containered Trade Product Pack (CTPP)	Yes	Yes	Yes	Yes	Yes
Trade Product Pack (TPP)	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 in the manual creation of descriptions. Full definitions are written from a technical point of view and may be used by those intending to auto-generate descriptions.

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

5.1.1 Single ingredient

A single-ingredient product is one in which there is only one active ingredient in each unit of use (i.e. MPUU or TPUU).

Concept examples (FSN) of single ingredient products include:

- MP: amoxycillin (medicinal product)
- MPUU: amoxycillin 500 mg capsule (medicinal product unit of use)
- TPUU: Amoxil (amoxycillin (as trihydrate) 500 mg) capsule: hard, 1 capsule (trade product unit of use)

5.1.2 Multi-ingredient

A multi-ingredient product is one where two or more ingredients are compounded together and cannot be separated, e.g. amoxycillin 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 (i.e. MPUU or TPUU).

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

- MP: amoxycillin + clavulanic acid (medicinal product)
- MPUU: amoxycillin 500 mg + clavulanic acid 125 mg tablet (medicinal product unit of use)
- TPUU: Augmentin Duo 500/125 (amoxycillin (as trihydrate) 500 mg + clavulanic acid (as potassium) 125 mg) tablet: film-coated, 1 tablet (trade product unit of use)

5.1.3 Single component

A single component product is one which contains only one unique unit of use within the pack (i.e. it may contain multiple units of use, but each of these units of use is identical).

5.1.4 Multi-component

A multi-component product is one which contains two or more different of units of use within the same pack (i.e. the MPP has multiple MPUUs; the CTPP or TPP has multiple TPUUs).

This includes both:

- Combination packs: where the one pack has different unit dose forms that are intended to be taken sequentially (e.g. Triphasil).
- Multi-component kits: where the one pack has different unit dose forms but where the dosage regimen for each type of unit dose form may be implemented concurrently (e.g. Nexium Hp7).

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

- MP: esomeprazole (medicinal product)

  clarithromycin (medicinal product)

  amoxycillin (medicinal product)
- MPP: amoxycillin 500 mg capsule [28 capsules] (&) clarithromycin 500 mg tablet [14 tablets] (&) esomeprazole 20 mg tablet [14 tablets], 1 pack (medicinal product pack)

  amoxycillin 500 mg capsule, 28 capsules (medicinal product pack)

  clarithromycin 500 mg tablet, 14 tablets (medicinal product pack)

  esomeprazole 20 mg tablet, 14 tablets (medicinal product pack)
- TPP: Nexium Hp7 (amoxycillin (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 (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:

> Vivaxim (hepatitis A virus inactivated vaccine 160 ELISA units + typhoid fever (Salmonella typhi Vi) live attenuated vaccine 25 microgram) injection: suspension, 1 mL syringe (trade product unit of use)

5.1.5 Subpacks

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 medicinal product. 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. An example of a secondary container is 'carton'. AMT does not include specific information on secondary containers but uses the term "composite pack" when referring to them.

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.

Subpacks are only represented for specific product categories. The categories currently include 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	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 tablet [28 tablets], 112 tablets [4 x 28 tablets] (medicinal product pack)	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 tablet [28 tablets], 112 tablets [4 x 28 tablets] (medicinal product pack)
MPP (Subpack)	ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet [10 tablets] (&) ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [6 tablets] (&) ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [5 tablets] (&) inert substance tablet [7 tablets], 28 tablets (medicinal product pack)	ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet [10 tablets] (&) ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [6 tablets] (&) ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [5 tablets] (&) inert substance tablet [7 tablets], 28 tablets (medicinal product pack)

Type of pack	Fully Specified Name	Preferred Term
CTPP	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) tablet: sugar-coated [20 tablets] (&) (inert substance) tablet: sugar-coated [28 tablets], 112 tablets [4 x 28 tablets], blister pack (containered trade product pack)	Triphasil, 112 tablets [4 x 28 tablets], blister pack
CTPP (Subpack)	Triphasil (ethinyloestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated [10 tablets] (&) (ethinyloestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated [6 tablets] (&) (ethinyloestradiol 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, 28 tablets, blister pack

5.1.6 Component 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 have component packs. The component packs within a composite product pack typically have different active ingredients. They may have the same form or have different forms.

It should be noted that some component packs which are described as an MPP or CTPP may not actually be available as a TPP (i.e. a component in a component pack may only be available as part of the combined CTPP and is not available individually).

The CTPP representing the composite product pack (i.e. containing all the component packs) will have an associated generic container type of "composite pack". The CTPP representing a component pack will have an associated specific container type e.g. blister pack, bottle, ampoule.

For example: Nexium Hp7 is a multi-component product. It will have four CTPPs (component packs): one to represent each of the three components and an additional CTPP to represent the overall product:

- Amoxil 500 mg capsule: hard, 28 capsules, blister pack
- Klacid 500 mg tablet: film-coated, 14 tablets, blister pack
- Nexium 20 mg tablet, 14, blister pack
- Nexium Hp7, 1 pack, composite pack (i.e. this is the overall product)

Note that component packs will **not** be created where:

- the CTPP FSN or CTPP PT contains the words 'cold', 'day' or 'night'; or
- the TP of the product is one of the following:
  - Tisseel Duo 500
  - Tisseel VH S/D

- Femoston 2/10
- Qlaira
- Trisequens

5.2 Medicinal Product (MP)

5.2.1 Medicinal Product definition

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

The term 'medicines' may include over-the-counter preparations, vitamin preparations, complementary medicines as well as prescription-only medicines.

AMT will not model excipients, or the absence thereof, unless presented with a clear use case, and agreed to by the relevant NEHTA governance body or bodies. A Medicinal Product will only define inactive (inert) ingredients where these are part of sequential multi-component products, or diluents provided for the preparation of the actual administrable form of a product.

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

- the precise ingredient (with salt) is specified, where this is therapeutically necessary or clinically significant (refer to Appendix C);
- the Medicinal Product defines a group of products, which contain substances with the same active entity; and
- where the ingredient is an enantiomer, (i.e. 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 (i.e. the segment of the molecule which has an intended therapeutic effect on the body). A 'salt' is defined as an additional segment which is combined with the base (but does not have an intended therapeutic effect on the body). A 'modified salt' is a salt 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 ingredient.

Table 12: Examples of ingredient types

Ingredient type	Ingredient name	base segment	salt segment	modification segment
base	atenolol	atenolol	N/A	N/A
salt	ranitidine hydrochloride	ranitidine	hydrochloride	N/A
modified salt	suxamethonium chloride dihydrate	suxamethonium	chloride	dihydrate

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 salt 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 sequential multi-component products or diluents provided for the preparation of the actual administrable form of a product.

Table 13: Examples of Medicinal Product FSNs and PTs

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

5.2.2 Medicinal Product descriptions

5.2.2.1 Medicinal Product Fully Specified Name brief definition

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

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

where the component parts are described as follows.

Table 14: MP description

Description Component	Description
MP_Ingredient_Details	An alphabetical list of the FSNs (without the semantic tag) of each of the MP's ingredients, with ingredients of the same MP component separated by a " + " and grouped together.
(medicinal product)	The semantic tag used in the FSN of all Medicinal Product concepts.

[4] For an explanation of syntax conventions, refer to Section 3.

5.2.2.2 Medicinal Product Fully Specified Name rules

Table 15: MPP FSN rules

Rule ID	Description
AMT–MP-FSN-1	All rules in Section 4.1.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.
AMT–MP–FSN-2	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 Australian Register of Therapeutic Goods [TGAM1999]. EXCEPTION This may, however, differ to meet requirements of clinical practice. Current exceptions are listed in Appendix D and will be added to on a case-by-case basis.
AMT–MP–FSN-3	The MP FSN will be derived from the base of the active ingredients. EXCEPTION The full name of an ingredient (i.e. including the salt) will be used in the case of: • discernible therapeutic differences to the base; or • enantiomers. Where a salt is not clinically significant but the representation of the salt is required for safety reasons, then the MP will be represented as a salt. See Appendix C for further information.
AMT–MP-FSN-4	The MP FSN will include all active ingredients for each multi-ingredient preparation. The MP FSN will also include the description “inert substance” as the actual ingredient name where inactive (inert) ingredients are part of sequential multi-component products or diluents provided for the preparation of the actual administrable form of a product.
AMT–MP-FSN-5	The MP FSN will describe a single component MP concept.

5.2.2.3 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 16: MPP PT description

Description Component	Description
Ingredient_Details	A list (alphabetical by default) of the PTs of each of the MP's ingredients, with: • ingredients of the same MP component separated by a " + " and grouped together; • MP components, which contain exactly the same ingredients, only shown once. By default the order of this list is alphabetical, 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. Refer to Appendix D.5 for further details on exceptions to alphabetical MP ingredient order.

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 E for exceptions).

5.2.2.4 Medicinal Product Preferred Term rules

Table 17: Medicinal Product Preferred Term rules

Rule ID	Description
AMT-MP-PT-1	All rules defined in Section 4.1.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.
AMT-MP-PT-2	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 Australian Register of Therapeutic Goods [TGAM1999]. EXCEPTION This may, however, differ to meet requirements of clinical practice. Current exceptions are listed in Appendix D and will be added to on a case-by-case basis.
AMT-MP-PT-3	The Medicinal Product PT will be derived from the base of the active ingredients. EXCEPTION The full name of an ingredient (i.e. including the salt) will be used in the case of: • discernible therapeutic differences to the base; or • enantiomers. Where a salt is not clinically significant but the representation of the salt is required for safety reasons, then the MP will be represented as a salt. See Appendix C for further information.

Rule ID	Description
AMT-MP-PT-4	For Medicinal Products with greater than three active ingredients, the AMT editors may create a clinically intuitive name based on the review of each individual product. Note that this is yet to be fully implemented. EXCEPTION Groups of products that will retain more than three active ingredients in the creation of the name include: • vaccines (note that vaccines may have an abbreviated term created regardless of the number of ingredients); and • large volume parenteral injections. The addition of items to the exceptions list will be reviewed on a case-by-case basis. Note: The identification of all active ingredients is available from the Medicinal Product (MP) HAS INTENDED ACTIVE INGREDIENT relationship with Substance (SUB). The current exception list is attached as Appendix E. The MP PT will also include the description "inert substance" as the actual ingredient name where inactive (inert) ingredients are part of sequential multi-component products or diluents provided for the preparation of the actual administrable form of a product.
AMT-MP-PT-5	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. EXCEPTION The order sequence for multi-ingredient products will be alphabetical, unless an altered sequence is determined as in Appendix D. This will be developed on a case-by-case basis. The complete list of exceptions may be found in Appendix D.5. Example: MP FSN: codeine + paracetamol (medicinal product) MP PT: paracetamol + codeine 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.

5.3 Medicinal Product Unit of Use (MPUU)

5.3.1 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 base active ingredient (or the same precise active ingredients, where the salt 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 sequential multi-component products) or diluents (provided for the preparation of the actual administrable form of a product).

A new MPUU will be created for each 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 salt or modified form for safety reasons or where this is the Australian BoSS representation of the active ingredient. For example:

- Where the salt or modified salt is not clinically significant but is required for reasons of safety. For example, perindopril erbumine and perindopril arginine. In this case, two salts exist where the Basis of Strength Substance is the salt. Although the salt 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 salt or modified form must be administered by a particular route that differs from other salts of the same base, for example, haloperidol decanoate. In this case, the product is intended for administration as an intramuscular injection to provide a sustained action, and is not suitable for intravenous administration. Although included as a salt representation, this is not deemed to be a clinically significant salt.

  In this instance the ingredient would not necessarily be represented as the full salt name. Where the Basis of Strength Substance is the base, the salt detail would still appear in the MPUU, but in brackets.

  Example: haloperidol (as decanoate) 50 mg/mL injection, ampoule

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

Table 18: 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 salt (refer to Appendix C)	diclofenac 46.54 mg | diclofenac sodium 50 mg tablet: enteric (medicinal product unit of use)	diclofenac sodium 50 mg tablet: enteric, 1 tablet
Single ingredient – clinically significant salt (refer to Appendix C)	sodium 3.54 g / 1000 mL | sodium chloride 9 g / 1000 mL injection, 1000 mL bag (medicinal product unit of use)	sodium chloride 0.9% (9 g/1000 mL) injection, bag

Type of product	Fully Specified Name	Preferred Term
Multi-ingredient	codeine 23.43 mg | codeine phosphate 30 mg + paracetamol 500 mg tablet (medicinal product unit of use)	paracetamol 500 mg + codeine phosphate 30 mg tablet
Multi-ingredient Multi-component Sequential	• 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) • inert substance tablet (medicinal product unit of use)	• levonorgestrel 50 microgram + ethinyloestradiol 30 microgram tablet • levonorgestrel 75 microgram + ethinyloestradiol 40 microgram tablet • levonorgestrel 125 microgram + ethinyloestradiol 30 microgram tablet • inert substance tablet
Multi-component Sequential	• etidronate 164.8 mg | etidronate disodium 200 mg tablet (medicinal product unit of use) • calcium 500 mg | calcium carbonate 1250 mg tablet (medicinal product unit of use)	• etidronate disodium 200 mg tablet • calcium (as carbonate) 500 mg tablet
Multi-component kit	• esomeprazole 20 mg tablet (medicinal product unit of use) • clarithromycin 500 mg tablet (medicinal product unit of use) • amoxycillin 500 mg capsule (medicinal product unit of use)	• esomeprazole 20 mg tablet • 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 less than 1 mL	fluphenazine 9.24 mg / 0.5 mL | 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
injection powder with diluent	• lantreotide 30 mg injection: modified release, vial (medicinal product unit of use) • inert substance diluent, ampoule (medicinal product unit of use)	• lantreotide 30 mg injection: modified release, vial • inert substance diluent, 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 F.1 for further details.

Table 19: Examples of Medicinal Product Unit of Use FSNs and PTs for all 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% (10 mg/g) cream
capsules and tablets, sunscreens, inhalations, powders for injection, nasal drops, oral liquids, spray solutions and spray suspensions	diclofenac 46.54 mg | diclofenac sodium 50 mg tablet: enteric (medicinal product unit of use)	diclofenac sodium 50 mg tablet: enteric, 1 tablet
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 (20 mg/patch) patch

5.3.2 Medicinal Product Unit of Use descriptions

5.3.2.1 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 20: MPUU description

Description Component	Description
Ingredients_With_Strength	An alphabetical list of the name and strength (if available) of each of the ingredients of the MPUU, where: • The name string and strength string (for the same ingredient) are separated by a space; AND • The name and strength pairs for different ingredients are separated by a " + "; AND • The strength component of Ingredient_Strength does not exist for certain MPUU FSN e.g. those representing inert substances, non-medicated dressings, diagnostic aids and nutritional supplements; AND • The ingredient is based on the MPUU's BoSS ingredient (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 salt 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. For example: diclofenac 46.54 mg | diclofenac sodium 50 mg tablet: enteric (medicinal product unit of use). Refer to Appendix C for further detail on bases and salts.
Form	The manufactured dose form of the MPUU, defined in a non-proprietary way. This is the PT of the Form (F) concept that is the destination of the MPUU HAS MANUFACTURED DOSE FORM F relationship.
Unit_Of_Use_Details	A list of the Unit of Use details (if populated), which may include: • Unit of Use Size (UOUS) • Unit of Use: The unit dose item that can be physically handled. When these values are shown, the first of these is preceded by a comma followed by a space. Note that the Unit of Use Size (value and units) is not shown when it has a value of "1" and a unit that matches the PT of the MPUU's Form (or one of this Form's parents in the 'Form is a Form' hierarchy).
(medicinal product unit of use)	The semantic tag used in the FSN of all Medicinal Product Unit of Use concepts.

Note that the PT of MPUUs with more than three active ingredients may 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 E for more details).

5.3.2.2 Medicinal Product Unit of Use Fully Specified Name rules

Table 21: MPUU FSN rules

Rule ID	Description
AMT-MPUU-FSN-1	All rules in Section 4.1.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.
AMT-MPUU-FSN-2	The Medicinal Product Unit of Use will be derived from the base or salt of the active ingredients, as defined for MP FSN. EXCEPTION Where representation of the salt in the MP is required for safety reasons (refer to Appendix C), the relevant MPUU will also represent the salt.
AMT-MPUU-FSN-3	The MP FSN naming convention for exceptions that require the representation of a salt will include both base and salt strength in the MPUU FSN, separated by " | ". Example: • calcium 600 mg | calcium carbonate 1500 mg tablet (medicinal product unit of use)
AMT-MPUU-FSN–4	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 F. EXCEPTIONS See AMT-APP-STR-9 in Appendix F.
AMT-MPUU-FSN–5	Form. The form is derived from the TGA Approved Terminology of Medicines, Dosage Forms [TGAM1999, Chapter 5]. The form expressed is the parent form (i.e. 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 (e.g. 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-signifcant form such as 'tablet: uncoated' would appear as the parent form of 'tablet'.

5.3.2.3 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 22: MPUU PT description

Description Component	Description
Ingredients_With_Strength	The name and strength (if available) of each of the ingredients of the MPUU, where: • the name string and strength string (for the same ingredient) are separated by a space; AND • the name and strength pairs for different ingredients are separated by a " + "; AND • 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. The following defines when the base and/or the salt is represented at the level of the MPUU (also refer to table below): • The ingredient(s) are based on the MPUU's BoSS ingredients (i.e. 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 salt substance. • The strength component is based on the strength of the MPUU's BoSS ingredient. • The strength component of a base ingredient is represented based on the Base form strength preferred representation, which may be one of the following: ○ A representation of the numerator and denominator strength components of the BoSS; OR ○ A representation of the numerator and denominator strength components of the BoSS followed by the Base form strength other representation; OR ○ Base form strength other representation; OR ○ Base form strength other representation followed by a representation of the numerator and denominator strength components of the BoSS. • The strength component of a salt ingredient is represented based on the Salt form strength preferred representation, which may be one of the following: ○ A representation of the numerator and denominator strength components of the BoSS; OR ○ A representation of the numerator and denominator strength components of the BoSS followed by the Salt form strength other representation; OR ○ Salt form strength other representation; OR ○ Salt form strength other representation followed by a representation of the numerator and denominator strength components of the BoSS. • 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.

Description Component	Description
Form	The manufactured dose form of the MPUU, defined in a non-proprietary way. This is the PT of the Form (F) concept that is the destination of the MPUU HAS MANUFACTURED DOSE FORM F relationship.
Unit_Of_Use_Details	A list of the Unit of Use details (if populated), which may include: • Unit of Use Size (UOUS) • Unit of Use: The unit dose item that can be physically handled. When these values are shown, the first of these is preceded by a comma followed by a space. Note that the Unit of Use Size (value and units) is not shown when: • it has a value of "1" and a unit that matches the 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 23: Examples of ingredient types and associated MPUU representations

Ingredient Type	BoSS	MP	MPUU
base: abciximab	base abciximab	base abciximab	base abciximab
salt: ranitidine hydrochloride	base ranitidine	base ranitidine	base ranitidine
salt: rabeprazole sodium	salt rabeprazole sodium	base rabeprazole sodium	salt rabeprazole sodium
clinically significant salt, BoSS = base: erythromycin ethylsuccinate	base erythromycin	salt 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).

5.3.2.4 Medicinal Product Unit of Use Preferred Term rules

Table 24: MPUU PT rules

Rule ID	Description
AMT-MPUU-PT-1	All rules defined in Section 4.1.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.
AMT-MPUU-PT-2	The MPUU ingredient will be derived from the base or salt of the active ingredient, as defined by its associated BoSS ingredient. Therefore, where a salt 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 (i.e. a salt will only be displayed if it is the BoSS).
AMT-MPUU-PT-3	Strength expression. The MPUU PT will include strength expression (if available). The strength expression general rules and application to specific medication forms is outlined in Appendix F. EXCEPTION See AMT-APP-STR-9 in Appendix F. Strength expression may include an alternate strength representation different to the typical numerator/denominator strength expression. It may include a dual strength representation. Refer to Appendices F.1 and F.2.
AMT-MPUU-PT-4	Form. The form is derived from the TGA Approved Terminology of Medicines, Dosage Forms. The form expressed is the parent form (i.e. 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 (e.g. 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'.

5.3.2.5 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 4.1.4.1 this is an additional description type which is not released in the terminology release files.

Table 25: 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 (e.g. 6, 0.25).
AMT-MPUU-BFSNV-2	This value is optional, but must be populated if 'Base form strength denominator value' is populated.

5.3.2.6 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 4.1.4.1 this is an additional description type which is not released in the terminology release files.

Table 26: 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 (e.g. 6, 0.25).
AMT-MPUU-BFSDV-2	This value is optional, but may only be populated if 'Base form strength numerator value' is populated.

5.3.2.7 Medicinal Product Unit of Use 'Base form strength other representation' definition and rules

Definition

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

Note that as per Section 4.1.4.1 this is an additional description type which is not released in the terminology release files.

Table 27: 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.

5.3.2.8 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 4.1.4.1 this is an additional description type which is not released in the terminology release files.

Table 28: 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 (e.g. 6, 0.25).
AMT-MPUU-SFSNV-2	This value is optional, but must be populated if 'Salt form strength denominator value' is populated.

5.3.2.9 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 4.1.4.1 this is an additional description type which is not released in the terminology release files.

Table 29: 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 (e.g. 6, 0.25).
AMT-MPUU-SFSDV-2	This value is optional, but may only be populated if 'Salt form strength numerator value' is populated.

5.3.2.10 Medicinal Product Unit of Use 'Salt form strength other representation' definition and rules

Definition

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

Note that as per Section 4.1.4.1 this is an additional description type which is not released in the terminology release files.

Table 30: 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.

5.3.2.11 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 4.1.4.1 this is an additional description type which is not released in the terminology release files.

Table 31: 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, i.e. 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.

5.4 Medicinal Product Pack (MPP)

5.4.1 Medicinal Product Pack definition

A Medicinal Product Pack (MPP) is an abstract concept representing the properties of one or more quantitatively equivalent Containered Trade Product Packs (CTPPs). Quantitatively equivalent CTPPs are those that have the same base active ingredient (or the same precise active ingredients, where the salt is therapeutically necessary), as well as the same strength, dose form, pack size and container type.

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

Table 32: 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 salt (refer to Appendix C)	diclofenac 46.54 mg | diclofenac sodium 50 mg tablet: enteric, 50 tablets (medicinal product pack)	diclofenac sodium 50 mg tablet: enteric, 50 tablets
Single ingredient – clinically significant salt (refer to Appendix C)	sodium 3.54 g / 1000 mL | sodium chloride 9 g / 1000 mL injection, 1 x 1000 mL bag (medicinal product pack)	sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag
Multi-ingredient	codeine 23.43 mg | 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-ingredient Multi-component Sequential	• 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 tablet [28 tablets], 112 tablets [4 x 28 tablets] (medicinal product pack) • ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet [10 tablets] (&) ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [6 tablets] (&) ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [4 tablets] (&) inert substance tablet [7 tablets], 28 tablets (medicinal product pack)	• levonorgestrel 50 microgram + ethinyloestradiol 30 microgram tablet [24 tablets] (&) levonorgestrel 75 microgram + ethinyloestradiol 40 microgram tablet [20 tablets] (&) levonorgestrel 125 microgram + ethinyloestradiol 30 microgram tablet [40 tablets] (&) inert substance tablet [28 tablets], 112 [4 x 28 tablets] • ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet [10 tablets] (&) ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [6 tablets] (&) ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [5 tablets] (&) inert substance tablet [7 tablets], 28 tablets
Multi-component Sequential	• calcium 500 mg | calcium carbonate 1250 mg tablet [76 tablets] (&) etidronate 164.8 mg | etidronate disodium 200 mg tablet [28 tablets], 104 tablets (medicinal product pack) • calcium 500 mg | calcium carbonate 1250 mg tablet, 76 tablets (medicinal product pack) • etidronate 164.8 mg | etidronate disodium 200 mg tablet, 28 tablets (medicinal product pack)	• etidronate disodium 200 mg tablet [28 tablets] (&) calcium (as carbonate) 500 mg tablet [76 tablets], 104 • calcium (as carbonate) 500 mg tablet, 76 • etidronate disodium 200 mg tablet, 28
Multi-component kit	• amoxycillin 500 mg capsule [28 capsules] (&) clarithromycin 500 mg tablet [14 tablets] (&) esomeprazole 20 mg tablet [14 tablets], 1 pack (medicinal product pack) • amoxycillin 500 mg capsule, 28 capsules (medicinal product pack) • clarithromycin 500 mg tablet, 14 tablets (medicinal product pack) • esomeprazole 20 mg tablet, 14 tablets (medicinal product pack)	• esomeprazole 20 mg tablet [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxycillin 500 mg capsule [28 capsules], 1 pack • esomeprazole 20 mg tablets, 14 • clarithromycin 500 mg tablet, 14 • amoxycillin 500 mg capsule, 28
patch	oestradiol 100 microgram / 24 hours patch, 8 patches (medicinal product pack)	oestradiol 100 microgram/24 hours patch, 8

Type of product	Fully Specified Name	Preferred Term
injection solution less than 1 mL	• fluphenazine 9.24 mg / 0.5 mL | fluphenazine decanoate 12.5 mg / 0.5 mL injection, 5 x 0.5mL ampoules (medicinal product pack)	• fluphenazine decanoate 12.5 mg/0.5 mL injection, 5 x 0.5 mL ampoules
injection powder with diluent	• inert substance diluent [1 x 2 mL ampoule] (&) lantreotide 30 mg injection: modified release [1 x 30 mg vial], 1 pack (medicinal product pack) • lanreotide 30 mg injection: modified release, 1 x 30 mg vial (medicinal product pack) • inert substance diluent, 1 x 2 mL ampoule (medicinal product pack)	• lantreotide 30 mg injection; modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack • lanreotide 30 mg injection: modified release, 1 x 30 mg vial • inert substance diluent, 1 x 2 mL ampoule

5.4.2 Medicinal Product Pack descriptions

5.4.2.1 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 33: MPP FSN description

Description Component	Description
MPUU_Details	The details about an individual MPUU that is contained within the MPP, including: • the list of ingredients and strengths (formatted as per MPUU 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 dose formulation 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 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 e.g. tablets, capsules, vials; with the exception of "microgram" and "microlitre"; 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). Unit of Use quantity is only shown for multi-component MPPs.

Description Component	Description
Total_Quantity_Size_Details	• This component includes the quantity value and units, derived from the value and unitId fields of Unit of Use quantity reference set (e.g. 25 tablets). If the value field is greater than "1", plural units description is used for the associated quantity units e.g. tablets, capsules, vials; with the exception of "microgram" and "microlitre". • If the MPP represents a multi-component product that has associated component packs this detail includes the MPP description 'total unit of use quantity value' and the preferred term of the unit of measure concept that is the destination of 'MPP has total unit of use quantity units' relationship (e.g. 25 tablets). If the quantity value is greater than "1", the plural units description is used for the associated quantity units e.g. tablets, capsules, vials; with the exception of "microgram" and "microlitre". • If the MPP has a total size, then the 'total unit of use quantity value' and its unit of measure is separated by the multiplication symbol (i.e. " x "), followed by the total size value and units (e.g. 2 x 5 mL vials). • If the MPP represents a sequential multi-component product that has a number of subpacks (i.e. Subpack quantity exists for the MPP) then the component is composed of the multiplication of MPP description 'total unit of use quantity value' with value of Subpack quantity followed by the preferred term of the unit of measure concept that is the destination of 'MPP has total unit of use quantity units' relationship (e.g. 112 tablets). This string is followed by subpack quantity details in square brackets. The subpack quantity details includes the value of Subpack quantity, followed by the multiplication symbol (i.e. " x "), followed by the MPP description 'total unit of use quantity value', together with the unit of measure from 'MPP has total unit of use quantity units'). If the quantity value is greater than "1", the plural units description is used for the associated quantity units e.g. tablets, capsules, vials; with the exception of "microgram" and "microlitre" (e.g. [4 x 28 tablets]).
(medicinal product pack)	The semantic tag used in the FSN of all Medicinal Product Pack concepts.

5.4.2.2 Medicinal Product Pack Fully Specified Name rules

Table 34: MPP FSN rules

Rule ID	Description
AMT-MPP-FSN-1	All rules in Section 4.1.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.
AMT-MPP-FSN-2	The Medicinal Product Unit of Use will be derived from the base or salt of the active ingredients, as defined for MP FSN. EXCEPTION Where representation of the salt in the MP is required for safety reasons (refer to Appendix C), the relevant MPP will also represent the salt.

Rule ID	Description
AMT-MPP-FSN-3	The MP FSN naming convention for exceptions that require the representation of a salt will include both base and salt strength in the MPP FSN, separated by " | ". Example: calcium 600 mg | calcium carbonate 1500 mg tablet, 120 tablets (medicinal product pack).
AMT-MPP-FSN-4	Form. The form is derived from the TGA Approved Terminology of Medicines, Dosage Forms. The form expressed is the parent form (i.e. 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 (e.g. 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'.
AMT-MPP-FSN-5	Pack_Units: If the Pack_Units is greater than one, then the Pack quantity units will be expressed as a plural form with the exception of "microgram" and "microlitre". See Appendix J for appropriate Pack Quantity Units of Measure. If all the components have the same unit dose form, the pack size is the total number of unit dose forms (e.g. if both components are tablets, the pack size = x tablets). • e.g. Didrocal contains 28 tablets + 76 tablets Pack size = 104 tablets MPP FSN: calcium 500 mg | calcium carbonate 1250 mg tablet [76 tablets] (&) etidronic acid 164.8 mg | etidronate disodium 200 mg tablet [28 tablets], 104 tablets (medicinal product pack) If the components are different forms but are both 'discrete', the pack size will equal "1 pack". • e.g. Nexium Hp7 contains 14 tablets + 28 capsules + 14 tablets Pack size = 1 pack MPP FSN: amoxycillin 500 mg capsule [28 capsules] (&) clarithromycin 500 mg tablet [14 tablets] (&) esomeprazole 20 mg tablet [14 tablets], 1 pack (medicinal product pack) If the pack consists of a discrete and continuous unit dose forms, the pack size will equal "1 pack". • e.g. Canesoral Duo (1 x 150 mg capsule, 1 x 10 g cream) Pack size = 1 pack MPP FSN: clotrimazole 10 mg / 1 g cream [10 g] (&) fluconazole 150 mg capsule [1 capsule], 1 pack (medicinal product pack)

5.4.2.3 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 35: MPP PT description

Description Component	Description
MPUU_Details	The details about an individual MPUU that is contained within the MPP, including: • The list of ingredients and strengths (formatted as per MPUU 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 4.1.4.1 'preferred component order' is an additional description type which is not released in the terminology release files.) • The dose formulation 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 e.g. tablets, capsules, vials; with the exception of "microgram" and "microlitre". • The quantity unit of measure is only used when it is different from the form of the MPUU (or one of the form's parents in the form hierarchy). • For those MPUU components with manually created PTs (e.g. 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. Unit of Use quantity is only shown for multi-component MPPs.
Total_Quantity_Size_Details	• This component includes the quantity value and units, derived from the value and unitId fields of Unit of Use quantity reference set (e.g. 25 tablets). If the value field is greater than "1", plural units description is used for the associated quantity units e.g. tablets, capsules, vials; with the exception of "microgram" and "microlitre". • If the MPP represents a multi-component product that has associated component packs this component includes the MPP description 'total unit of use quantity value' and the preferred term of the unit of measure concept that is the destination of 'MPP has total unit of use quantity units' relationship (e.g. 25 tablets). If the quantity value is greater than "1", the plural units description is used for the associated quantity units e.g. tablets, capsules, vials; with the exception of "microgram" and "microlitre". • However, if the total unit of use quantity units is the same as every form in the pack (or one of the form's parents in the 'Form is a Form' hierarchy) then this quantity units will be omitted.

Description Component	Description
	• Optionally if the MPP has a total size, then quantity value and units is separated by the multiplication symbol (i.e. " x "), followed by the total size value and units, derived from the value and unitId fields of Unit of Use Size reference set (e.g. 2 x 5 mL vials). • If the MPP represents a sequential multi-component product that has a number of subpacks (i.e. Subpack quantity reference set exists for the MPP) then the component is composed of the multiplication of MPP description 'total unit of use quantity value' with value field of Subpack quantity reference set followed by the preferred term of the unit of measure concept that is the destination of 'MPP has total unit of use quantity units' relationship. Example '112 tablets'. This string is followed by subpack quantity details in square brackets. The subpack quantity details includes the value field of Subpack quantity reference set, followed by the multiplication symbol (i.e. " x "), followed by the MPP description 'total unit of use quantity value', together with the unit of measure from 'MPP has total unit of use quantity units'). If the quantity value is greater than "1", the plural units description is used for the associated quantity units e.g. tablets, capsules, vials; with the exception of "microgram" and "microlitre" (e.g. [4 x 28 tablets]).

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

For example: for a product containing potassium available from multiple sources (e.g. 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

- **Created term:**

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

5.4.2.4 Medicinal Product Pack Preferred Term rules

Table 36: MPP PT rules

Rule ID	Description
AMT-MPP-PT-1	All rules defined in Section 4.1.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.
AMT-MPP-PT-2	The MPP ingredient will be derived from the base or salt of the active ingredient, as defined by its associated BoSS ingredient. Therefore, where a salt 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 (i.e. a salt will only be displayed if it is the BoSS). The MPP PT will also include the description "inert substance" as the actual ingredient name where inactive (inert) ingredients are part of sequential multi-component products or diluents provided for the preparation of the actual administrable form of a product.
AMT-MPP-PT-3	Strength expression All MPP PT will include a strength expression when available. The strength expression general rules and application to specific medication forms are outlined in Appendix F. EXCEPTION There are occasions when this is not applicable. Examples of this include Calamine lotion, Vitamin B compound tablets, Aqueous cream. Note: The addition to the exceptions list will be reviewed on a case-by-case basis. Refer to Appendix F. Strength expression may include an alternate strength representation different to the typical numerator/denominator strength expression. It may include a dual strength representation. Refer to Appendices F.1 and F.2.
AMT-MPP-PT-4	Form. The form is derived from the TGA Approved Terminology of Medicines, Dosage Forms. The form expressed is the parent form (i.e. 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 (e.g. 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'.

Rule ID	Description
AMT-MPP-PT-5	Pack_Units: If the Pack_Units is greater than one, then the Pack quantity units will be expressed as a plural form. See Appendix J for appropriate Pack Quantity Units of Measure. If all the components have the same unit dose form, the pack size is the total number of unit dose forms (e.g. if both components are tablets, the pack size = x tablets). • e.g. Didrocal contains 28 tablets + 76 tablets Pack size = 104 tablets MPP PT: etidronate disodium 200 mg tablet [28 tablets] (&) calcium (as carbonate) 500 mg tablet [76 tablets], 104 tablets If the components are different forms but are both 'discrete', the pack size will equal "1 pack". • e.g. Nexium Hp7 contains 14 tablets + 28 capsules + 14 tablets Pack size = 1 pack MPP PT: esomeprazole 20 mg tablet [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxycillin 500 mg capsule [28 capsules], 1 pack If the pack consists of a discrete and continuous unit dose forms, the pack size will equal "1 pack". • e.g. Canesoral Duo (1 x 150 mg capsule, 1 x 10 g cream) Pack size = 1 pack MPP PT: fluconazole 150 mg capsule [1 capsule] (&) clotrimazole 1% (10 mg/g cream) [10 g], 1 pack

5.4.2.5 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.

Note that as per Section 4.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 37: 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.

5.4.2.6 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 4.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 38: 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 (e.g. 6, 0.25).
AMT-MPP-TUUQV-2	This value is optional.

5.4.2.7 Medicinal Product Pack 'Total subpack quantity' definition and rules

Definition

Within each pack (MPP) there may be multiple subpacks (e.g. each in a container, such as a bottle, a tube, or a blister pack, etc). 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 (MPPSubpack).

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

Note that as per Section 4.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 39: Examples of MPP 'Total subpack quantity' FSN and PT

Trade Product Preferred Term	Fully Specified Name	Preferred Term
Triphasil	• 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 tablet [28 tablets], 112 tablets [4 x 28 tablets] (medicinal product pack) • ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet [10 tablets] (&) ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [6 tablets] (&) ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [5 tablets] (&) inert substance tablet [7 tablets], 28 tablets (medicinal product pack)	• levonorgestrel 50 microgram + ethinyloestradiol 30 microgram tablet [24 tablets] (&) levonorgestrel 75 microgram + ethinyloestradiol 40 microgram tablet [20 tablets] (&) levonorgestrel 125 microgram + ethinyloestradiol 30 microgram tablet [40 tablets] (&) inert substance tablet [28 tablets], 112 [4 x 28 tablets] • levonorgestrel 50 microgram + ethinyloestradiol 30 microgram tablet [6 tablets] (&) levonorgestrel 75 microgram + ethinyloestradiol 40 microgram tablet [5 tablets] (&) levonorgestrel 125 microgram + ethinyloestradiol 30 microgram tablet [10 tablets] (&) inert substance tablet [7 tablets], 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 40: 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.

5.5 Trade Product (TP)

5.5.1 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 alternate name which has market recognisability.

Table 41: Examples of Trade Product FSNs and PTs

Type of product	Fully Specified Name	Preferred Term
Single ingredient	Amoxil (trade product)	Amoxil
Single ingredient	Morphine Sulfate (Mayne) (trade product)	Morphine Sulfate (Mayne)
Multi-ingredient	Panadeine Forte (trade product)	Panadeine Forte
Combination product	Triphasil (trade product)	Triphasil
Multi-component kit	• Nexium Hp7 (trade product) • Nexium (trade product) • Klacid (trade product) • Amoxil (trade product)	• Nexium Hp7 • Nexium • Klacid • Amoxil
Single ingredient exception	Canesten Clotrimazole (trade product)	Canesten Clotrimazole
Single ingredient exception	Canesten Bifonazole (trade product)	Canesten Bifonazole

5.5.1.1 Trade Product details

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

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

Table 42: TP description

Component	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
Alternate name which is well recognised in the market	yes	Compound Sodium Lactate (Hartmann's) (Baxter)

Component	Include in Trade Product name	Preferred Term Example
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	Bactroban Nasal
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.

Component	Include in Trade Product name	Preferred Term Example
Information that denotes a particular monograph (e.g. APF, BP, etc) 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

5.5.2 Trade Product descriptions

5.5.2.1 Trade Product Fully Specified Name brief definition

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

```
TP FSN := TF_Name [" (" TF_Supplier ")"] " (trade product)"
```

where the component parts are described as follows.

Table 43: TP FSN description

Description Component	Description
TF_Name	The product brand name shared by items containing the same active ingredients or components of multi-component items which contain the same combination of active ingredients.
TF_Supplier	The supplier name for products available as an unbranded generic medicine, or the housebrand (e.g. Terry White Chemists, Chemmart).
(trade product)	The semantic tag used in the FSN of all Trade Product concepts.

5.5.2.2 Trade Product Fully Specified Name rules

Table 44: TP FSN rules

Rule ID	Description
AMT-TP-FSN-1	All rules in Section 4.1.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.
AMT-TP-FSN-2	The TF_Name will be derived from the product brand name and any additional detail that is necessary to define the product. For example: textual description that is necessary to distuinguish between items in a product range; strength representation for multi-ingredient products (where required for differentiation); proprietary form, delivery device or container. Each TF_Name will consist of products with the same Medicinal Product (e.g. Canesten Clotrimazole and Canesten Bifonazole will be created as two TF_Names). The TF_Name may differentiate between different available strengths (e.g. Panadeine and Panadeine Forte). For multi-ingredient products with multiple strengths available, then to avoid ambiguity, the TF_Name will include a representation of the strength (e.g. Caduet 10/10 and Caduet 5/20). Strength representation in the TF_Name may be omitted for multi-ingredient products when only one strength is currently marketed in Australia (e.g. Moduretic tablets). Note that additional detail such as "thiomersal free", "preservative free" etc will only be included in the TF_Name when it occurs as part of the registered product name.
AMT-TP-FSN-3	For generic products, the TF_Name will be populated with the generic name followed by a " " and the sponsor/manufacturer/house brand name surrounded by "(" and ")". For example: • Simvastatin (GenRx) Methotrexate (Ebewe) Where a generic product name includes an abbreviation for sponsor/manufacturer/house brand name as a hyphenated suffix, the TF_Name will be populated with generic name followed by a " " and the abbreviation for the sponsor/manufacturer/house brand name surrounded by "(" and ")". For example: Meloxicam (GA). Salts will only be included as part of the TF_Name where the strength of the product is expressed in terms of the salt, i.e. the salt form is the basis of strength substance. For example: Perindopril Erbumine (GenRx). Where a salt is included as part of the Trade Product Name, the first letter will be uppercased. NOTE: This rule also applies to products that consist of a standard formulation, e.g. Calamine Lotion.
AMT-TP-FSN-4	For products where the name consists of a housebrand name and a brand name, the TF_Name will consist of the brand name followed by the housebrand name surrounded by "(" and ")". For example: Macu-Vision (Blackmores).

5.5.2.3 Trade Product Preferred Term brief definition

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

```
TP PT := TF_Name [" (" TF_Supplier ")"]
```

where the component parts are described as follows.

Table 45: TP PT description

Description Component	Description
TF_Name	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 alternate name which has market recognisability.
TF_Supplier	The supplier name for products available as an unbranded generic medicine, or the housebrand (e.g. Terry White Chemists, Chemmart).

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

For example: a product which requires additional detail for disambiguation at the TP level would contain additional information as follows:

Term according to rules: Coveram 5 mg / 10 mg

Created term: Coveram 5 mg / 10 mg (perindopril/amlodipine)

5.5.2.4 Trade Product Preferred Term rules

Table 46: TP PT rules

Rule ID	Description
AMT-TP-PT-1	All rules defined in Section 4.1.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.

Rule ID	Description
AMT-TP-PT-2	The TF_Name will be derived from the product brand name and any additional detail that is necessary to define the product. For example: textual description that is necessary to distuinguish between items in a product range; strength representation for multi-ingredient products (where required for differentiation); proprietary form, delivery device or container. Each TF_Name will consist of products with the same Medicinal Product (e.g. Canesten Clotrimazole and Canesten Bifonazole will be created as two TF_Names). The TF_Name may differentiate between different available strengths (e.g. Panadeine and Panadeine Forte). For multi-ingredient products with multiple strengths available, then to avoid ambiguity, the TF_Name will include a representation of the strength (e.g. Caduet 10/10 and Caduet 5/20). Strength representation in the TF_Name may be omitted for multi-ingredient products when only one strength is currently marketed in Australia (e.g. Moduretic tablets). Note that additional detail such as "thiomersal free", "preservative free" etc will only be included in the TF_Name when it occurs as part of the registered product name.
AMT-TP-PT-3	For generic products, the TF_Name will be populated with the generic name followed by a " " and the sponsor/manufacturer/house brand name surrounded by "(" and ")". For example: • Simvastatin (GenRx) • Methotrexate (Ebewe) Where a generic product name includes an abbreviation for sponsor/manufacturer/house brand name as a hyphenated suffix, will be populated with generic name followed by a " " and the abbreviation for the sponsor/manufacturer/house brand name surrounded by "(" and ")". For example: Meloxicam (GA). Salts will only be included as part of the Trade_Product_Term where the strength of the product is expressed in terms of the salt, i.e. the salt form is the basis of strength substance. For example: Perindopril Erbumine (GenRx). Where a salt is included as part of the Trade Product Name, the first letter will be uppercased. NOTE: This rule also applies to products that consist of a standard formulation, e.g. Calamine Lotion.
AMT-TP-PT-4	For products where the name consists of a housebrand name and a brand name, the TF_Name will consist of the brand name followed by the housebrand name surrounded by "(" and ")". For example: Macu-Vision (Blackmores).

5.5.2.5 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 4.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 47: TP 'Proprietary form' rules

Rule ID	Description
AMT-TP-PF-1	All rules defined in Section 4.1.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.
AMT-TP-PF-2	Population of this field is optional.

5.5.2.6 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 (e.g. Terry White Chemists, Chemmart).

Note that as per Section 4.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 48: TP 'Trade family supplier' rules

Rule ID	Description
AMT-TP-TFS-1	All rules defined in Section 4.1.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.
AMT-TP-TFS-2	This value is mandatory for all generic products.

5.6 Trade Product Unit of Use (TPUU)

5.6.1 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, e.g. liquid or cream) that contains a specified amount of an active ingredient substance and is grouped within a particular Trade Product. A Trade Product Unit of Use will include single dose units of inactive (inert) ingredients where these are part of sequential 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 e.g. tablet, capsule, vial, ampoule or patch.

Table 49: Examples of TPUU FSNs and PTs

Type of product	Fully Specified Name	Preferred Term
Single ingredient	Amoxil (amoxycillin (as trihydrate) 500 mg) capsule: hard, 1 capsule (trade product unit of use)	Amoxil 500 mg capsule: hard, 1 capsule
Single ingredient – clinically relevant salt (see Appendix C)	Voltaren 50 (diclofenac sodium 50 mg) tablet: enteric, 1 tablet (trade product unit of use)	Voltaren 50 mg tablet: enteric, 1 tablet
Single ingredient – clinically significant salt (see Appendix C)	Sodium Chloride 0.9% (Baxter) (sodium chloride 9 g / 1000 mL) injection: intravenous infusion, 1000 mL bag (trade product unit of use)	Sodium Chloride (Baxter) 0.9% (9 g/1000 mL)) intravenous infusion, bag
Multi-ingredient	Panadeine Forte (codeine phosphate 30 mg + paracetamol 500 mg) tablet: uncoated, 1 tablet (trade product unit of use)	Panadeine Forte tablet: uncoated, 1 tablet
Multi-ingredient Multi-component Sequential	• Triphasil (ethinyloestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated, 1 tablet (trade product unit of use) • Triphasil (ethinyloestradiol 40 microgram + levonorgestrel 75 microgram) tablet: sugar-coated, 1 tablet (trade product unit of use) • Triphasil (ethinyloestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated, 1 tablet (trade product unit of use) • Triphasil (inert substance) tablet: sugar-coated,1 tablet (trade product unit of use)	• Triphasil (levonorgestrel 50 microgram + ethinyloestradiol 30 microgram) tablet: sugar-coated, 1 tablet • Triphasil (levonorgestrel 75 microgram + ethinyloestradiol 40 microgram) tablet: sugar-coated, 1 tablet • Triphasil (levonorgestrel 125 microgram + ethinyloestradiol 30 microgram) tablet: sugar-coated, 1 tablet • Triphasil (inert substance) tablet: sugar-coated, 1 tablet
Multi-component Sequential	• Didronel (etidronate disodium 200 mg) tablet: uncoated, 1 tablet (trade product unit of use) • Calcium carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg) tablet: film-coated, 1 tablet (trade product unit of use)	• Didronel 200 mg tablet: uncoated, 1 tablet • Calcium Carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg) tablet: film-coated, 1 tablet

Type of product	Fully Specified Name	Preferred Term
Multi-component kit	Nexium (esomeprazole (as magnesium trihydrate) 20 mg) tablet: enteric, 1 tablet (trade product unit of use) Klacid (clarithromycin 500 mg) tablet: film-coated, 1 tablet (trade product unit of use) Amoxil (amoxycillin (as trihydrate) 500 mg) capsule: hard, 1 capsule (trade product unit of use)	Nexium 20 mg tablet: enteric, 1 tablet Klacid 500 mg tablet: film-coated, 1 tablet Amoxil 500 mg capsule
patch	Estraderm 100 (oestradiol 100 microgram / 24 hours) patch (trade product unit of use)	Estraderm 100 microgram/24 hours patch
injection solution less than 1 mL	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, ampoule
injection powder with diluent	• Somatuline LA (lantreotide (as acetate) 30 mg) injection: modified release, vial (trade product unit of use) • Somatuline LA (inert substance) diluent, ampoule (trade product unit of use)	• Somatuline LA 30 mg injection: modified release, vial • Somatuline LA diluent, 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 is one current instance of a TPUU PT which would show the ingredient to avoid an incorrect expression of strength. The affected description is the calcium carbonate component (TPUU) for Actonel Combi.

TPUU FSN: Calcium carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg) tablet: film-coated, 1 tablet (trade product unit of use)

TPUU PT: Calcium carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg) tablet: film-coated, 1 tablet

Note that without the ingredient detail the TPUU PT would be 'Calcium carbonate (Sanofi-Aventis) 500 mg tablet: film-coated, 1 tablet'.

Exceptions for multi-ingredient products

There are a small number of multi-ingredient products which require additional detail in the TPUU. These are products where the strength of the TPUUs is the only differing factor. In these instances, the unit dose form size details are included in the TPUU PT to avoid duplicated PTs which have different conceptIds.

TPUU FSN: Potassium Chloride and Sodium Chloride and Glucose 0.15% / 0.18% / 4% (Baxter) (potassium chloride 0.15% (1.5 g/1000 mL) + sodium chloride 0.18% (1.8 g/1000 mL) + glucose 4% (40 g/1000 mL)) injection: intravenous infusion, bag (trade product unit of use)

TPUU PT: Potassium Chloride and Sodium Chloride and Glucose 0.15% / 0.18% / 4% (Baxter) injection: intravenous infusion, 1000 mL bag

TPUU FSN: Potassium Chloride and Sodium Chloride and Glucose 0.15% / 0.18% / 4% (Baxter) (potassium chloride 0.15% (750 mg/500 mL) + sodium chloride 0.18% (900 mg/500 mL) + glucose 4% (20 g/500 mL)) injection: intravenous infusion, bag (trade product unit of use)

TPUU PT: Potassium Chloride and Sodium Chloride and Glucose 0.15% / 0.18% / 4% (Baxter) injection: intravenous infusion, 500 mL bag

Note that without this detail being added, they would share a common TPUU PT of 'Potassium Chloride and Sodium Chloride and Glucose 0.15% / 0.18% / 4% (Baxter) injection: intravenous infusion, bag'.

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, 1 tablet trade product unit of use)

TPUU PT: Brevinor 28 day (norethisterone 500 microgram + ethinyloestradiol 35 microgram) tablet: uncoated, 1 tablet

TPUU FSN: Brevinor 28 day (inert substance) tablet: uncoated, 1 tablet (trade product unit of use)

TPUU PT: Brevinor 28 day (inert substance) tablet: uncoated, 1 tablet

Note that without the ingredient detail, they would share a common TPUU PT of 'Brevinor 28 day tablet: uncoated, 1 tablet'.

5.6.2 Trade Product Unit of Use descriptions

5.6.2.1 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 [" (" TF_Supplier ")"]
              [" " 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 50: TPUU 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. 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 alternate name which has market recognisability.
TF_Supplier	The supplier name for products available as an unbranded generic medicine, or the housebrand (e.g. Terry White Chemists, Chemmart).
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 product unit of use (e.g. '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. Where the ingredient's BoSS is the active ingredient itself (including the salt), then the format used will be 'Salt_Ingredient Salt_Strength'. Where the ingredient's BoSS is the base of the ingredient, then the format used will be 'Base_Ingredient (as Salt_Ingredient_Minus_Base) Base_Strength'.
Form	This is the PT of the Form (F) concept that is the destination of the MPUU HAS MANUFACTURED DOSE FORM F relationship.
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.

5.6.2.2 Trade Product Unit of Use Fully Specified Name rules

Table 51: TPUU FSN rules

Rule ID	Description
AMT-TPUU-FSN-1	All rules in Section 4.1.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.
AMT-TPUU-FSN–2	Strength expression. The strength expression general rules and application to specific medication forms is outlined in Appendix F. 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-TPUU-FSN–3	Form The form is derived from the TGA Approved Terminology of Medicines, Dosage Forms. The form expressed in the TPUU is the specific form (i.e. 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 (e.g. tablet, ampoule). Where the TF_Name includes a proprietary form, the corresponding form, as shown in Appendix I must be used. 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; e.g. 'Flo Nozoil' will become 'Flo Nozoil nasal spray'.
AMT-TPUU-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_Identifying_Information (e.g. sugar free, refill, flavour). For example: • Lemsip Max Cold and Flu blackcurrant (paracetamol 1 g) oral liquid: powder for, 1 sachet (trade product unit of use) • Dimetapp 12 Hour refill (oxymetazoline hydrochloride 500 microgram / 1 mL) nasal spray (trade product unit of use)

5.6.2.3 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 [" (" TF_Supplier ")"]
            [" " Other_Identifying_Information]
            [" (" Ingredient_Strength ")"] [" " Form]
            [", " Unit_Of_Use_Details]
```

where the component parts are described as follows.

Table 52: TPUU PT description

Description Component	Description
TF_Name	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 alternate name which has market recognisability.
TF_Supplier	The supplier name for products available as an unbranded generic medicine, or the housebrand (e.g. Terry White Chemists, Chemmart).
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 Product Unit of Use (e.g. 'sugar free', 'refill', 'strawberry').
Ingredient_Strength	For single ingredient products, ingredient strength (but not ingredient name) is displayed. For multi-ingredient products, neither ingredient strength nor ingredient name are displayed. EXCEPTIONS: There are a small number of exceptions to inclusion of ingredient name. Refer to Section 5.6.1.
Form	This is the PT of the Form (F) concept that is the destination of the MPUU HAS MANUFACTURED DOSE FORM relationship.
Unit_Of_Use_Details	The Unit_Of_Use Details are derived exactly from the associated MPUU PT.

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.

5.6.2.4 Trade Product Unit of Use Preferred Term rules

Table 53: TPUU PT rules

Rule ID	Description
AMT-TPUU-PT–1	All rules defined in Section 4.1.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.
AMT-TPUU-PT–2	If the Trade Product represents different strengths then the following strength expressions as defined in AMT-TPUU-PT-3 may not be populated (e.g. Marcain with Adrenaline 0.25% / 1 in 400 000).
AMT-TPUU-PT-3	Strength expression. 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 F. EXCEPTIONS See AMT-APP-STR-9 in Appendix F. Strength expression may include an alternate strength representation different to the typical numerator/denominator strength expression. It may include a dual strength representation. Refer to Appendices F.1 and F.2.

Rule ID	Description
AMT-TPUU-PT–4	Form The form is derived from the TGA Approved Terminology of Medicines, Dosage Forms. The form expressed in the TPUU is the specific form (i.e. 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 (e.g. tablet, ampoule). Where the TF_Name includes a proprietary form, the corresponding form, as shown in Appendix I must be used. 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, e.g. 'Flo Nozoil' will become 'Flo Nozoil nasal spray'.
AMT-TPUU-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_Identifying_Information (e.g. sugar free, refill, flavour). For example: • Lemsip Max Cold and Flu blackcurrant 1 g oral liquid: powder for, 1 sachet • Dimetapp 12 Hour refill 0.05% (500 microgram/mL) nasal spray

5.6.2.5 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 (e.g. sugar free, refill, flavour, etc). 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 4.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 54: TPUU 'Other identifying information' rules

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

5.7 Trade Product Pack (TPP)

5.7.1 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 Containered Trade Product Pack (CTPP). It may, however, imply a container type, when this information is included in the Total Qty Size Details.

Table 55: Examples of TPP FSNs and PTs

Type of product	Fully Specified Name	Preferred Term
Single ingredient	Amoxil (amoxycillin (as trihydrate) 500 mg) capsule: hard, 20 capsules (trade product pack)	Amoxil 500 mg capsule: hard, 20 capsules
Single ingredient – clinically relevant salt (refer to Appendix C)	Voltaren 50 (diclofenac sodium 50 mg) tablet: enteric, 50 tablets (trade product pack)	Voltaren 50 mg tablet: enteric, 50 tablets
Single ingredient – clinically significant salt (refer to Appendix C)	Sodium Chloride 0.9% (Baxter) (sodium chloride 9 g / 1000 mL) injection: intravenous infusion, 1 x 1000 mL bag (trade product pack)	Sodium Chloride (Baxter) 0.9% (9 g/1000 mL) intravenous infusion, 1 x 1000 mL bag
Multi-ingredient	Panadeine Forte (codeine phosphate 30 mg + paracetamol 500 mg) tablet: uncoated, 20 tablets (trade product pack)	Panadeine Forte tablet: uncoated, 20 tablets
Multi-ingredient Multi-component Sequential	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) tablet: sugar-coated [20 tablets] (&) (inert substance) tablet: sugar-coated [28 tablets], 112 tablets [4 x 28 tablets] (trade product pack)	Triphasil, 112 tablets [4 x 28 tablets]
Multi-component Sequential	Didrocal (calcium (as carbonate) 500 mg) tablet: film-coated [76 tablets] (&) (etidronate disodium 200 mg) tablet: uncoated [28 tablets], 104 tablets (trade product pack	Didrocal, 104 tablets

Type of product	Fully Specified Name	Preferred Term
Multi-component kit	Nexium Hp7 (amoxycillin (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 (trade product pack)	Nexium Hp7, 1 pack
patch	Estraderm 100 (oestradiol 100 microgram / 24 hours) patch, 8 patches (trade product pack)	Estraderm 100 microgram/24 hours patch, 8
injection solution less than 1 mL	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] (&) (lantreotide (as acetate) 30 mg) injection: modified release [1 x 30 mg vial], 1 pack (trade product pack)	Somatuline LA (1 x 30 mg vial), 1 pack

5.7.2 Trade Product Pack descriptions

5.7.2.1 Trade Product Pack Fully Specified Name brief definition

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

```
TPP FSN :=  TF_Name [" (" TF_Supplier ")"]
            [" " Other_Pack_Information] TPUU_Details
            {" (&) " TPUU_Details} ", "
            Total_Quantity_Size_Details " (trade product pack)"
```

where the component parts are described as follows.

Table 56: 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. 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 alternate name which has market recognisability.
TF_Supplier	The supplier name for products available as an unbranded generic medicine, or the housebrand (e.g. Terry White Chemists, Chemmart).
Other_Pack_Information	Additional details that are required to avoid ambiguity or duplication in the constructed description. This information should be descriptive information that is relevant to the Trade Product Pack (e.g. 'sugar free', 'refill', 'strawberry').

Description Component	Description
TPUU_Details	The ingredients, strengths, form and quantity (for multi-component TPPs) of each of the TPUU components, enclosed in round brackets, with a " + " between ingredient, strength pairs and followed by the form of the TPUU and the quantity value (placed inside square brackets). Note that the quantity value is only shown here for multi-component TPPs). The quantity units are only included when they are different from the TPUU's manufactured form (and all the form's parents in the Form hierarchy). Note that where the ingredient's BoSS is the active ingredient itself (including the salt), then the format used will be 'Salt_Ingredient Salt_Strength'. Where the ingredient's BoSS is the base of the ingredient, then the format used will be 'Base_Ingredient (as Salt_Ingredient_Minus_Base) Base_Strength'. Note also that the order of components is alphabetical, based on the first and then subsequent ingredients. Where these are the same, then the order is based on the strength of the first and then subsequent ingredients. The order of ingredients within a component is the same as that of the associated TPUU FSN. If the total unit of use quantity value is greater than 1, the plural units description is used for the associated quantity units, e.g. tablets, capsules, vials; with the exception of "microgram" and "microlitre".
TPP_Total_Quantity_Size_Details	This component includes the description 'total unit of use quantity value' and the preferred term of the unit of measure from 'TPP has total unit of use quantity units' (e.g. 25 tablets). If the TPP has a total size, then the 'total unit of use quantity value' and its unit of measure is separated by the multiplication symbol (i.e. " x "), followed by the total size value and units (e.g. 2 x 5 mL vials). If 'total unit of use quantity value' is greater than "1", the plural units description is used for the associated quantity units, e.g. tablets, capsules, vials; with the exception of "microgram" and "microlitre".
(trade product pack)	The semantic tag used in the FSN of all Trade Product Pack concepts.

5.7.2.2 Trade Product Pack Fully Specified Name rules

Table 57: TPP FSN rules

Rule ID	Description
AMT-TPP-FSN-1	All rules in Section 4.1.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.

Rule ID	Description
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 (e.g. 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 (e.g. 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 (e.g. Moduretic tablets).
AMT-TPP-FSN–3	Strength expression The strength expression general rules and application to specific medication forms are outlined in Appendix F. 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 (e.g. sugar free, refill, flavour). For example: Panadol Rapid Handipak (paracetamol 500 mg) tablet: film-coated, 20 tablets (trade product pack).
AMT-TPP-FSN-5	Pack_Units: If the Pack_Units is greater than one, then the Pack quantity units will be expressed as a plural form with the exception of "microgram" and "microlitre". See Appendix J for appropriate Pack Quantity Units of Measure. If all the components have the same unit dose form, the pack size is the total number of unit dose forms (e.g. if both components are tablets, the pack size = x tablets). • e.g. Didrocal contains 28 tablets + 76 tablets Pack size = 104 tablets If the components are different forms but are both 'discrete', the pack size will equal "1 pack". • e.g. Nexium Hp7 contains 14 tablets + 28 capsules + 14 tablets Pack size = 1 pack If the pack consists of a discrete and continuous unit dose forms, the pack size will equal "1 pack". • e.g. Canesoral Duo (1 x 150 mg capsule, 1 x 10 g cream) Pack size = 1 pack

5.7.2.3 Trade Product Pack Preferred Term brief definition

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

```
TPP PT :=  TF_Name [" (" TF_Supplier ")"]
           [" " Other_Pack_Information] [" " BoSS_Strength]
           [" " Form] [" " PT_Other_Identifying_Information]
           ", " Total_Quantity_Size_Details
```

where the component parts are described as follows.

Table 58: TPP PT description

Description Component	Description
TF_Name	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 alternate name which has market recognisability.
TF_Supplier	The supplier name for products available as an unbranded generic medicine, or the housebrand (e.g. Terry White Chemists, Chemmart).
Other_Pack_Information	Additional details that are required to avoid ambiguity or duplication in the constructed description. This information should be descriptive information that is relevant to the trade product pack (e.g. 'sugar free', 'refill', 'strawberry').
BoSS_Strength	A valid representation of the strength for the Basis of Strength Substance (BoSS) as derived from the associated MPUU. This is only populated if the TPP has a single TPUU component with only one active ingredient.
Form	This is only populated if the TPP has a single TPUU, or if all TPUUs in the pack have the same form. This is the form, as derived from the destination of the associated MPUU HAS MANUFACTURED DOSE FORM RELATIONSHIP. Where a proprietary dose form is included as part of the TF_Name, then the associated dose form (as indicated in Appendix I) should be included here.
PT_Other_Identifying_Information	Some TPPs require additional information (for example component summary information) to be included to ensure that the PT uniquely identifies the TPP. Note: In the case of vaccines, this information will be kept to a minimum (due to the lengthy nature of the descriptions which would usually be contained here) and will consist of the pack quantity size value and unit dose type.
Total_Quantity_Size_Details	This component includes the description 'total unit of use quantity value' and the preferred term of the unit of measure from 'TPP has total unit of use quantity units' (e.g. '25 tablets'). If the 'total unit of use quantity units' is the same as every form in the pack (or one of the form's parents in the Form hierarchy), then this total quantity units is not included. If the TPP has a total size, then the 'total unit of use quantity value' and its unit of measure is separated by the multiplication symbol (i.e. " x "), followed by the total size value and units (e.g. 2 x 5 mL vials). If 'total unit of use quantity value' is greater than "1", the plural units description is used for the associated quantity units, e.g. tablets, capsules, vials; with the exception of "microgram" and "microlitre".

5.7.2.4 Trade Product Pack Preferred Term rules

Table 59: TPP PT rules

Rule ID	Description
AMT-TPP-PT-1	All rules defined in Section 4.1.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix B 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 (e.g. 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 (e.g. 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 (e.g. Moduretic tablets).
AMT-TPP-PT-3	Strength expression The strength expression general rules and application to specific medication forms is outlined in Appendix F. Strength expression may include an alternate strength representation different to the typical numerator/denominator strength expression. It may include a dual strength representation. Refer to Appendices F.1 and F.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, e.g. ‘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 (e.g. ‘sugar free’, ‘refill’, ‘flavour’). For example: Panadol Rapid Handipak 500 mg tablet: film-coated, 20 tablets.

Rule ID	Description
AMT-TPP-PT-6	Pack_Units: If the Pack_Units is greater than one, then the Pack quantity units will be expressed as a plural form, with the exception of "microgram" and "microlitre". See Appendix J for appropriate Pack Quantity Units of Measure. If all the components have the same unit dose form, the pack size is the total number of unit dose forms (e.g. if both components are tablets, the pack size = x tablets). • e.g. Didrocal contains 28 tablets + 76 tablets Pack size = 104 tablets If the components are different forms but are both 'discrete', the pack size will equal "1 pack". • e.g. Nexium Hp7 contains 14 tablets + 28 capsules + 14 tablets Pack size = 1 pack If the pack consists of a discrete and continuous unit dose forms, the pack size will equal "1 pack". • e.g. Canesoral Duo (1 x 150 mg capsule, 1 x 10 g cream) Pack size = 1 pack

5.7.2.5 Trade Product Pack 'Other pack information' definition and rules

Definition

The TPP 'Other pack information' allows optional descriptive information about the TPP to be displayed (e.g. sugar free, refill, flavour, etc). 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 4.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 60: TPP 'Other pack information' rules

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

5.7.2.6 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 4.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 61: 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.

5.7.2.7 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 4.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 62: 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 (e.g. 6, 0.25).
AMT-TPP-TUUQV-2	This value is optional.

5.8 Contained Trade Product Pack (CTPP)

5.8.1 Contained Trade Product Pack definition

The Contained 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, vial, etc.

Table 63: Examples of Contained Trade Product Pack FSNs and PTs

Type of product	Fully Specified Name	Preferred Term
Single ingredient	Amoxil (amoxycillin (as trihydrate) 500 mg) capsule: hard, 20 capsules, blister pack (contained trade product pack)	Amoxil 500 mg capsule: hard, 20 capsules, blister pack
Single ingredient – clinically relevant salt (refer to Appendix C)	Voltaren 50 (diclofenac sodium 50 mg) tablet: enteric, 50 tablets, bottle (contained trade product pack)	Voltaren 50 mg tablet: enteric, 50 tablets, bottle

Type of product	Fully Specified Name	Preferred Term
Single ingredient – clinically significant salt (refer to Appendix C)	Sodium Chloride 0.9% (Baxter) (sodium chloride 9 g / 1000 mL) injection: intravenous infusion, 1 x 1000 mL bag, bag (containered trade product pack)	Sodium Chloride (Baxter) 0.9% (9 g/1000 mL) injection: intravenous infusion, 1 x 1000 mL bag AHB 1324
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 tablets, blister pack
Multi-ingredient Multi-component Sequential	• 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) tablet: sugar-coated [20 tablets] (&) (inert substance) tablet: sugar-coated [28 tablets], 112 tablets [4 x 28 tablets], blister pack (containered trade product pack) • Triphasil (ethinyloestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated [10 tablets] (&) (ethinyloestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated [6 tablets] (&) (ethinyloestradiol 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, 112 tablets [4 x 28 tablets], blister pack • Triphasil, 28 tablets, blister pack

Type of product	Fully Specified Name	Preferred Term
Multi-component Sequential	• Didrocal (calcium (as carbonate) 500 mg) tablet: film-coated [76 tablets] (&) (etidronate disodium 200 mg) tablet: uncoated [28 tablets], 104 tablets, blister pack (containered trade product pack) • Calcium Carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg) tablet: film-coated, 76 tablets, blister pack (containered trade product pack) • Didronel (etidronate disodium 200 mg) tablet: uncoated, 28 tablets, blister pack (containered trade product pack)	• Didrocal, 104 tablets, blister pack • Calcium Carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg tablet), 76 tablets, blister pack • Didronel 200 mg tablet, 28 tablets, blister pack
Multi-component kit	• Nexium Hp7 (amoxycillin (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 (containered trade product pack) • Amoxil (amoxycillin (as trihydrate) 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 (as magnesium trihydrate) 20 mg) tablet: enteric, 14 tablets, blister pack (containered trade product pack)	• Nexium Hp 7, 1 pack, composite pack • Amoxil 500 mg capsule, 28, blister pack • Klacid 500 mg tablet: film-coated, 14 tablets, blister pack • Nexium 20 mg tablet, 14, blister pack
patch	Estraderm 100 (oestradiol 100 microgram / 24 hours) patch, 8 patches, sachet (containered trade product pack)	Estraderm 100 microgram/24 hours patch, 8, sachet
injection solution less than 1 mL	Modecate (fluphenazine decanoate 12.5 mg / 0.5 mL) injection: solution, 5 x 0.5 mL ampoules, ampoule (containered trade product pack)	Modecate 12.5 mg/0.5 mL injection: solution, 5 x 0.5 mL ampoules

Type of product	Fully Specified Name	Preferred Term
injection powder with diluent	• Somatuline LA (inert substance) diluent [1 x 2 mL ampoule] (&) (lantreotide (as acetate) 30 mg) injection: modified release [1 x 30 mg vial], 1 pack, composite pack (containered trade product pack) • Somatuline LA (lanreotide (as acetate) 30 mg) injection: modified release, 1 x 30 mg vial, vial (containered trade product pack) • Somatuline LA (inert substance) diluent, 1 x 2 mL ampoule, ampoule (containered trade product pack)	• Somatuline LA (1 x 30 mg vial), 1 pack, composite pack • Somatuline LA 30 mg injection: modified release, 1 x 30 mg vial • Somatuline LA diluent, 1 x 2 mL ampoule

5.8.2 Containered Trade Product Pack descriptions

5.8.2.1 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
              [" (" Other_Containered_Pack_Information ")"]
              " (containered trade product pack)"
```

where the component parts are described as follows.

Table 64: CTPP FSN description

Description Component	Description
TPP_FSN_Details	The details included in the FSN of the associated TPP, but without the semantic tag (i.e. without "(trade product pack)"). If the given CTPP represents a component pack the details included are TF_Name, ingredient(s), strength(s) and form as derived from the associated TPUU FSN and Total_Quantity_Size_Details as derived from the associated MPP FSN.
Container	The PT of the container type of the CTPP, as defined by the relationship CTPP 'HAS CONTAINER TYPE'.
Other_Containered_Pack_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 containered trade product pack (e.g. 'pack includes applicator').
(containered trade product pack)	The semantic tag used in the FSN of all Containered Trade Product Pack concepts.

5.8.2.2 Containered Trade Product Pack Fully Specified Name rules

Table 65: CTPP FSN rules

Rule ID	Description
AMT-CTPP-FSN-1	All rules in Section 4.1.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.
AMT-CTPP-FSN-2	ContainerType Container type will always be populated, as defined by the TGA. See Appendix K.

5.8.2.3 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
            [" (" Other_Containered_Pack_Information ")"]
            [" " Manufacturers_Code]
```

where the component parts are described as follows.

Table 66: CTPP PT description

Description Component	Description
TPP_PT_Details	The details included in the PT of the associated TPP. If the given CTPP represents a component pack the details included are TF_Name, strength(s) and form as derived from the associated TPP PT (i.e. without the TPP PT's Total_Quantity_Size_Details) and Total_Quantity_Size_Details as derived from the associated MPP PT.
Container	The PT of the container type of the CTPP, as defined by the relationship CTPP HAS CONTAINER TYPE.
Other_Containered_Pack_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 containered trade product pack (e.g. 'pack includes applicator').
Manufacturers_Code	The product code assigned by the manufacturer of the product. This code may be displayed on the commercial product packaging.

5.8.2.4 Containered Trade Product Pack Preferred Term rules

Table 67: CTPP PT rules

Rule ID	Description
AMT-CTPP-PT-1	All rules defined in Section 4.1.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.
AMT-CTPP-PT-2	ContainerType Container type will always be populated as defined by the TGA.

5.8.2.5 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 4.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 68: 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.

5.8.2.6 Containered Trade Product Pack 'Other containered pack information' definition and rules

Definition

The CTPP 'Other containered pack information' allows optional descriptive information about the CTPP to be displayed (e.g. pack includes applicator, etc). 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.

Note that as per Section 4.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 69: CTPP 'Other containered pack information' rules

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

5.8.2.7 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 mullti-component pack.

Note that as per Section 4.1.4.1, this is an additional description type which is not released in the terminology release files.

Table 70: CTPP 'Other containered pack information' rules

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

6 Substance concepts

These concepts represent the ingredients within products.

6.1 Substance (SUB)

6.1.1 Substance definition

These are concepts that represent the chemical entities that may act as ingredients of medicinal products, as follows.

- Complete substances that act as actual active ingredients of medicinal products, for example, heparin sodium, perindopril arginine and dexamethasone sodium phosphate. This class of substance may or may not be a salt 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 or dilute 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 salt ingredient to its related base ingredient within the medicinal substance hierarchy (e.g. acamprosate calcium is a modification of acamprosate). An IS MODIFICATION OF relationship also exists to link a modified salt (i.e. an ingredient that is further modified than the initial salt) to its related salt ingredient (e.g. piperazine oestrone sulfate is modification of oestrone sulfate sodium).

Table 71: 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

6.1.2 Substance descriptions

6.1.2.1 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 72: 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.

6.1.2.2 Substance Fully Specified Name rules

Table 73: Substance FSN rules

Rule ID	Description
AMT-SUB-FSN-1	All rules in Section 4.1.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.
AMT-SUB-FSN-2	The substance FSN will be derived from the Australian Approved Name (AAN)[5], followed by other approved or clinically intuitive names as specified in the Australian Register of Therapeutic Goods [TGAM1999]. The base form of the substance as well as the salt will be represented. EXCEPTION This may, however, differ to meet requirements of clinical practice. Current exceptions are listed in Appendix D 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 e.g. animal origin, plant part and plant preparation. Note: Exception list TBC. Additions to the exceptions list will be reviewed on a case-by-case basis.

6.1.2.3 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.

Table 74: Substance PT description

Description Component	Description
Ingredient_Name	The name of the substance.

[5] See: www.tga.gov.au/pdf/medicines-approved-terminology.pdf.

6.1.2.4 Substance Preferred Term rules

Table 75: Substance PT rules

Rule ID	Description
AMT-SUB-PT-1	All rules defined in Section 4.1.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix B apply.
AMT-SUB-PT-2	The substance PT will be derived from the Australian Approved Name (AAN)[6], 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 salt will be represented. EXCEPTION This may, however, differ to meet requirements of clinical practice. Current exceptions are listed in Appendix D 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, e.g. animal origin, plant part and plant preparation. Note: Exception list TBC. Additions to the exceptions list will be reviewed on a case-by-case basis.

[6] See: www.tga.gov.au/pdf/medicines-approved-terminology.pdf.

7 Australian Qualifier concepts

7.1 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 76: 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 etc.	The name is derived from the TGA Approved Terminology for Medicines.
Form (F)	This qualifier concept describes the dose formulation, for example, tablet, capsules or eye drops. The form may also be described in the terminology as a dose form. The dose form is the form in which the product is manufactured and transported (i.e. the dose form created by the manufacturer, e.g. 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, e.g. oral liquid: suspension, which is reconstituted from the manufactured dose form of powder for reconstitution.) As the dose form is a defining characteristic of medication and is linked with knowledge regarding medicine administration, it is important that there is a standard defining list of dose forms.	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.

Concept Name	Definition	Source of Data
Unit of Measure (UOM)	Unit of Measure is used to describe the units used to measure various quantities within the AMT. Units of Measure are used to describe the following: • Base form strength numerator units • Base form strength denominator units • Proportion units (see Appendix G.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.
Unit of Use (UOU)	The Unit of Use describes a discrete unit dose form (e.g. tablet, capsule) or a continuous substance where a consistent physically measurable unit or sub-unit cannot be identified (e.g. cream, eye drops).	The Unit of Use name is derived from the Dosage Forms and Container Types specified in the TGA Approved Terminology for Medicines [TGAM1999, Chapter 5]. 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 77: 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

7.2 Australian Qualifier descriptions

7.2.1 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 78: 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 4.1.4.3.1 (Fully Specified Name Definition and Rules) apply.

7.2.2 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 79: Australian Qualifier PT description

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

Table 80: Australian Qualifier PT rules

Rule ID	Description
AMT-AQ-PT-1	All rules defined in Section 4.1.4.3.2 (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 H for Preferred Term Forms.

7.3 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 4.1.4.1, this is an additional description type which is not released in the terminology release files.

8 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* [STIG2012].

8.1 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*.

8.2 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*.

8.3 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*.

9 References

9.1 NEHTA

Note: Access to documents in the NCTIS website requires a (free) SNOMED CT licence, which can be applied for at the following URL: <https://nehta.org.au/aht/index.php?option=com_licences&task=r>

[AMT2012] *Australian Medicines Terminology Implementation Plan,* v.1.0, NEHTA, 2012. Available from: <http://www.nehta.gov.au/connecting-australia/terminology-and-information/clinical-terminology/australian-medicines-terminology>

[NEHT2011] *NCTIS Development Approach for Reference Sets*, release 20110531, NEHTA, 2011. Available from: <https://nehta.org.au/aht/index.php?option=com_docman&task=cat_view&gid=34&Itemid=40> (NCTIS website)

9.2 IHTSDO

[STIG2012] *SNOMED CT Technical Implementation Guide*, Jan 2012. Available from: <http://www.snomed.org/doc>

[SUG2012] *SNOMED CT User Guide*, Jan 2012. Available from: <http://www.snomed.org/doc>

9.3 Other

[AIH2008] Australian Government Department of Health and Ageing and the National Health and Medical Research Council, *Australian Immunisation Handbook*, 9th edition 2008. Available from: <http://www.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook-home>

[HNSG2007] Braun, Lesley and Cohen, Marc, 2007. *Herbs & Natural Supplements: An Evidence-based Guide,* 2nd edition. Australia: Elsevier.

[MCDP2012] The Pharmaceutical Press, 2012, *Martindale: The Complete Drug Reference*. Available from: <http://www.medicinescomplete.com/mc/martindale/current/> (Subscription required.)

[TGAM1999] Australian Government Department of Health and Ageing and the Therapeutic Goods Administration, *TGA Approved Terminology for Medicines*, July 1999. Available from: <http://www.tga.gov.au/pdf/medicines-approved-terminology.pdf>

[TGO2009] Australian Government Attorney-General's Department, *Therapeutic Good Order No. 69 – General requirements for labels for medicines*, registered 2009. Available from: <http://www.comlaw.gov.au/Details/F2009C00264>

Appendix A. Glossary

Acronym	Term	Meaning
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	
ATC	WHO Anatomical Therapeutic Chemical Classification	
base	base	Within the AMT a 'base' is defined as the active moiety of the ingredient name (i.e. the segment of the molecule which has an intended therapeutic effect on the body).
BoSS	Basis of Strength Substance	
CT	Container Type	
CTPP	Contained Trade Product Pack	
dm+d	UK Dictionary of Medicines and Devices	
EBNF	Extended Backus-Naur Form	
F	Form	
FSN	Fully Specified Name	
ID	Identifier	
IEC	International Electrotechnical Commission	
IHTSDO	International Health Terminology Standards Development Organisation	
ING	Ingredient	
ISO	International Organization for Standardization	
IUPAC	International Union of Pure and Applied Chemistry	
MCCA	Medicines Coding Council of Australia	

Acronym	Term	Meaning
modified salt	modified salt	Within the AMT a 'modified salt' is a salt 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 ingredient
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	
PF	Proprietary Form	
PT	Preferred Term	
R	Route	The route of adminstration for a medicine.
RPBS	Repatriation Pharmaceutical Benefits Scheme	
salt	salt	Within the AMT a 'salt' is defined as an additional segment which is combined with the base (but does not have an intended therapeutic effect on the body).
SCTID	SNOMED Clinical Terms Identifier	
SNOMED	Systematized Nomenclature of Medicine	
SNOMED CT	Systematized Nomenclature of Medicine, Clinical Terms	
SNOMED CT-AU	SNOMED CT Australian Release	
SPO	Sponsor	
TBC	To be created	
TF	Trade Family	
TGA	Therapeutic Goods Administration	Australia's regulatory agency for medical drugs and devices.
TP	Trade Product	
TPP	Trade Product Pack	

Acronym	Term	Meaning
TPUU	Trade Product Unit of Use	
UOM	Unit of Measure	
UOU	Unit of Use	
UOUS	Unit of Use Size	
UTF-8	Unicode Transformation Format (8-bit)	
UUID	Universally Unique Identifier	
WHO	World Health Organisation	

Appendix B. Capitalisation

Table 81: Capitalisation rules

Rule ID	Description
AMT-APP-CAP-1	The first character of a description (FSN, Preferred term, 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-8 inclusive.
AMT-APP-CAP-2	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 (e.g. Dimetapp Chesty Cough Elixir). Individual words which appear as all upper or all lower cased will be title cased (e.g. Ganfort not GANFORT, Elevit not elevit). Each word in a hyphenated name will be expressed as title case (e.g. Duro-Tuss, Anti-Inflammatory). EXCEPTIONS Unique brand specific casing will be maintained only if it assists with readability. This also applies to concatenated terms (e.g. DaktaGold not DaktaGOLD, GlucoOz). Articles such as 'the' will be in lower case. Conjunctions such as 'and' and prepositions such as 'with' will be in lower case. Certain words, such as 'plus' may be either in title case or lower case, depending on their use (e.g. Coversyl Plus, Day plus Night).
AMT-APP-CAP-3	Proper nouns will always be expressed in title case (e.g. Bacillus Calmette and Guerin, Brisbane).
AMT-APP-CAP-4	Roman numerals will always be expressed in upper case (e.g. 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 (e.g. carbon (C), chromium (51Cr) edetate, cyanocobalamin (57Co)).
AMT-APP-CAP-6	Single letters following a substance name will be expressed in upper case (e.g. 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 (e.g. Haemophilus influenzae).

Rule ID	Description
AMT-APP-CAP-8	Organic chemical names. 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 (e.g. methyl-2-methoxy-3-pyrazine). Chemical ring position will always be expressed in lower case (e.g. ortho-dichlorobenzene, para-dichlorobenzene). 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 (e.g. D-alpha tocopherol, L-lysine, N-acetyl, 2-methyl, N-acetyl-L-cysteine). Isomeric names which have the full expression of the isomer embedded in the name will be entirely in lower case (e.g. dextromethorphan, levodopa, cisatracurium). Greek letters will be expressed as the actual English spelling of the word rather than using the traditional Greek symbol (e.g 'alpha' and not 'α').

Appendix C. 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 salt or modification.

Note: Where it is considered that the physiological salt (or 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 salt, e.g.

salt	**base**
calcium gluconate	calcium
clodronate sodium	clodronate

- The abstract representation of an active moiety of a compound, e.g.

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.

C.1 Discernible therapeutic differences to the base (clinically significant salts)

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 salts or 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 salt 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 salt exert a therapeutic effect (e.g. hexamine hippurate, silver sulphadiazine);
- where both the base and salt exert a different therapeutic effect resulting in the substance having more than one therapeutic purpose (e.g. calcium carbonate in calcium supplements (due to calcium content) versus calcium carbonate in antacids (due to carbonate content)); and
- where the type of salt results in a distinct use of the active ingredient (e.g. 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 D. Ingredient naming conventions

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

D.1 Ingredients ending in '-ate'

In a small number of instances, ingredients that end in '-ate' when available as a salt, shall be changed so that the base is represented by ending in '-ic acid' where appropriate. The current edition of *Martindale: The Complete Drug Reference* [MCDP2012] will be the reference source. Only the ingredients listed in the following table will be changed.

Additional exceptions will be added when required.

Table 82: Examples of ingredients ending in '-ate'

TGA Ingredient Name	AMT Ingredient Name
folinate	folinic acid

D.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 salt name is represented first. 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
sodium valproate	valproate sodium

D.3 Waters of hydration

Waters of hydration shall only be expressed for each ingredient in the Fully Specified Name where hydration is present and the salt is deemed to be clinically significant (according to Appendix C). Where an ingredient is found to be anhydrous, 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.

(This is yet to be implemented.)

Example:

MP FSN:	atropine sulfate (medicinal product)
MP PT:	atropine sulfate
MPUU FSN:	atropine 499.8 microgram | atropine sulfate monohydrate 600 microgram tablet (medicinal product unit of use)
MPUU PT:	atropine sulfate 600 microgram tablet

D.4 Insulins

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

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

D.5 Medicinal Product Preferred Term sequence of ingredients

The following table lists some examples of medicinal products where the sequence of ingredients is not alphabetical. This may be an exception based on one of the following reasons:

- clinical practice;
- one or more of the ingredients has no inherent action in its own right; or
- local anaesthetic agents are listed first in all topical preparations, including those for oral/buccal use, followed by all other ingredients in alphabetical order.

Note that this exception list is incomplete and is under review.

Table 84: Examples of non-alphabetical sequences of ingredients

Alphabetical order MP	Exception order MP	Trade Product or Trade Product Group example
acetate + magnesium chloride + potassium chloride + sodium chloride + sodium gluconate	sodium + potassium + magnesium + acetate	Plasma-Lyte 148
acetic acid + hydroxyquinoline + ricinoleic acid	hydroxyquinoline + acetic acid + ricinoleic acid	Aci-Jel
adrenaline + articaine	articaine + adrenaline	Bucanest
adrenaline + bupivacaine	bupivacaine + adrenaline	Marcaine with Adrenaline
adrenaline + lignocaine	lignocaine + adrenaline	Xylocaine with Adrenaline
adrenaline + mepivacaine	mepivacaine + adrenaline	Scandonest Special
adrenaline + prilocaine	prilocaine + adrenaline	Citanest with Adrenaline
alcohol + benzalkonium chloride + coal tar solution + polyoxyethylene ethers + salicylic acid	salicylic acid + benzalkonium chloride + alcohol + coal tar solution + polyoxyethylene ethers	Ionil-T
alcohol + benzalkonium chloride + polyoxyethylene ethers + salicylic acid	salicylic acid + benzalkonium chloride + alcohol + polyoxyethylene ethers	Ionil
alginate sodium + bicarbonate + calcium	alginate sodium + calcium + bicarbonate	Gaviscon
alginic acid + bicarbonate + magaldrate	alginic acid + magaldrate + bicarbonate	Mylanta 2go Antacid Dual Action
alpha amylase + lipase + protease	lipase + protease + alpha amylase	Cotazyme
aluminium + magnesium + magnesium trisilicate	aluminium + magnesium trisilicate + magnesium	Gastrogel
amiloride + hydrochlorothiazide	hydrochlorothiazide + amiloride	Moduretic
aminacrine + lignocaine	lignocaine + aminacrine	Medijel
ammonium + senega	senega + ammonium	Senega and Ammonia (Gold Cross)
amylmetacresol + dichlorobenzyl alcohol + lignocaine	lignocaine + amylmetacresol + dichlorobenzyl alcohol	Strepsils Plus
aqueous cream + salicylic acid	salicylic acid + aqueous cream	Salicylic Acid in Aqueous Cream (David Craig)

Alphabetical order MP	Exception order MP	Trade Product or Trade Product Group example
aqueous cream + salicylic acid + sulfur precipitated	salicylic acid + sulfur precipitated + aqueous cream	Salicylic Acid and Sulphur in Aqueous Cream (David Craig)
arachis oil + chlorbutol + ortho-dichlorobenzene + para-dichlorobenzene	ortho-dichlorobenzene + para-dichlorobenzene + chlorbutol + arachis oil	Cerumol
arachis oil extract of coal tar + cade oil + coal tar + tar	tar + cade oil + coal tar + arachis oil extract of coal tar	Polytar
ascorbic acid + biotin + cocarboxylase + colecalciferol + cyanocobalamin + dexpanthenol + dl-alpha-tocopherol + folic acid + nicotinamide + pyridoxine + retinyl palmitate + riboflavine	pyridoxine + retinyl palmitate + riboflavine + ascorbic acid + biotin + colecalciferol + cocarboxylase + cyanocobalamin + dexpanthenol + dl-alpha-tocopherol + folic acid + nicotinamide	Cernevit
ascorbic acid + ferrous sulfate dried	ferrous sulfate-dried + ascorbic acid	Ferro-Grad C
aspirin + dipyridamole	dipyridamole + aspirin	Asasantin
atropine + diphenoxylate	diphenoxylate + atropine	Lomotil
bacitracin zinc + neomycin	neomycin + bacitracin zinc	Nemdyn
benserazide + levodopa	levodopa + benserazide	Madopar
benzalkonium chloride + ethanol + salicylic acid	benzalkonium chloride + salicylic acid + ethanol	Ora-sed
benzalkonium chloride + idoxuridine + lignocaine	lignocaine + benzalkonium chloride + idoxuridine	Virasolve
benzalkonium chloride + lignocaine	lignocaine + benzalkonium chloride	Paxyl
benzoic acid + bicarbonate + thymol	thymol + benzoic acid + bicarbonate	Thymol Compound mouthwash (APF 15)
benzydamine + dichlorobenzyl alcohol + lignocaine	lignocaine + benzydamine + dichlorobenzyl alcohol	Logicin Rapid Relief
benzyl benzoate + peru balsam + zinc	zinc + peru balsam + benzyl benzoate	Anusol
betamethasone + calcipotriol	calcipotriol + betamethasone	Daivobet

Alphabetical order MP	Exception order MP	Trade Product or Trade Product Group example
bicarbonate + carbonate + citric acid	citric acid + bicarbonate + carbonate	Eno
bicarbonate + concentrated compound gentian infusion	concentrated compound gentian infusion + bicarbonate	Gentian Alkaline Mixture (APF 20)
bicarbonate + gentian	gentian + bicarbonate	Gentian Alkaline Mixture (David Craig)
bicarbonate + macrogol-3350 + potassium + sodium	macrogol-3350 + sodium + potassium + bicarbonate	Movicol
boric acid + sodium	sodium + boric acid	Amosan
bufexamac + chlorhexidine + lignocaine	lignocaine + bufexamac + chlorhexidine	Paraderm Plus
butyl hydroxybenzoate + propionic acid + salicylic acid	butyl hydroxybenzoate + salicylic acid + propionic acid	Mycoderm
butyl methoxydibenzoylmethane + octyl methoxycinnamate	octyl methoxycinnamate + butyl methoxydibenzoylmethane	Aquasun
calcium + chloride + potassium + polygeline + sodium	polygeline + potassium + sodium + calcium + chloride	Haemaccel
calcium + glucose + lactate + potassium + sodium	lactate + sodium + potassium + calcium + glucose	Compound Sodium Lactate (Hartmann's) and Glucose (Baxter)
calcium + lactate + potassium + sodium	lactate + sodium + potassium + calcium	Compound Sodium lactate (Baxter)
calcium + potassium + sodium	sodium + potassium + calcium	Compound Sodium Chloride (Baxter)
camphor + menthol + salicylic acid	camphor + salicylic acid + menthol	Rubesal
carbidopa + levodopa	levodopa + carbidopa	Sinemet
carbidopa anhydrous + entecapone + levodopa	levodopa + carbidopa anhydrous + entecapone	Stalevo
cetomacrogol aqueous cream + salicylic acid	salicylic acid + cetomacrogol aqueous cream	Salicylic Acid in Sorbolene Cream (David Craig)
cetrimide + chlorhexidine	chlorhexidine + cetrimide	Savlon
cetrimide + chlorhexidine + lignocaine + menthol	lignocaine + cetrimide + chlorhexidine + menthol	Burn and Bite (Amcal)

Alphabetical order MP	Exception order MP	Trade Product or Trade Product Group example
cetrimide + chlorhexidine + lignocaine + phenoxyisopropanol	lignocaine + cetrimide + chlorhexidine + phenoxyisopropanol	SOOV
cetrimide + lignocaine	lignocaine + cetrimide	SOOV Burn
chloral hydrate + menthol + methyl salicylate + zinc	methyl salicylate + menthol + chloral hydrate + zinc	Methyl Salicylate Compound (Gold Cross) (ointment)
chlorhexidine + lignocaine	lignocaine + chlorhexidine	Lignocaine with Chlorhexidine Gluconate (Pfizer (Perth))
chlorhexidine + sulfadiazine silver	sulfadiazine silver + chlorhexidine	Silvazine
chlorphenesin + maize starch + talc purified + zinc	zinc + maize starch + chlorphenesin + talc purified	Z.S.C. (Sigma)
chromium + cupric chloride dihydrate + manganese	cupric chloride dihydrate + chromium + manganese	Copper, Chromium and Manganese (Phebra)
cinchocaine + hydrocortisone	hydrocortisone + cinchocaine	Proctosedyl
cinchocaine + prednisolone	prednisolone + cinchocaine	Scheriproct
citric acid + glucose + potassium + sodium	sodium + potassium + glucose + citric acid	Repalyte
citric acid + lauryl sulfoacetate sodium + sorbitol	sorbitol + citric acid + lauryl sulfoacetate sodium	Microlax
clavulanic acid + ticarcillin	ticarcillin + clavulanic acid	Timentin
clioquinol + flumethasone	flumethasone + clioquinol	Locacorten-Vioform
coal tar solution + phenol + sulfur precipitated	coal tar solution + sulfur precipitated + phenol	EgoPsoryl
coal tar solution + salicylic acid + tar + undecylenamide dea	coal tar solution + tar + salicylic acid + undecylenamide	Sebitar
cocoamphodiacetic acid + paraffin light liquid	paraffin light liquid + cocoamphodiacetic acid	Hamilton Skin Therapy wash
codeine + paracetamol	paracetamol + codeine	Panadeine
cyanocobalamin + iron + lysine + pyridoxine + thiamine	iron + thiamine + pyridoxine + cyanocobalamin + lysine	Accomin
drosperinone + oestradiol	oestradiol + drospirenone	Angeliq

Alphabetical order MP	Exception order MP	Trade Product or Trade Product Group example
dydrogesterone + oestradiol	oestradiol + dydrogesterone	Femoston
emtricitabine + tenofovir	tenofovir + emtricitabine	Truvada
enalapril + lercanidipine	lercanidipine + enalapril	Zan-Extra
ethanol + glycerol + lignocaine + menthol + salicylic acid + tannic acid + thymol	lignocaine + ethanol + glycerol + menthol + salicylic acid + tannic acid + thymol	SM-33 Gel
ethanol + laureth-9 + povidone-iodine	povidone-iodine + ethanol + laureth-9	Betadine Cold Sore Paint
ethanol + lignocaine + rheum palmatum + salicylic acid + tannic acid	lignocaine + ethanol + rheum palmatum + salicylic acid + tannic acid	SM-33 Adult Formula Liquid
ethanol + povidone-iodine	povidone-iodine + ethanol	Betadine Alcoholic Skin Preparation
ethinyloestradiol + levonorgestrel	levonorgestrel + ethinyloestradiol	Triphasil
ethinyloestradiol + norethisterone	norethisterone + ethinyloestradiol	Brevinor
eucalyptus oil + menthol	menthol + eucalyptus oil	Menthol and Eucalyptus Inhalation (Gold Cross)
felodipine + ramipril	ramipril + felodipine	Triasyn
felypressin + prilocaine	prilocaine + felypressin	Citanest with Octapressin
fentanyl + ropivacaine	ropivacaine + fentanyl	Naropin with Fentanyl
fluorescein + lignocaine	lignocaine + fluorescein	Lignocaine Hydrochloride and Fluorescein Sodium (Bausch & Lomb)
folic acid + iron	iron + folic acid	Ferro-f
glibenclamide + metformin	metformin + glibenclamide	Glucovance
glucose + lignocaine	lignocaine + glucose	Lignocaine in Glucose (Baxter)
glucose + magnesium + potassium + sodium	sodium + potassium + magnesium + glucose	Plasma-Lyte 56 Maintenance in Glucose
glucose + potassium	potassium + glucose	Potassium Chloride and Glucose (Baxter)
glucose + potassium + sodium	potassium + sodium + glucose	Potassium Chloride and Sodium Chloride and Glucose (Baxter)
glucose + sodium	sodium + glucose	Sodium Chloride and Glucose (Baxter)
glycerol + magnesium	magnesium + glycerol	Magnoplasm

Alphabetical order MP	Exception order MP	Trade Product or Trade Product Group example
gramicidin + neomycin sulfate + nystatin + triamcinolone	triamcinolone + neomycin sulfate + gramicidin + nystatin	Kenacomb
hydrochlorothiazide + irbesartan	irbesartan + hydrochlorothiazide	Karvezide
hydrochlorothiazide + olmesartan	olmesartan + hydrochlorothiazide	Olmetec Plus
hydrochlorothiazide + quinapril	quinapril + hydrochlorothiazide	Accuretic
hydrochlorothiazide + telmisartan	telmisartan + hydrochlorothiazide	Micardis Plus
hydrochlorothiazide + valsartan	valsartan + hydrochlorothiazide	Co-Diovan
hydrocortisone + lignocaine	lignocaine + hydrocortisone	Xyloproct
indapamide + perindopril	perindopril + indapamide	Coversyl Plus
insulin isophane human + insulin neutral human	insulin neutral human + insulin isophane human	Humulin 30/70
lactate + potassium + sodium	lactate + sodium + potassium	Darrow's Solution
lactic acid + urea	urea + lactic acid	Calmurid
lanolin oil + paraffin liquid	paraffin liquid + lanolin oil	Alpha Keri oil
macrogol-3350 + potassium + sodium	macrogol-3350 + sodium + potassium	Glycoprep-C
medroxyprogesterone + oestrogens conjugated	oestrogens conjugated + medroxyprogesterone	Premia
mestranol + norethisterone	norethisterone + mestranol	Norinyl
metformin + rosiglitazone	rosiglitazone + metformin	Avandamet
norethisterone + oestradiol	oestradiol + norethisterone	Kliovance
phenylephrine + prednisolone	prednisolone + phenylephrine	Prednefrin Forte
phenylephrine + zinc	zinc + phenylephrine	Zincfrin
potassium bicarbonate + potassium carbonate + potassium chloride	potassium chloride + potassium bicarbonate + potassium carbonate	Chlorvescent
rhamnus frangula + sterculia	sterculia + rhamnus frangula	Normacol Plus

Alphabetical order MP	Exception order MP	Trade Product or Trade Product Group example
sulfamethoxazole + trimethoprim	trimethoprim + sulfamethoxazole	Septrin
testosterone decanoate + testosterone isocaproate + testosterone phenylpropionate + testosterone propionate	tesetosterone propionate + testosterone phenylpropionate + testosterone isocaproate + testosterone decanoate	Sustanon 250
testosterone isocaproate + testosterone phenylpropionate + testosterone propionate	tesetosterone propionate + testosterone phenylpropionate + testosterone isocaproate	Sustanon 100
timolol + travoprost	travoprost + timolol	Duotrav

Appendix E. 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 Preferred Term.

This list currently contains specific examples, but may contain product groups (e.g. vaccines, parenteral nutrition solutions, etc).

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 85: Examples of products with more than three ingredients

Exception Examples	Trade Product
hepatitis B + diphtheria + 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)

Appendix F. General strength formats

Table 86: General strength format rules

Rule ID	Description
AMT-APP-STR-1	Strength is to be expressed in accordance with the requirements stipulated by the Therapeutic Goods Administration for the labelling of medicine [TGO2009].
AMT-APP-STR-2	The strength units will be consistent with the *Unit of Measure*.
AMT-APP-STR-3	Note that any overage contained in the product to allow the formulated amount to be administered is not specified.
AMT-APP-STR-4	In general, the strength of an active ingredient should be expressed by a number between 1 and 999 metric units. If the number of units is less than 1, the next lower unit level should be used (e.g. 500 micrograms should be used in preference to 0.5 mg). If the number of units is equal to or greater than 1000, the next higher unit level should be used (e.g. 2 g should be used in preference to 2000 mg). This means that the units of strength may vary across a range of products. For example ceftriaxone may have powder for injection strengths of 500 mg, 1 g and 2 g. Where the strength unit of measure would vary within a single product for the ingredient and/or BoSS and/or base according to the above rule, all strength units for the ingredient will be standardised according to the strength unit for the BoSS. For example: • Elocon (mometasone furoate 0.1% (1 mg/g)) cream • Pharmaceutical ingredient strength: mometasone furoate 1 mg/g • BoSS strength: mometasone furoate 1 mg/g • Base strength: mometasone 0.82 mg/g (not mometasone 820 microgram/g) 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 (e.g. Naprosyn SR 1000 (naproxen 1 g) tablet: modified release, 1 tablet (trade product unit of use)). EXCEPTIONS Safety considerations will be taken into account when converting units. If dose titration is likely to occur across a range of products, then strength units for the product group will be reviewed on an individual basis, especially if titration involves use of more than one strength unit. Current exceptions (listed at the base level) are: • fentanyl will always be expressed as micrograms, e.g. fentanyl 1600 microgram lozenge. • 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, e.g. calcitriol 0.25 microgram capsule (not 250 nanograms). • Large volume liquids (e.g. oral solutions, parenteral injections, irrigation solutions, haemodialysis solutions, peritoneal dialysis solutions) will not be converted to "L" and will always be displayed as millilitres ("mL"), e.g. sodium chloride 0.9% (18 g/2000 mL) solution, bag. • Where the value for volume is less than 1 millilitre it will not be

Rule ID	Description
	converted (i.e. to conform to current clinical practice these volumes will not be expressed as microlitres), e.g. dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, syringe. • Where the molar value is less than 1 micromole it will not be converted (i.e. to conform to current clinical practice these values will not be expressed as nanomoles), e.g. no examples currently exist in the AMT. • Where the unit of measure is an index of reactivity (IR) with a value of less than 1, it will not be converted, as there is no appropriate unit to convert it to (e.g. it will continue to exist as 0.5 IR). For example: e.g. house dust mite American + European 0.1 IR/mL injection, vial.
AMT-APP-STR-5	A space will be inserted between the strength value and strength unit of measure. This space must be a non-breaking space to ensure that the strength value and strength unit expressions are always kept together. Note that non-breaking spaces are yet to be implemented.
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. (Note that the use of plurals is not yet fully implemented.) EXCEPTION: The strength units of measure of "microgram" and "microlitre" 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. Where a product is a multi-ingredient vaccine or 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. EXCEPTIONS LIST • Aqueous cream • Calamine lotion • Vitamin B group 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. (To be implemented in future releases.) 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 (i.e. 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. (To be implemented in future releases.) For example: Meruvax II (rubella virus live attenuated vaccine minimum 1000 TCID50 units) injection: powder for, vial.

F.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 alternate representation of the strength or dual representation of strength. This will be used for preparations such as lignocaines, adrenalines, and other preparations. 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 87: Examples of exceptions and associated rules for strength expressions

Medication Form	Rules
Solid unit dose forms – tablets, capsules, pessaries, suppositories, urethral stick, lozenge, pastille, chewing gum, etc.	Strength is to be expressed as the amount per unit dose form, for example: • amoxycillin 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 international units/mL injection: solution.
Liquid unit dose forms – large volume injections for electrolyte replacement, nutritional therapy, plasma volume expander, etc.	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, e.g. sachets of liquid	Strength is to be expressed as the amount of drug per mL, e.g. 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 per container, e.g. sodium bicarbonate 1.76 g/4 g sachet.
Continuous semi-solid preparations – creams, gels, ointments	Strength is to be expressed as a percentage, e.g. aciclovir 5% (50 mg/g) cream.
Continuous liquid preparations – other than for ingestion – mouthwash, paints, eye drops, ear drops, nasal drops, etc.	Strength is to be expressed as weight or volume per gram and/or mL (or other weight or volume of the product as appropriate), e.g. gentamicin 0.3% (3 mg/mL) eye drops.

Medication Form	Rules
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, e.g. • 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, e.g. 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, e.g. psyllium husk powder 535 mg/g powder: oral.
Patches	Strength will be expressed as the amount of active drug released over a stated time, e.g. 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, e.g. 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, e.g. oestradiol 20 mg implant.
Dry powder injections	The strength is expressed as the amount per vial (usually as a weight), e.g. amoxycillin 500 mg injection: powder for.

F.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, e.g. 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 salt (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: This list is not exhaustive and additional examples will be added as determined by clinical practice.

Appendix G. Units of Measure

G.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, e.g. Quantity = 28, Unit of Measure = tablet.

Table 88: 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	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). Note: for large volume parenteral injections, irrigation solutions, haemodialysis and peritoneal dialysis solutions display as millilitres (mL). If the value is less than one millilitre do not convert. If the value is less than one micromole do not convert. Where the strength unit of measure will vary for the actual ingredient, BoSS and base ingredient according to this rule, all units of measure for the ingredient will be standardised according to the unit of measure for the BoSS. For example: • Elocon (mometasone furoate 0.1% (1 mg/g)) cream • Pharmaceutical ingredient strength: mometasone furoate 1 mg/g • BoSS strength: mometasone furoate 1 mg/g • Base strength: mometasone 0.82 mg/g (not mometasone 820 microgram/g)

G.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.

Note: This is yet to be implemented.

Table 89: Examples of Preferred Terms

Fully Specified Name	Preferred Term
International units	units
Kallikrein Inactivator units	units
pressor units	units

G.3 Units of Measure

The following Units of Measure lists are derived from TGA Units [TGAM1999, Chapter 7].

Table 90: Area

Description	Abbreviation
centimetre unit	cm
metre unit	m
millimetre unit	mm
square centimetre unit	square cm

Table 91: Biological units

Description	Abbreviation
allergy unit	allergy unit
antigen unit	antigen unit
anti-Xa international unit	anti-Xa international unit
D antigen unit	D antigen unit
Enzyme-Linked ImmunoSorbent Assay	ELISA unit
index of reactivity unit	IR
kallikrein inactivator unit	KI unit
Kyowa unit	Kyowa unit
million unit	million unit
pressor unit	pressor unit
protein nitrogen unit	protein nitrogen unit
titre unit	titre
unit	unit

Table 92: Mass

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

Table 93: Microbiological cultures

Description	Abbreviation
billion organisms unit	billion organisms
billion vibrios unit	billion vibrios
cell culture infectious dose 50% unit	CCID50 unit
colony forming unit	colony forming unit
international opacity unit	international opacity units
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
thousand organisms unit	thousand organisms
tissue culture infectious dose 50% unit	TCID50 unit
tuberculin unit	tuberculin unit

Table 94: Molecular equivalents

Description	Abbreviation
micromole unit	micromole
millimole unit	mmol
milliosmol unit	mOsm
mole unit	mol
nanomole unit	Nmol

Table 95: Time

Description	Abbreviation
hour unit	hour

Table 96: Type of International Units

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

Table 97: Type of Pharmacopoeial Units

Description	Abbreviation
British Pharmacopoeial unit	BP unit
Pharmacopoeia Europe unit	Ph Eur unit
United States Pharmacopoeial unit	USP unit

Table 98: Volume

Description	Abbreviation
drop unit	drop
litre unit	L
microlitre unit	microlitre
millilitre unit	mL
nanolitre unit	nanolitre

Table 99: Miscellaneous Units

Description	Abbreviation
each unit	each
part unit	part
millions parts unit	million parts

G.4 Proportions

The following Units of Measure list is derived from TGA Expressions of Proportion [TGAM1999, Chapter 7].

Table 100: Proportions

Description	Unit/Proportion
antigen unit/millilitre unit	antigen unit/mL
anti-Xa international unit/millilitre unit	anti-Xa international unit/mL
British Pharmacopoeial unit/each unit	BP unit/each
ELISA unit/millilitre unit	ELISA unit/mL
gram/each unit	g/each
gram/gram unit	g/g
gram/litre unit	g/L
gram/millilitre unit	g/mL

Description	Unit/Proportion
index of reactivity/millilitre unit	IR/mL
international unit/gram unit	international unit/g
international unit/millilitre unit	international unit/mL
kallikrein inactivator unit/millilitre unit	KI unit/mL
kilogram/litre unit	kg/L
litre/litre unit	L/L
microgram/24 hour unit	microgram/24 h
microgram/actuation unit	microgram/actuation
microgram/each unit	microgram/each
microgram/gram unit	microgram/g
microgram/hour unit	microgram/hour
microgram/litre unit	microgram/L
microgram/metered dose unit	microgram/metered dose
microgram/microlitre unit	microgram/microlitre
microgram/millilitre unit	microgram/mL
microlitre/litre unit	microlitre/L
microlitre/millilitre unit	microlitre/mL
micromole/litre unit	micromole/L
micromole/millilitre unit	micromole/mL
milligram/24 hour unit	mg/24 h
milligram/actuation unit	mg/actuation
milligram/each unit	mg/each
milligram/gram unit	mg/g
milligram/hour unit	mg/hour
milligram/litre unit	mg/L
milligram/metered dose unit	mg/metered dose
milligram/milligram unit	mg/mg
milligram/millilitre unit	mg/mL
millilitre/gram unit	mL/g
millilitre/litre unit	mL/L
millilitre/millilitre unit	mL/mL
millimole/litre unit	mmol/L
millimole/millilitre unit	mmol/mL
million cell culture infectious dose 50% unit/millilitre unit	million CCID50 units/mL
million international units/millilitre unit	million international units/mL

Description	Unit/Proportion
million units/millilitre unit	million units/mL
mole/litre unit	mol/L
nanogram/gram unit	nanogram/g
nanogram/millilitre unit	nanogram/mL
nanolitre/millilitre unit	nanolitre/mL
tuberculin unit/millilitre unit	tuberculin unit/mL
unit/gram unit	unit/g
unit/microgram unit	unit/microgram
unit/milligram unit	unit/mg
unit/millilitre unit	unit/mL

G.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

G.5.1 Valid descriptive units of measure

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

- %
- % w/v
- % w/w
- actuation
- aerosol can
- ampoule
- application
- applicator
- bag
- bandage
- bar
- bead
- blister
- bottle
- can
- capsule
- carton
- cartridge
- chamber
- component
- device
- diagnostic strip
- diagnostic tablet
- dose
- dressing
- drop
- drug delivery system
- enema
- film
- glove

- gum
- implant
- inhalation
- inhalation capsule
- jar
- lozenge
- measure
- metered dose
- pack
- pad
- parts per million
- pastille
- patch
- pessary
- prefilled injection device
- prefilled syringe
- ring
- roll
- rope
- sachet
- square
- stick
- strip
- suppository
- syringe
- system
- tablet
- tube
- unit dose
- vial
- wafer

Appendix H. Form

The form will be derived from the *TGA Approved Dosage Forms* [TGAM1999, Chapter 5], but may include additional forms created where necessary.

Where there is more than one subtype of a dosage form (e.g. 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.

Note: Additional forms have been added to provide further defining information, e.g. capsule: sustained release.

Table 101: 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
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

Fully Specified Name	Description	Preferred Term
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
bulk	A large or bulk quantity of a substance.	bulk
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
cement	A cement applied to parts of the body to enable adherence.	cement
cement: medicated	A cement containing active ingredients applied to parts of the body to enable adherence.	cement: medicated

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
cone	Preformed plug containing active ingredients.	cone
cone: dental	Preformed plug containing active ingredients for topical use in the mouth.	cone: dental
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

Fully Specified Name	Description	Preferred Term
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
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: ocular	A system containing active ingredients for release of these ingredients in the lower conjunctival fornix at a constant rate over a period of time.	drug delivery system: ocular
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: 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.	ear drops: emulsion
ear drops: powder for	One or more active ingredients in a dry form to be reconstituted for use as ear drops.	ear drops: powder for
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.	ear drops: suspension
enema	A liquid preparation composed of, or containing, one or more active ingredients for rectal administration.	enema
essential oil	A class of generally aromatic volatile oils extracted from plants.	essential oil
EXTRACT	A substance prepared by the use of solvents or evaporation to separate the substance from the original material.	
extract	A substance prepared by the use of solvents or evaporation to separate the substance from the original material.	extract
extract: concentrated	A concentrated form of an extract.	extract: concentrated

Fully Specified Name	Description	Preferred Term
extract: dry	A solid dried form of an extract.	extract: dry
extract: liquid	A liquid form of an extract.	extract: liquid
extract: soft	A soft solid form of an extract.	extract: soft
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 and ear ointment	A sterile semi-solid preparation of homogeneous appearance intended for application to the conjunctiva or aural canal. It may contain one or more active ingredients dissolved or dispersed in a suitable base.	eye/ear ointment
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: 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.	eye drops: emulsion
eye drops: powder	One or more active ingredients in a dry form to be reconstituted for use as eye drops.	eye drops: powder
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.	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
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

Fully Specified Name	Description	Preferred Term
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
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
gel: modified release	A semi-solid preparation usually consisting of a solution or dispersion in a suitable base, prepared with the aid of a suitable gelling agent, which has a modified rate of release.	gel: modified release
GLOVE	A sterile or clean fitted covering for the hands, usually with a separate sheath for each finger and thumb.	

Fully Specified Name	Description	Preferred Term
glove	A sterile or clean fitted covering for the hands, usually with a separate sheath for each finger and thumb.	glove
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
herb	Plant or parts of plants including mixtures of such, used for the extemporaneous preparation of infusions, decoctions or similar preparations for therapeutic use by oral administration.	herb

Fully Specified Name	Description	Preferred Term
herb: dried	Dried plant or parts of plants including mixtures of such, used for the extemporaneous preparation of infusions, decoctions or similar preparations for therapeutic use by oral administration.	herb: dried
implant	A sterile solid or semi-solid preparation containing one or more active ingredients for introduction or grafting into body tissue.	implant
implant: radioactive	An implant containing radioactive material.	implant: radioactive
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	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 (e.g. hand actuated pump, nebuliser etc.) 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.	

Fully Specified Name	Description	Preferred Term
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
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
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

Fully Specified Name	Description	Preferred Term
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.	liquid: suspension
liquid: tincture	A solution of one or more active ingredients which has been extracted into an alcoholic base.	liquid: tincture
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
lotion: powder for	Solid substance to be reconstituted in an appropriate liquid before application to the unbroken skin.	lotion: powder for
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
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: 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.	nasal drops: emulsion
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

Fully Specified Name	Description	Preferred Term
nasal 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.	nasal drops: suspension
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 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.	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
ointment: modified	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 non-aqueous base with a formula that has been modified from the standard formula to provide additional therapeutic benefits.	ointment: modified
oral application	A liquid or semi-solid preparation formulated specifically for use within the oral cavity.	oral application
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

Fully Specified Name	Description	Preferred Term
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 liquid: syrup	A concentrated solution of sugar in water to which one or more active ingredients may be added.	oral liquid: syrup
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: impregnated	A pad or mat, usually made of an absorbent material, impregnated with active ingredient(s) for release into the atmosphere.	pad: impregnated
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
paint: concentrated	A liquid which must be diluted with another liquid in order to prepare a paint.	paint: concentrated

Fully Specified Name	Description	Preferred Term
paint: powder for	One or more active ingredients in a dry form to be reconstituted for use as a paint.	paint: powder for
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
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
pastille	A solid preparation containing one or more active ingredients incorporated in a mass of sweetened gum, glycerol, and gelatin base which is intended to be sucked.	pastille
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

Fully Specified Name	Description	Preferred Term
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
powder: oral	A finely divided powder composed of, or containing one or more active ingredients for oral or nasogastric administration, generally with water. The dose is obtained either by measuring a volume of the powder or from an individual container, e.g. sachet, paper tube or vial.	powder: oral
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 ribbon or rope intended for packing a wound.	rope
scratch test unit	A test applicator unit consisting of a sharp device (e.g. needle, lancet) coated with the test substance for application by scratching the skin.	scratch test unit
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: concentrated dialysis	A solution to be diluted for use in dialysis by means of a dialyser.	solution: concentrated dialysis
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

Fully Specified Name	Description	Preferred Term
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 dialysis	One or more active ingredients in a dry form, to be reconstituted for use as a solution for dialysis.	solution: powder for dialysis
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
solution: powder for irrigation	One or more active ingredients in a dry form to be reconstituted in a sterile liquid before use as an irrigation.	solution: powder for 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
spray: 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.	spray: suspension
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
stick: urethral	A sterile solid preparation containing one or more active ingredients in stick form designed to be inserted in the urethra.	stick: urethral
strip	A long narrow piece of solid material intended for use in testing, screening or assaying a biological substance.	strip

Fully Specified Name	Description	Preferred Term
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
suppository: shell	A solid preparation, similar to a soft capsule, but intended for rectal administration, also known as a rectal capsule.	suppository: shell
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
suspension: powder for	A finely divided powder composed of, or containing, one or more active ingredients to be reconstituted in a suitable liquid for use as a suspension.	suspension: powder for
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

Fully Specified Name	Description	Preferred Term
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
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
tea	A beverage prepared from the leaves and leaf buds of a plant.	tea
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

Fully Specified Name	Description	Preferred Term
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
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
wipe	A small towel, soaked in or impregnated with a preparation intended to be used to apply the preparation to the skin.	wipe
wipe: medicated	A small towel, soaked in or impregnated with a preparation containing the active ingredient(s) and intended to be used to apply the preparation to the skin.	wipe: medicated

Appendix I. 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 102: 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	Filmtab
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 103: 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
Filmtab	tablet: film-coated	tablet: film-coated
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 J. Pack Quantity Unit of Measure

Note: For mass and volume, units may vary according to the pack size, e.g. 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 does form indicator may vary between products. A discrete dose form is a form which is available as distinct or individual parts (e.g. 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 (e.g. cream, oral liquid). In some instances, the unit does form indicator may vary between products (e.g. granules in a single dose sachet would be discrete, but granules in a bulk container would be continuous).

Table 104: 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
bulk	(dependent on form)	(dependent on form)
capsule	capsule	capsules
capsule: enteric	capsule	capsules
capsule: hard	capsule	capsules
capsule: modified release	capsule	capsules
capsule: soft	capsule	capsules
cement	(dependent on container type)	(dependent on container type)
cement: medicated	(dependent on container type)	(dependent on container type)
collodion	mL	mL
conditioner	mL	mL
cone	cone	cones
cone: dental	cone	cones
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

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
drug delivery system: ocular	drug delivery system: ocular	drug delivery systems: ocular
drug delivery system: vaginal	drug delivery system: vaginal	drug delivery systems: vaginal
ear drops	mL	mL
ear drops: emulsion	mL	mL
ear drops: powder for	mL	mL
ear drops: solution	mL	mL
ear drops: suspension	mL	mL
enema	mL	mL
essential oil	mL	mL
extract	mL	mL
extract: concentrated	mL	mL
extract: dry	g	g
extract: liquid	mL	mL
extract: soft	g	g
eye and ear	g or mL (dependent on form)	g or mL (dependent on form)
eye and ear drops	mL	mL
eye and ear ointment	g	g
eye drops	mL	mL
eye drops: emulsion	mL	mL
eye drops: powder	mL	mL
eye drops: solution	mL	mL
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

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
film: sublingual	film	films
foam	g	g
gas	L	L
gas: medicinal	L	L
gel	g	g
gel: intestinal	g	g
gel: modified	g	g
gel: modified release	g	g
glove	glove	gloves
glove: large	glove	gloves
glove: medium	glove	gloves
glove: small	glove	gloves
granules[7]	g or sachet	g or sachets
granules: effervescent[8]	g or sachet	g or sachets
granules: enteric-coated[9]	g or sachet	g or sachets
granules: modified release[10]	g or sachet	g or sachets
gum	piece	pieces
gum: chewing	piece	pieces
herb	g	g
herb: dried	g	g
implant	implant	implants
implant: radioactive	implant	implants
inhalation	mL	mL
inhalation: breath activated	activation	activation
inhalation: powder for	capsule, dose unit (dependent on container type)	capsules, dose units (dependent on container type)

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

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

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

[10] 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: 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
liquid: suspension	mL	mL
liquid: tincture	mL	mL
lotion	mL	mL
lotion: powder for	mL	mL
lozenge	lozenge	lozenges
lozenge with integral application	lozenge	lozenges
mouthwash	mL	mL
mouthwash: powder for	g	g

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
nasal cream	g	g
nasal drops	mL	mL
nasal drops: emulsion	mL	mL
nasal drops: powder for	mL	mL
nasal drops: solution	mL	mL
nasal drops: suspension	mL	mL
nasal gel	g	g
nasal spray	mL	mL
oil	mL	mL
oil: bath	mL	mL
oil: oral	mL	mL
ointment	g	g
ointment: fatty	g	g
ointment: modified	g	g
oral application	g	g
oral gel	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 liquid: syrup	mL	mL
oral spray	mL	mL
pad	pad	pads
pad: impregnated	pad	pads
pad: waterproof	pad	pads
paint	mL	mL
paint: concentrated	mL	mL

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
paint: powder for	g	g
paste	g	g
paste: oromucosal	g	g
pastille	pastille	pastilles
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
powder: oral	g	g
roll	rol	rolls
roll: wrapped pack	roll	rolls
rope	rope	ropes
scratch test unit	scratch test unit	scratch test units
shampoo	mL	mL
sheet	sheet	sheets
solution	mL	mL
solution: concentrated dialysis	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 dialysis	mL	mL

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
solution: powder for intraocular irrigation	mL	mL
solution: powder for irrigation	mL	mL
spray	mL	mL
spray: pressurised	mL	mL
spray: solution	mL	mL
spray: suspension	mL	mL
stick	tube, stick (dependent on container type)	tubes, sticks (dependent on container type)
stick: lip	tube	tubes
stick: urethral	stick	sticks
strip	strip	strips
strip: diagnostic	strip	strips
suppository	suppository	suppositories
suppository: compressed	suppository	suppositories
suppository: moulded	suppository	suppositories
suppository: shell	suppository	suppositories
suspension	mL	mL
suspension: powder for	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
tablet: modified release	tablet	tablets
tablet: multilayer	tablet	tablets

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
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
tea	mL	mL
tincture	mL	mL
toothpaste	g	g
wafer	wafer	wafers
wafer: sublingual	wafer	wafers
wipe	wipe	wipes
wipe: medicated	wipe	wipes

Appendix K. Container Types

Container Types will be derived from TGA Approved Container Types [TGAM1999, Chapter 4] as listed below. Additional container types will be added if required.

Table 105: Examples of Container Types

Container Type	Description	Abbreviation
aerosol	A container intended to contain a substance, usually liquid, which may be released in aerosol form upon actuation.	AR
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.	ARC
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.	ARCMD
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.	ARPAC
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.	ARPAM
ampoule	A container, usually tubular in shape, made of glass or plastic and sealed by fusion after filling.	AMPL
applicator	A container that acts as a device for the application of a drug dosage form to a particular site.	APPL
bag	A container made of flexible material, usually of plastic. Note that pre-filled blood and parenteral nutrition bags are drug-device combinations.	BAG
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.	BLPK
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.	BTTLE

Container Type	Description	Abbreviation
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.	BTTLEDISP
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.	BTTLEPSN
buffer pack	A container that protects against or reduces the effect of damage or impact.	BFRPK
bulk container	A container (material and shape not specified) for use in the transhipment of bulk quantities of product between manufacturers.	BULK
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.	CAN
carton	A container made from cardboard, cardboard laminate or similar material. It is normally closed but not sealed.	CARTN
cartridge	A cylindrical container of plastic or glass which is sealed at one end by a rubber or plastic membrane, and at or near the other end by an inserted rubber or plastic stopper intended to act as a syringe plunger. The syringe plunger to be of a standard, aspirating or self-aspirating type.	CART
chamber	One of the compartments within a dual chamber or multi-chamber bag or syringe in which an active ingredient or diluent is located.	CHMBR
compact	A wide flat container usually made of plastic or metal and having a clip closure.	COMP
composite pack	A container for a multi-component pack that contains a number of different container types.	Depends on constituent container type or types.
device	A container that acts also as a device for delivery of a drug dosage form to a particular site.	DEV
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.	DDPACK

Container Type	Description	Abbreviation
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.	DISPK
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.	DRPCONT
drum	A large cylindrical container generally made of metal or plastic, used to store large bulk amounts of powders, liquids or other chemicals.	DRUM
dual chamber bag	A bag 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.	DCBAG
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.	DCCP
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.	DCSYRNG
gas cylinder	A gas-tight container designed to hold a gas under pressure.	GASCYC
inhaler	A container that acts also as a device for delivery of an inhaled dosage form.	INHL
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.	INHDP
inhaler: metered dose	A container, usually an aerosol can, intended to contain a solution. 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.	INHMD
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.	JAR
jar/can	A wide container, normally cylindrical in shape, with a short wide neck usually made of metal, glass or plastic and having a stopper or a screw closure.	JRCN

Container Type	Description	Abbreviation
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.	JARSC
multi chamber bag	A bag in which the active ingredients, or ingredients and diluents, are located in individual chambers. The connections between multiple chambers are breached to allow mixing of the active ingredients, or ingredients and diluents, immediately prior to administration.	MCBAG
multi chamber composite pack	A container in which the active ingredients, or ingredients and diluents, are located in individual chambers. The connections between multiple chambers are breached to allow mixing of the active ingredients, or ingredients and diluents, immediately prior to administration.	MCCP
multi chamber syringe	A syringe in which the active ingredients, or ingredients and diluents, are located in individual chambers. The connections between multiple chambers are breached to allow mixing of the active ingredients, or ingredients and diluents, immediately prior to administration.	MCSYRNG
multiple container types	A description referring to products that are available as multiple varieties of container types, and that cannot be limited to one specific container type description.	MULTI
prefilled injection device	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.	PFINJDEV
puffer pack	A container whose walls are flexible and from which the liquid or powder contents may be ejected by squeezing the container.	PFRPK
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.	PMPK
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.	SACHT
shrink wrap	A covering which follows the contours of a product and is applied by means of heat shrinkage of a plastic material.	SHKWP
spray	A container that acts as a delivery device intended to contain a substance, usually liquid, which is released as a spray dose form.	SPRAY

Container Type	Description	Abbreviation
spray: elasticity driven	A container, usually made of plastic and/or rubber, intended to contain a substance, usually liquid, held under pressure without propellant. The pressure is generated by the elasticity of the container walls. The contents are released by actuation of a valve.	SPRAYE
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.	STPPK
syringe	A cylindrical tube with nozzle and piston into which a liquid is first drawn by suction and then ejected in a fine stream. Note that pre-filled syringes are drug-device combinations.	SYRNG
tea bag	A small permeable container, enclosing dry plants, their parts or other substances for preparing an infusion by immersion in water - usually made of paper.	TEABAG
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, e.g. rigid elongated tube for effervescent tablets, flexible tube for cream.	TUBE
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.	VIAL
vitrella	A thin-walled container, usually made of glass, containing one or more volatile substances. It is intended to be used by crushing the container and inhaling the vapour.	VITRL
wrapping	A thin flexible material such as paper, plastic or aluminium foil folded around the product.	WRAPG

Appendix L. 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.

L.1 Vaccines

L.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 (e.g. meningitis may be due to Neisseria meningitidis (meningococci) or Haemophilus influenzae type B).
- A causative organism may cause more than one specific disease (e.g. 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 (e.g. "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 (e.g. "BCG (Bacillus Calmette and Guerin) 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.

L.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".

L.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.

L.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.

L.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

L.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 (e.g. 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).

L.1.7 Year of issue

In cases where viruses or bacteria causing a disease change over time such that different strains may included in the vaccine, the vaccine name will include the year of issue in Australia (or other specified date), e.g. 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, e.g. H1N1 pandemic influenza vaccine 2009.

L.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* [AIH2008]) 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 influenza type b conjugate (PRP-OMP) vaccine".
- Hiberix will be represented as "Haemophilus influenza type b conjugate (PRP-T) vaccine".

L.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* [AIH2008].

L.1.10 Additional information – preservatives, etc.

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

L.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 106: Examples of strength variations for different populations

Product	AMT Preferred Term
Adacel	• MP: diphtheria + pertussis + tetanus vaccine • MPUU: diphtheria + pertussis + tetanus vaccine (adult) injection, 0.5 mL vial
Tripacel	• MP: diphtheria + pertussis + tetanus vaccine • MPUU: diphtheria + pertussis + tetanus vaccine (child) injection, 0.5 mL vial
Hepatitis B vaccines	• hepatitis B vaccine (child) • hepatitis B vaccine (adult) • hepatitis B vaccine (dialysis)

L.2 Antivenoms

L.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", e.g. tiger snake (Notechis scutatus) antivenom.

L.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", e.g. tiger snake antivenom.

L.2.3 Strength

Strength will be expressed as units of antivenom per unit of use (e.g. per vial).

Volume of vials or ampoules may vary but in all cases a complete unit (i.e. vial or ampoule) is administered.

L.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.

L.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 (e.g. glucose indicator blood, glucose and ketone indicator urine). They do not routinely display a strength.

L.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.

L.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 (e.g. low in protein) or the absence of an ingredient (e.g. carbohydrate free, without phenylalanine).

L.7 Extemporaneous preparations

Extemporaneous preparations included in the AMT are currently comprised of such products as listed in the PBS and RPBS. This class of products are modelled closely to a typical AMT generic branded product, where the sponsor details are replaced by the pharmaceutical standard details (e.g. APF 15). At present the only extemporaneous products modelled in the AMT and those listed on the PBS, and as such, the pack size is representative of the quantity available on the PBS.

Example: Thymol Compound mouthwash (APF 15) (benzoic acid 8 mg / 1 mL + sodium bicarbonate 3 mg / 1 mL + thymol 1.5 mg / 1 mL) mouthwash, 200 mL, bottle: dispensing (containered trade product pack).

L.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* [HNSG2007]. 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 M. Product Concepts – Full Definitions

M.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 107: MP FSN description

Description Component	Definition
Medicinal Product FSN	MP_Ingredient_Details [1] " (medicinal product)" 1: MP_Ingredient_Details represents Medicinal Products that contain one or more medicinal substances.
MP_Ingredient_Details	Ingredient_Name { " + " Ingredient_Name } [1 2 3] 1: An Ingredient_Name represents a medicinal substance. 2: Multiple instances of Ingredient_Name may exist. These represent multi-ingredient Medicinal Products. 3: Ingredient_Names are ordered alphabetically.
Ingredient_Name	MP.has intended active ingredient.PT The ingredient is the PT of the medicinal substance concept that is the destination of the MP HAS INTENDED ACTIVE INGREDIENT relationship.
(medicinal product)	The semantic tag used in the FSN of all Medicinal Product concepts.

M.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 108: MP PT description

Description Component	Definition
Medicinal Product PT	Ingredient_Details [1] 1: Ingredient_Details represents Medicinal Products that contain one or more medicinal substance.
Ingredient_Details	Ingredient_Name { " + " Ingredient_Name } [1 2 3] 1: An Ingredient_Name represents a medicinal substance. 2: Multiple instances of Ingredient_Name may exist; these represent multi-ingredient Medicinal Products. 3: Ingredient_Names are ordered by their preferred term order.
Ingredient_Name	MP.has intended active ingredient.PT The ingredient is the PT of the medicinal substance concept that is the destination of the MP HAS INTENDED ACTIVE INGREDIENT relationship.

M.3 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 109: MPUU FSN description

Description Component	Definition
Medicinal Product Unit of Use FSN	Ingredients_With_Strength " " Form [", " Unit_Of_Use_Details] [1]" (medicinal product unit of use)" 1: Unit_Of_Use_Details are included if they exist, based on the definition below.
Ingredients_With_Strength	Ingredient_Strength {" + " Ingredient_Strength} [1 2 3] 1: One Ingredient_Strength is included for each MPUU HAS AUSTRALIAN BoSS relationship that exists for the given MPUU. 2: The strength component of Ingredient_Strength does not exist for certain MPUU FSNs, e.g. those representing inert substances, non-medicated dressings, diagnostic aids and nutritional supplements. 3: The Ingredient_Strengths are ordered alphabetically based on the Preferred Term of the MPUU's Basis of Strength Substance.

Description Component	Definition
Ingredient_Strength	BoSS_Ingredient " " BoSS_Strength [1 2 3] 1: BoSS_Ingredient is the Preferred Term of the Substance concept that is the destination of MPUU HAS AUSTRALIAN BoSS relationship. This may be a base or a salt substance. 2: BoSS_Strength is a representation of the numerator and denominator strength components of the BoSS. 3: BoSS_Strength may be representated differently to the strength value (i.e. value field) in the Strength reference set.
BoSS_Ingredient	Base_Ingredient | Salt_Ingredient
Base_Ingredient	MPUU.has Australian BoSS.PT [1] 1: Base_Ingredient is the Preferred Term of the Substance concept that is the destination of MPUU HAS AUSTRALIAN BoSS relationship, and the Substance concept does not have an IS MODIFICATION OF relationship.
Salt_Ingredient	MPUU.has Australian BoSS.PT [1] 1: Salt_Ingredient is the Preferred Term of the Substance concept that is the destination of MPUU HAS AUSTRALIAN BoSS relationship, and the Substance concept has an IS MODIFICATION OF relationship.
BoSS_Strength	Base_Strength | Salt_Strength
Base_Strength	MPUU.base form strength numerator value " " MPUU.has base form strength numerator units.PT 1 [" / " MPUU.base form strength denominator value " " MPUU.has base form strength denominator units.PT] [1 2] 1: If associated strength value > 1 then use plural units description for the associated strength units. Exceptions: For the units of measure of "microgram"' and "microlitre" the Preferred Term is used instead of the plural units. 2: Include denominator details if values are not null.
Salt_Strength	MPUU.salt form strength numerator value " " MPUU.has salt form strength numerator units.PT 1 [" / " MPUU.salt form strength denominator value " " MPUU.has salt form strength denominator units.PT] [1 2] 1: If associated strength value > 1, then use plural units description for the associated strength units. Exceptions: For the units of measure of "microgram" and "microlitre" the Preferred Term is used instead of the plural units. 2: Include denominator details if values are not null.
Form	MPUU.has manufactured dose form.PT [1] 1: Form is the Preferred Term of the Form concept that is the destination of MPUU HAS MANUFACTURED DOSE FORM relationship.

Description Component	Definition
Unit_Of_Use_Details	[“ ” Unit_Of_Use_Size] [1] “ ” [Unit_Of_Use] [2] 1: Do not include Unit_Of_Use_Size if either: • Unit of Use Size reference set.value is null; or • Unit of Use Size reference set.value = 1 and Unit of Use Size reference set.unitId equals MPUU.has manufactured dose form (or one of its parents in the *Form* hierarchy). 2: Include Unit_Of_Use if: • MPUU.has unit of use exists; and • MPUU.has unit of use does not equal MPUU.has manufactured dose form (or one of its parents in the *Form* hierarchy); and • MPUU.has unit of use does not equal Unit of Use Size reference set.unitId.
Unit_Of_Use_Size	Unit of Use Size reference set.value “ ” Unit of Use Size reference set.unitId [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 FSN.
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 MPUU HAS UNIT OF USE relationship.
(medicinal product unit of use)	The semantic tag used in the FSN of all Medicinal Product Unit of Use concepts.

M.4 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 110: MPUU PT description

Description Component	Definition
Medicinal Product Unit of Use PT	Ingredients_With_Strength " " Form [", " Unit_Of_Use_Details] [1] 1: Unit_Of_Use_Details are included if they exist, based on the definition below.
Ingredients_With_Strength	Ingredient_Strength {" + " Ingredient_Strength} [1 2 3] 1: One Ingredient_Strength is included for each MPUU HAS AUSTRALIAN BoSS relationship that exists for the given MPUU. 2: The strength component of Ingredient_Strength does not exist for certain MPUU PT, e.g. those representing inert substances, non-medicated dressings, diagnostic aids and nutritional supplements. 3: The Ingredient_Strengths are ordered based on the MPUU.preferred term order. If MPUU.preferred term order does not exist then Ingredient_Strengths are ordered alphabetically based on the Preferred Term of the MPUU's Basis of Strength Substance.
Ingredient_Strength	BoSS_Ingredient " " BoSS_Strength [1 2 3] 1: BoSS_Ingredient is the Preferred Term of the Substance concept that is the destination of MPUU HAS AUSTRALIAN BoSS relationship. This may be a base or a salt substance. 2: BoSS_Strength is a representation of the numerator and denominator strength components of the BoSS. 3: BoSS_Strength may be representated differently to the strength value (i.e. value field) in the *Strength reference set*.
BoSS_Ingredient	Base_Ingredient | Salt_Ingredient
Base_Ingredient	MPUU.has Australian BoSS.PT [1] 1: Base_Ingredient is the Preferred Term of the Substance concept that is the destination of MPUU HAS AUSTRALIAN BoSS relationship, and the Substance concept does not have an IS MODIFICATION OF relationship.
Salt_Ingredient	MPUU.has Australian BoSS.PT [1] 1: Salt_Ingredient is the Preferred Term of the Substance concept that is the destination of MPUU HAS AUSTRALIAN BoSS relationship, and the Substance concept has an IS MODIFICATION OF relationship.
BoSS_Strength	Base_Strength | Salt_Strength

Description Component	Definition
Base_Strength	IF MPUU.has base form strength preferred representation.PT = "N" or not exists THEN Base_Strength_N ELSIF MPUU.has base form strength preferred representation.PT = "NA" THEN Base_Strength_N " (" Base_Strength_A ")" ELSIF MPUU.has base form strength preferred representation.PT = "A" THEN Base_Strength_A ELSIF MPUU.has base form strength preferred representation.PT = "AN" THEN Base_Strength_A " (" Base_Strength_N ")" ENDIF
Base_Strength_N	MPUU.base form strength numerator value " " MPUU.has base form strength numerator units.PT ["/" [MPUU.base form strength denominator value " "] [1] [2] MPUU.has base form strength denominator units.PT] [3] 1: If associated strength value > 1 then use plural units description for the associated strength units. Exceptions: • For the units of measure of "microgram" and "microlitre" the Preferred Term is used instead of the plural units. 2: Include base form strength denominator value if not equal to 1. 3: Include base form strength denominator units if denominator units exists.
Base_Strength_A	MPUU.base form strength other representation
Salt_Strength	IF MPUU.has salt form strength preferred representation.PT = "N" or not exists THEN Salt_Strength_N ELSIF MPUU.has salt form strength preferred representation.PT = "NA" THEN Salt_Strength_N " (" Salt_Strength_A ")" ELSIF MPUU.has salt form strength preferred representation.PT = "A" THEN Salt_Strength_A ELSIF MPUU.has salt form strength preferred representation.PT = "AN" THEN Salt_Strength_A " (" Salt_Strength_N ")" ENDIF
Salt_Strength_N	MPUU.salt form strength numerator value " " MPUU.has salt form strength numerator units.PT ["/" [MPUU.salt form strength denominator value " "] [1] [2] MPUU.has salt form strength denominator units.PT] [3] 1: If associated strength value > 1 then use plural units description for the associated strength units. Exceptions: For the units of measure of "microgram" and "microlitre" the Preferred Term is used instead of the plural units. 2: Include salt form strength denominator value if not equal to 1. 3: Include salt form strength denominator units if denominator units exists.
Salt_Strength_A	MPUU.salt form strength other representation

Description Component	Definition
Form	MPUU.has manufactured dose form.PT [1] 1: Form is the Preferred Term of the Form concept that is the destination of MPUU HAS MANUFACTURED DOSE FORM relationship.
Unit_Of_Use_Details	[" " Unit_Of_Use_Size] [1] [" " Unit_Of_Use] [2] 1: Do not include Unit_Of_Use_Size if either: • Unit of Use Size reference set.value is null; or • Unit of Use Size reference set.value = 1 and Unit of Use Size reference set.unitId equals MPUU.has manufactured dose form (or one of its parents in the Form hierarchy); or • Unit of Use Size reference set.value equals to MPUU.base form strength denominator value and Unit of Use Size reference set.unitId equals to MPUU.has base form strength denominator units; or • MPUU has exactly one BoSS, and for that MPUU, MPUU.base form strength denominator value does not exist and Unit of Use Size reference set.value = MPUU.base form strength numerator value and Unit of Use Size reference set.unitId = MPUU.has base form strength numerator units. 2: Include Unit_Of_Use if: • MPUU.has unit of use exists; and • MPUU.has unit of use does not equal MPUU.has manufactured dose form (or one of its parents in the Form hierarchy); and • MPUU.has unit of use does not equal Unit of Use Size reference set.unitId; and • Unit_Of_Use.PT ≠ 'measure'
Unit_Of_Use_Size	Unit of Use Size reference set.value " " Unit of Use Size reference set.unitId [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 FSN.
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 MPUU HAS UNIT OF USE relationship.

M.5 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 111: 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 i.e. every MPUU that exists as the destination of MPP HAS MPUU relationship. 2: 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.

MPUU_ISFO	[" " Ingredient_Strength {" + " Ingredient_Strength} [1] [2] [3]] " " Form 1: One Ingredient_Strength is included for each MPUU HAS AUSTRALIAN BoSS relationship that exists for the given MPUU. 2: The strength component of Ingredient_Strength does not exist for certain MPUU FSN, e.g. those representing inert substances, non-medicated dressings, diagnostic aids and nutritional supplements. 3: 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 FSN.
Form	Form, as defined for the given MPUU's FSN.

Description Component	Definition
MPUU_Qty_Size	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] 1: Size value and size units are included when Unit of Use Size reference set.value exists 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 focus concept of this MPUU FSN. 3: Unit of Use quantity units is included when Unit of Use quantity reference set.unitId ≠ MPUU.has manufactured dose form.PT. 4: 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.

Total_Quantity_Size_Details	Total_Quantity_Size [1 2] [" [" Subpack_Details "]"] [3]
	1: IF there exists more than one MPUU M such that MPP has MPUU M AND the given MPP is not a destination of MPP.has component pack THEN
	Total_Quantity_Size
	ELSE
	Quantity_Size
	ENDIF
	2: These relate to cases where the MPP represents a multi-component product and the MPP has associated component packs.
	3: Subpack_Details are included if Subpack quantity reference set.value exists.

Total_Quantity_Size	MPP.total unit of use quantity value [" × " Unit of Use Size reference set.value " " Unit of Use Size reference set.unitId] [1] " " MPP.has total unit of use quantity units.PT 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.
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 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.
Subpack_Details	Subpack quantity reference set.value " × " (MPP.total unit of use quantity value ÷ Subpack quantity reference set.value) " " MPP.has total unit of use quantity units.PT
(medicinal product pack)	The semantic tag used in the FSN of all Medicinal Product Pack concepts.

M.6 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 112: 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 i.e. every MPUU that exists as the destination of MPP HAS MPUU relationship. 2: The MPUU_Details are ordered, based on the associated MPP.preferred component order (if this exists, otherwise alphabetically as per MPP.FSN).
MPUU_Details	MPUU_ISFO [" [" MPUU_Qty_Size "]"] [1] 1: MPUU_Qty_Size is included when more than one MPUU exists, such that MPP.has MPUU. These relate to cases where the MPP represents a multi-component product.
MPUU_ISFO	(" " Ingredient_Strength {" + " Ingredient_Strength} [1 2 3]) " " Form 1: One Ingredient_Strength is included for each MPUU HAS AUSTRALIAN BoSS relationship that exists for the given MPUU. 2: The strength component of Ingredient_Strength does not exist for certain MPUU FSN, e.g. those representing inert substances, non-medicated dressings, diagnostic aids and nutritional supplements. 3: Ingredient_Strengths are ordered by MPUU.preferred term order (where this exists, otherwise alphabetically as per MPP.FSN).
Ingredient_Strength	Ingredient_Strength as defined for the given MPUU PT.
Form	Form as defined for the given MPUU PT.
MPUU_Qty_Size	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] 1: Size value and size units are included when Unit of Use Size reference set.value exists. 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 focus concept of this MPUU FSN. 3: Unit of Use quantity units is included when Unit of Use quantity reference set.unitId ≠ MPUU.has manufactured dose form.PT. 4: 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.

Description Component	Definition

Total_Quantity_Size_Details	Total_Quantity_Size [1] [2] [“ [” Subpack_Details “]”] [3]
	1: IF there exists more than one MPUU M such that MPP has MPUU M AND the given MPP is not a destination of MPP.has component pack THEN
	Total_Quantity_Size
	ELSE
	Quantity_Size
	ENDIF
	2: These relate to cases where the MPP represents a multi-component product and the MPP has associated component packs.
	3: Subpack_Details are included if Subpack quantity reference set.value exists.

Total_Quantity_Size	MPP.total unit of use quantity value [“ × ” Unit of Use Size reference set.value “ ” Unit of Use Size reference set.unitId] [1] [“ ” MPP.has total unit of use quantity units.PT] [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: Total unit of use quantity units is included when MPP.has total unit of use quantity units.PT ≠ MPUU.has manufactured dose form.PT (or one of its parents in the form hierarchy) for all associated MPUUs via MPP has MPUU relationships.
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 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.
Subpack_Details	Subpack quantity reference set.value “ × ” (MPP.total unit of use quantity value ÷ Subpack quantity reference set.value) “ ” MPP.has total unit of use quantity units.PT

M.7 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 [“ (” TF_Supplier “)”] “ (trade product)”
```

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

Table 113: TP FSN description

Description Component	Definition
Trade Product FSN	TF_Name [“(” TF_Supplier “)”] [1] “ (trade product)” 1: TF_Supplier is included for generic medicines
TF_Name	TP [“ ” Trade product suffix] [“ ” Proprietary form] [1] Where TP is TPUU.is a (TP).PT (* without the TF_Supplier, where relevant *) 1: TF_Name includes the following information: Trade product suffix (refer to Section 5.5.1.1 on p.59) Proprietary form (refer to Appendix I)
TF_Supplier	TPUU.is a (TP).PT (* without the TF_Name *)
(trade product)	The semantic tag used in the FSN of all Trade Product concepts.

M.8 Trade Product Preferred Term full definition

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

```
TP PT :=  TF_Name [“ (” TF_Supplier “)”]
```

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

Table 114: TP PT description

Description Component	Definition
Trade Product PT	TF_Name [“(” TF_Supplier “)”] [1] 1: TF_Supplier is included for generic medicines
TF_Name	TP [“ ” Trade product suffix] [“ ” Proprietary form] [1] Where TP is TPUU.is a (TP).PT (* without the TF_Supplier, where relevant *) 1: TF_Name includes the following information: Trade product suffix (refer to Section 5.5.1.1 on p.59) Proprietary form (refer to Appendix I)
TF_Supplier	TPUU.is a (TP).PT (* without the TF_Name *)

M.9 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 [“ (” TF_Supplier “)”]
             [“ ” Other_Identifying_Information]
             [“ (” Ingredient_Strength
             {“ + ” Ingredient_Strength} “)”] “ ” Form
             [“, ” 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 115: TPUU FSN description

Description Component	Definition
Trade Product Unit of Use FSN	TF_Name [" (" TF_Supplier ")"] [1] [" " Other_Identifying_Information] [2] [" (" Ingredient_Strength {" + " Ingredient_Strength} ")" [3 4]] " " Form [", " Unit_Of_Use_Details] [5] " (trade product unit of use)" 1: TF_Supplier is included only if the TF_Name is a Generic name. 2: Other_Identifying_Information is included if it exists. 3: One Ingredient_Strength is included for each MPUU HAS AUSTRALIAN BoSS relationship that is associated with the given TPUU. 4: The Ingredient_Strengths are ordered alphabetically based on the Preferred Term of the MPUU's Basis of Strength Substance. 5: Unit_Of_Use_Details are included if they exist, based on the definition below.
TF_Name	TF_Name, as derived from the associated TP FSN.
TF_Supplier	TF_Supplier, as derived from the associated TP FSN.
Other_Identifying_Information	TPUU.other identifying information
Ingredient_Strength	Ingredient_Strength, as derived from the associated MPUU FSN.
Form	Form, as derived from the associated MPUU FSN.
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.

M.10 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 [" (" TF_Supplier ")"]
            [" " Other_Identifying_Information]
            [" (" Ingredient_Strength ")"] [" " Form]
            [", " Unit_Of_Use_Details]
```

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

Table 116: TPUU PT description

Description Component	Definition
Trade Product Unit of Use PT	TF_Name [" (" TF_Supplier ")"] [1] [" " Other_Identifying_Information] [2] [" (" Ingredient_Strength ")"] [" " Form] [3] [", " Unit_Of_Use_Details] [4] 1: TF_Supplier is included only if the TF_Name is a Generic name. 2: Other_Identifying_Information is included if it exists. 3: Form is not included if TF_Name includes the form. 4: Unit_Of_Use_Details are included if they exist, based on the definition below.
TF_Name	TF_Name, as derived from the associated TP PT.
TF_Supplier	TF_Supplier, as derived from the associated TP PT.
Other_Identifying_Information	TPUU.other identifying information
Ingredient_Strength	[BoSS_Ingredient " " BoSS_Strength] [1 2 3] IF one MPUU.has Australian BoSS exists AND MPUU.has Australian BoSS.PT = 'inert substance' THEN BoSS_Ingredient " " BoSS_Strength. Additionally for the other TPUU PT associated with the same CTPP (i.e. CTPP.Has TPUU with the same source concept for the given TPUU and other associated TPUU) = BoSS_Ingredient " " BoSS_Strength ELSIF one MPUU.has Australian BoSS exists AND MPUU.has manufactured dose form.PT = 'diluent' THEN BoSS_Ingredient " " BoSS_Strength ELSE BoSS_Strength IF one or more MPUU.has Australian BoSS exists THEN exclude both BoSS_Ingredient and BoSS_Strength. 1: BoSS_Ingredient is the Preferred Term of the Substance concept that is the destination of the associated MPUU HAS AUSTRALIAN BoSS relationship. This may be a base or a salt substance. 2: BoSS_Strength is a representation of the numerator and denominator strength components of the BoSS. 3: BoSS_Strength may be representated differently to the strength value (i.e. value field) in the *Strength reference set*.
BoSS_Ingredient	BoSS_Ingredient, as derived from the associated MPUU PT.
BoSS_Strength	BoSS_Strength , as derived from the associated MPUU PT.
Form	Form, as derived from the associated MPUU PT.
Unit_Of_Use_Details	Unit_Of_Use_Details, as derived from the associated MPUU PT.

M.11 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
             [" (" Other_Containered_Pack_Information ")"]
             " (containered trade product pack)"
```

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

Table 117: CTPP FSN description

Description Component	Definition
Containered Trade Product Pack FSN	TPP_FSN_Details ", " Container [" (" Other_Containered_Pack_Information ")"] [1] " (containered trade product pack)" 1: Other_Containered_Pack_Information is included if it exists and if CTPP.other containered pack information ≠ CTPP.has (TPP).other pack information.

TPP_FSN_Details	IF the given CTPP is a destination of CTPP.has component pack [1]
	THEN
	TPUU_NISF_Total_Quantity_Size_Details
	ELSE
	TPP_FSN_Details [2]
	ENDIF
	1: These relate to cases where the CTPP represents a component pack.
	2: CTPP.has (TPP).FSN, as defined for the associated TPP's FSN, but without the semantic tag (i.e. without " (trade product pack)")

TPUU_NISF_ Total_Quantity_Size_Details	TPUU_NISF ", " Total_Quantity_Size_Details
TPUU_NISF	TF_Name [" (" TF_Supplier ")"] " " TPUU_ISF
TF_Name	TF_Name, as derived from the associated TP FSN.
TF_Supplier	TF_Supplier, as derived from the associated TP FSN.
TPUU_ISF	TPUU_ISF, as derived from the associated TPP FSN.
Total_Quantity_Size_Details	Total_Quantity_Size_Details, as derived from the associated MPP FSN.
Container	CTPP.has container type.PT [1] 1: If the given CTPP is a destination of CTPP.has component pack then Container represents the component container type.
Other_Containered_Pack_Information	CTPP.other containered pack information
(containered trade product pack)	The semantic tag used in the FSN of all Containered Trade Product Pack concepts.

M.12 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
             [" ("  Other_Containered_Pack_Information ")"]
             [" " Manufacturers_Code]
```

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

Table 118: CTPP PT description

Description Component	Definition
Containered Trade Product Pack PT	TPP_PT_Details ", " Container [" (" Other_Containered_Pack_Information ")"] [1] [" " Manufacturers_Code] 1: Other_Containered_Pack_Information is included if it exists and if CTPP.other containered pack information ≠ CTPP.has (TPP).other pack information.

TPP_PT_Details	IF the given CTPP is a destination of CTPP.has component pack [1]
	THEN
	TPP_PT_Details AND
	TPP PT.Total_Quantity_Size_Details is replaced by MPP PT.Total_Quantity_Size_Details
	ELSE
	TPP_PT_Details [2]
	ENDIF
	1: These relate to cases where the CTPP represents a component pack.
	2: CTPP.has (TPP).PT, as defined for the associated TPP's PT.

TPP PT.Total_Quantity_Size_Details	Total_Quantity_Size_Details, as derived from the associated TPP PT.
MPP PT.Total_Quantity_Size_Details	Total_Quantity_Size_Details, as derived from the associated MPP PT.
Container	CTPP.has container type.PT [1] 1: If the given CTPP is a destination of CTPP.has component pack then Container represents the component container type.
Other_Containered_Pack_Information	CTPP.other containered pack information
Manufacturers_Code	CTPP.manufacturers code

M.13 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 [" (" TF_Supplier ")"]
            [" " Other_Pack_Information] TPUU_ Details
            {" (&) " TPUU_Details} ", "
            Total_Quantity_Size_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	TPP FSN := TF_Name [" (" TF_Supplier ")"] [1] [" " Other_Pack_Information] [2] TPUU_Details {" (&) " TPUU_Details} [3 4] ", " Total_Quantity_Size_Details " (trade product pack)" 1: TF_Supplier is included only if the TF_Name is a Generic name. 2: Other_Pack_Information is included if it exists. 3: One TPUU_Details is included for each TPUU associated with the given TPP i.e. every TPUU that exists as the destination of TPP HAS TPUU relationship. 4: These are ordered alphabetically on Ingredient_Strength.
TF_Name	TF_Name, as derived from the associated TP FSN.
TF_Supplier	TF_Supplier, as derived from the associated TP FSN.
Other_Pack_Information	TPP.other pack information
TPUU_Details	TPUU_ISF [" [" TPUU_Qty "]"] [1] 1: TPUU_Qty is included if there exists more than one distinct TPUU such that TPP has TPUU. These relate to cases where the TPP represents a multi-component product.
TPUU_ISF	[" (" Ingredient_Strength {" + " Ingredient_Strength} ")" [1 2 3]] Form 1:.One Ingredient_Strength is included for each MPUU HAS AUSTRALIAN BoSS relationship that is associated with the given TPP. 2: The strength component of Ingredient_Strength does not exist for certain TPP FSN, e.g. those representing inert substances, non-medicated dressings, diagnostic aids and nutritional supplements. 3: The Ingredient_Strengths are ordered alphabetically based on the Preferred Term of the associated MPUU's Basis of Strength Substance.
Ingredient_Strength	Ingredient_Strength, as derived from the associated MPUU FSN.
Form	Form, as derived from the associated MPUU FSN.

Description Component	Definition
TPUU_Qty	Unit of Use quantity reference set.value [" × " Unit of Use Size reference set.value " " Unit of Use Size reference set.unitId] [1 2 3] [" " Unit of Use quantity reference set.unitId] [4 5 6] 1: Size value and size units are included when Unit of Use Size reference set.value exists. 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 focus concept of this MPUU FSN. 3: If Unit of Use Size reference set.value > 1 then use plural units description for the associated size units. Exceptions: • For the units of measure of "microgram" and "microlitre" the Preferred Term is used instead of the plural units. 4: Unit of Use quantity units is included when Unit of Use quantity reference set.unitId ≠ MPUU.has manufactured dose form.PT. 5: 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. 6: If Unit of Use quantity reference set.value > 1 then use plural units description for the associated quantity units. Exceptions: • For the units of measure of "microgram" and "microlitre" the Preferred Term is used instead of the plural units.
Total_Quantity_Size_Details	Total_Quantity_Size [" [" Subpack_Details "]"] [1] 1: Subpack_Details are included if Subpack quantity reference set.value exists.
Total_Quantity_Size	TPP.total unit of use quantity value [" × " Unit of Use Size reference set.value " " Unit of Use Size reference set.unitId] [1] " " TPP.has total unit of use quantity units.PT 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.
Subpack_Details	Subpack quantity reference set.value " × " (TPP.total unit of use quantity value ÷ Subpack quantity reference set.value) " " TPP.has total unit of use quantity units.PT
(trade product pack)	The semantic tag used in the FSN of all Trade Product Pack concepts.

M.14 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 [" (" TF_Supplier ")"]
           [" " Other_Pack_Information] [" " BoSS_Strength]
           [" " Form] [" " PT_Other_Identifying_Information]
           ", " 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	TF_Name [“ (” TF_Supplier “)”] [1] [“ ” Other_Pack_Information] [2] [“ ” BoSS_Strength] [3] [“ ” Form] [4] [“ ” PT_Other_Identifying_Information] [5] “, ” Total_Quantity_Size_Details 1: TF_Supplier is included only if the TF_Name is a Generic name. 2: Other_Pack_Information is included if it exists. 3: BoSS_Strength is included when exactly one MPUU.has Australian BoSS exists (i.e. there is exactly one BoSS ingredient in the MPUU associated with the given TPP). 4: Form is included when the TPP has exactly one TPUU (TPP.has TPUU) and TF_Name does not include the Form. 5: PT_Other_Identifying_Information is included if the TPP has more than one TPUU (TPP.has TPUU).
TF_Name	TF_Name, as derived from the associated TP PT.
TF_Supplier	TF_Supplier, as derived from the associated TP PT.
Other_Pack_Information	TPP.other pack information
BoSS_Strength	BoSS_Strength, as derived from the associated MPUU PT.
Form	Form, as derived from the associated MPUU PT.
PT_Other_Identifying_Information	TPP.PT_Other_Identifying_Information (* This is not part of the terminology, but can be recorded for each TPP PT *)
Total_Quantity_Size_Details	Total_Quantity_Size [“ [” Subpack_Details “]”] [1] 1: Subpack_Details are included if Subpack quantity reference set.value exists.
Total_Quantity_Size	TPP.total unit of use quantity value [“ × ” Unit of Use Size reference set.value “ ” Unit of Use Size reference set.unitId] [1] “ ” TPP.has total unit of use quantity units.PT 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.
Subpack_Details	Subpack quantity reference set.value “ × ” (TPP.total unit of use quantity value ÷ Subpack quantity reference set.value “ ” TPP.has total unit of use quantity units.PT

Appendix N. Fully Specified Name (FSN) examples

Table 121: Fully Specified Name examples

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

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

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	CTPP FSN	TPP 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 (as sodium) 500 mg) injection: powder for, 500 mg vial (trade product unit of use)	Austrapen (ampicillin (as sodium) 500 mg) injection: powder for, 5 x 500 mg vials, vial (containered trade product pack)	Austrapen (ampicillin (as sodium) 500 mg) injection: powder for, 5 x 500 mg vials (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 (as monohydrate) 125 mg / 5 mL) oral liquid: powder for, 5 mL measure (trade product unit of use)	Ceclor (cefaclor (as monohydrate) 125 mg / 5 mL) oral liquid: powder for, 100 mL, bottle (containered trade product pack)	Ceclor (cefaclor (as monohydrate) 125 mg / 5 mL) oral liquid: powder for, 100 mL (trade product pack)
diclofenac (medicinal product)	diclofenac 46.54 mg | diclofenac sodium 50 mg tablet: enteric (medicinal product unit of use)	diclofenac 46.54 mg | diclofenac sodium 50 mg tablet: enteric, 50 tablets (medicinal product pack)	Voltaren (trade product)	Voltaren 50 (diclofenac sodium 50 mg) tablet: enteric, 1 tablet (trade product unit of use)	Voltaren 50 (diclofenac sodium 50 mg) tablet: enteric, 50 tablets, bottle (containered trade product pack)	Voltaren 50 (diclofenac sodium 50 mg) tablet: enteric, 50 tablets (trade product pack)
terbinafine (medicinal product)	terbinafine 8.89 mg / 1 g | terbinafine hydrochloride 10 mg / 1 g cream (medicinal product unit of use)	terbinafine 8.89 mg / 1 g | 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, tube (containered trade product pack)	Lamisil (terbinafine hydrochloride 10 mg / 1 g) cream, 15 g (trade product pack)
budesonide + eformoterol (medicinal product)	budesonide 100 microgram / 1 actuation + eformoterol 4.92 microgram / 1 actuation | eformoterol fumarate dihydrate 6 microgram / 1 actuation inhalation: powder for (medicinal product unit of use)	budesonide 100 microgram / 1 actuation + eformoterol 4.92 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 (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, inhaler: dry powder (containered trade product pack)	Symbicort Turbuhaler 100/6 (budesonide 100 microgram / 1 actuation + eformoterol fumarate dihydrate 6 microgram / 1 actuation) inhalation: powder for, 120 actuations (trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	CTPP FSN	TPP FSN
fluphenazine decanoate (medicinal product)	fluphenazine 9.24 mg / 0.5 mL | fluphenazine decanoate 12.5 mg / 0.5 mL injection, 0.5 mL ampoule (medicinal product unit of use)	fluphenazine 9.24 mg / 0.5 mL | 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, ampoule (containered trade product pack)	Modecate (fluphenazine decanoate 12.5 mg / 0.5 mL) injection: solution, 5 x 0.5 mL ampoules (trade product pack)
sodium chloride (medicinal product)	sodium 3.54 g / 1000 mL | sodium chloride 9 g / 1000 mL injection, 1000 mL bag (medicinal product unit of use)	sodium 3.54 g / 1000 mL | sodium chloride 9 g / 1000 mL injection, 1 x 1000 mL bag (medicinal product pack)	Sodium Chloride (Baxter) (trade product)	Sodium Chloride 0.9% (Baxter) (sodium chloride 9 g / 1000 mL) injection: intravenous infusion, 1000 mL bag (trade product unit of use)	Sodium Chloride 0.9% (Baxter) (sodium chloride 9 g / 1000 mL) injection: intravenous infusion, 1 x 1000 mL bag, bag (containered trade product pack)	Sodium Chloride 0.9% (Baxter) (sodium chloride 9 g / 1000 mL) injection: intravenous infusion, 1 x 1000 mL bag (trade product pack)
ipratropium (medicinal product)	ipratropium 403.1 microgram / 1 mL | ipratropium bromide anhydrous 500 microgram / 1 mL inhalation: solution for, 1 mL ampoule (medicinal product unit of use)	ipratropium 403.1 microgram / 1 mL | ipratropium bromide anhydrous 500 microgram / 1 m L inhalation: solution for, 30 x 1 mL ampoules (medicinal product pack)	Atrovent Adult UDV (trade product)	Atrovent Adult UDV (ipratropium bromide anhydrous (as bromide monohydrate) 500 microgram / 1 mL) inhalation: solution for, 1 mL ampoule (trade product unit of use)	Atrovent Adult UDV (ipratropium bromide anhydrous (as bromide monohydrate) 500 microgram / 1 mL) inhalation: solution for, 30 x 1 mL ampoules, ampoule (containered trade product pack)	Atrovent Adult UDV (ipratropium bromide anhydrous (as bromide monohydrate) 500 microgram / 1 m L) inhalation: solution for, 30 x 1 mL ampoules (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, 1 tablet (trade product unit of use)	Combivir (lamivudine 150 mg + zidovudine 300 mg) tablet: film-coated, 60 tablets, bottle (containered trade product pack)	Combivir (lamivudine 150 mg + zidovudine 300 mg) tablet: film-coated, 60 tablets (trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	CTPP FSN	TPP FSN
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 (as besylate) 10 mg + atorvastatin (as calcium) 20 mg) tablet: film-coated, 1 tablet (trade product unit of use)	Caduet 10/20 (amlodipine (as besylate) 10 mg + atorvastatin (as calcium) 20 mg) tablet: film-coated, 30 tablets, blister pack (containered trade product pack)	Caduet 10/20 (amlodipine (as besylate) 10 mg + atorvastatin (as calcium) 20 mg) tablet: film-coated, 30 tablets (trade product pack)
antazoline + naphazoline (medicinal product)	antazoline 4.1 mg / 1 mL | antazoline phosphate 5 mg / 1 mL + naphazoline 426 microgram / 1 mL | naphazoline hydrochloride 500 microgram / 1 mL eye drops (medicinal product unit of use)	antazoline 4.1 mg / 1 mL | antazoline phosphate 5 mg / 1 mL + naphazoline 426 microgram / 1 m L | naphazoline hydrochloride 500 microgram / 1 m L 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, bottle (containered trade product pack)	Albalon-A Liquifilm 0.5% / 0.05% (antazoline phosphate 5 mg / 1 mL + naphazoline hydrochloride 500 microgram / 1 m L) eye drops: solution, 15 mL (trade product pack)
codeine + paracetamol (medicinal product)	codeine 23.43 mg | codeine phosphate 30 mg + paracetamol 500 mg tablet (medicinal product unit of use)	codeine 23.43 mg | 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, 1 tablet (trade product unit of use)	Panadeine Forte (codeine phosphate 30 mg + paracetamol 500 mg) tablet: uncoated, 20 tablets, blister pack (containered trade product pack)	Panadeine Forte (codeine phosphate 30 mg + paracetamol 500 mg) tablet: uncoated, 20 tablets (trade product pack)
• ethinyloestradiol + levonorgestrel (medicinal product) • inert substance (medicinal product)	• ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet (medicinal product unit of use) • ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet (medicinal	• ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet [40 tablets] (&) ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [24 tablets] (&)	Triphasil (trade product)	• Triphasil (ethinyloestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated, 1 tablet (trade product unit of use) • Triphasil (ethinyloestradiol	• Triphasil (ethinyloestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated [40 tablets] (&) (ethinyloestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated	• Triphasil (ethinyloestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated [40 tablets] (&) (ethinyloestradiol 30 microgram + levonorgestrel 50 microgram)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	CTPP FSN	TPP FSN
	product unit of use) • ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet (medicinal product unit of use) • inert substance tablet (medicinal product unit of use)	ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [20 tablets] (&) inert substance tablet [28 tablets], 112 tablets [4 x 28 tablets] (medicinal product pack) • ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet [10 tablets] (&) ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [6 tablets] (&) ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [4 tablets] (&) inert substance tablet [7 tablets], 28 tablets (medicinal product pack)		40 microgram + levonorgestrel 75 microgram) tablet: sugar-coated, 1 tablet (trade product unit of use) • Triphasil (ethinyloestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated, 1 tablet (trade product unit of use) • Triphasil (inert substance) tablet: sugar-coated, 1 tablet (trade product unit of use)	[24 tablets] (&) (ethinyloestradiol 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 (containered trade product pack) • Triphasil (ethinyloestradiol 30 microgram + levonorgestrel 125 microgram) tablet: sugar-coated [10 tablets] (&) (ethinyloestradiol 30 microgram + levonorgestrel 50 microgram) tablet: sugar-coated [6 tablets] (&) (ethinyloestradiol 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)	tablet: sugar-coated [24 tablets] (&) (ethinyloestradiol 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)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	CTPP FSN	TPP FSN
ethinyloestradiol + norethisterone (medicinal product)	ethinyloestradiol 35 microgram + norethisterone 500 microgram tablet (medicinal product unit of use)	• 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)	Brevinor 21 Day (trade product)	Brevinor 21 Day (ethinyloestradiol 35 microgram + norethisterone 500 microgram) tablet: uncoated, 1 tablet (trade product unit of use)	• Brevinor 21 Day (ethinyloestradiol 35 microgram + norethisterone 500 microgram) tablet: uncoated, 84 tablets [4 x 21 tablets], blister pack (containered trade product pack) • Brevinor 21 Day (ethinyloestradiol 35 microgram + norethisterone 500 microgram) tablet: uncoated, 21 tablets, blister pack (containered trade product pack)	Brevinor 21 Day (ethinyloestradiol 35 microgram + norethisterone 500 microgram) tablet: uncoated, 84 tablets [4 x 21 tablets] (trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	CTPP FSN	TPP FSN
• norethisterone acetate + oestradiol (medicinal product) • oestradiol (medicinal product)	• oestradiol 2 mg tablet (medicinal product unit of use) • norethisterone 0.876 mg | norethisterone acetate 1 mg + oestradiol 2 mg tablet (medicinal product unit of use) • oestradiol 1 mg tablet (medicinal product unit of use)	norethisterone 0.876 mg | norethisterone acetate 1 mg + oestradiol 2 mg tablet [10 tablets] (&) oestradiol 1 mg tablet [6 tablets] (&) oestradiol 2 mg tablet [12 tablets], 28 tablets (medicinal product pack)	Trisequens (trade product)	• Trisequens (oestradiol (as hemihydrate) 2 mg) tablet: film-coated, 1 tablet (trade product unit of use) • Trisequens (norethisterone acetate 1 mg + oestradiol (as hemihydrate) 2 mg) tablet: film-coated, 1 tablet (trade product unit of use) • Trisequens (oestradiol (as hemihydrate) 1 mg) tablet: film-coated, 1 tablet (trade product unit of use)	Trisequens (norethisterone acetate 1 mg + oestradiol (as hemihydrate) 2 mg) tablet: film-coated [10 tablets] (&) (oestradiol (as hemihydrate) 1 mg) tablet: film-coated [6 tablets] (&) (oestradiol (as hemihydrate) 2 mg) tablet: film-coated [12 tablets], 28 tablets, dial dispenser pack (containered trade product pack)	Trisequens (norethisterone acetate 1 mg + oestradiol (as hemihydrate) 2 mg) tablet: film-coated [10 tablets] (&) (oestradiol (as hemihydrate) 1 mg) tablet: film-coated [6 tablets] (&) (oestradiol (as hemihydrate) 2 mg) tablet: film-coated [12 tablets], 28 tablets (trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	CTPP FSN	TPP FSN
• calcium carbonate (medicinal product) • etidronate disodium (medicinal product)	• etidronate 164.8 mg | etidronate disodium 200 mg tablet (medicinal product unit of use) • calcium 500 mg | calcium carbonate 1250 mg tablet (medicinal product unit of use)	• calcium 500 mg | calcium carbonate 1250 mg tablet [76 tablets] (&) etidronate 164.8 mg | etidronate disodium 200 mg tablet [28 tablets], 104 tablets (medicinal product pack) • calcium 500 mg | calcium carbonate 1250 mg tablet, 76 tablets (medicinal product pack) • etidronate 164.8 mg | etidronate disodium 200 mg tablet, 28 tablets (medicinal product pack)	• Didronel (trade product) • Calcium Carbonate (Sanofi-Aventis) (trade product) • Didrocal (trade product)	• Didronel (etidronate disodium 200 mg) tablet: uncoated, 1 tablet (trade product unit of use) • Calcium Carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg) tablet: film-coated, 1 tablet (trade product unit of use)	• Didrocal (calcium (as carbonate) 500 mg) tablet: film-coated [76 tablets] (&) (etidronate disodium 200 mg) tablet: uncoated [28 tablets], 104 tablets, blister pack (containered trade product pack) • Calcium Carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg) tablet: film-coated, 76 tablets, blister pack (containered trade product pack) • Didronel (etidronate disodium 200 mg) tablet: uncoated, 28 tablets, blister pack (containered trade product pack)	Didrocal (calcium (as carbonate) 500 mg) tablet: film-coated [76 tablets] (&) (etidronate disodium 200 mg) tablet: uncoated [28 tablets], 104 tablets (trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	CTPP FSN	TPP FSN
• risperidone (medicinal product) • inert substance (medicinal product)	• risperidone 25 mg injection: modified release, vial (medicinal product unit of use) • inert substance diluent, syringe (medicinal product unit of use)	• inert substance diluent [1 x 2 mL syringe] (&) risperidone 25 mg injection: modified release [1 x 25 mg vial], 1 pack (medicinal product pack) • risperidone 25 mg injection: modified release, 1 x 25 mg vial (medicinal product pack) • inert substance diluent, 1 x 2 mL syringe (medicinal product pack)	Risperdal Consta (trade product)	• Risperdal Consta (risperidone 25 mg) injection: modified release, vial (trade product unit of use) • Risperdal Consta (inert substance) diluent, syringe (trade product unit of use)	• 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 (containered trade product pack) • Risperdal Consta (risperidone 25 mg) injection: modified release, 1 x 25 mg vial, vial (containered trade product pack) • Risperdal Consta (inert substance) diluent, 1 x 2 mL syringe, syringe (containered trade product pack)	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)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	CTPP FSN	TPP FSN
• lantreotide (medicinal product) • inert substance (medicinal product)	• lantreotide 30 mg injection: modified release, vial (medicinal product unit of use • inert substance diluent, ampoule (medicinal product unit of use)	• inert substance diluent [1 x 2 mL ampoule] (&) lantreotide 30 mg injection: modified release [1 x 30 mg vial], 1 pack (medicinal product pack) • lanreotide 30 mg injection: modified release, 1 x 30 mg vial (medicinal product pack) • inert substance diluent, 1 x 2 mL ampoule (medicinal product pack)	Somatuline LA (trade product)	• Somatuline LA (lantreotide (as acetate) 30 mg) injection: modified release, vial (trade product unit of use) • Somatuline LA (inert substance) diluent, ampoule (trade product unit of use)	• Somatuline LA (inert substance) diluent [1 x 2 mL ampoule] (&) (lantreotide (as acetate) 30 mg) injection: modified release [1 x 30 mg vial], 1 pack, composite pack (containered trade product pack • Somatuline LA (lanreotide (as acetate) 30 mg) injection: modified release, 1 x 30 mg vial, vial (containered trade product pack) • Somatuline LA (inert substance) diluent, 1 x 2 mL ampoule, ampoule (containered trade product pack)	Somatuline LA (inert substance) diluent [1 x 2 mL ampoule] (&) (lantreotide (as acetate) 30 mg) injection: modified release [1 x 30 mg vial], 1 pack (trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	CTPP FSN	TPP FSN
• epoprostenol (medicinal product) • inert substance (medicinal product)	• epoprostenol 500 microgram injection, vial (medicinal product unit of use) • inert substance diluent, vial (medicinal product unit of use)	• epoprostenol 500 microgram injection [1 x 500 microgram vial] (&) inert substance diluent [1 x 50 mL vial], 1 pack (medicinal product pack) • epoprostenol 500 microgram injection, 1 x 500 microgram vial (medicinal product pack) • inert substance diluent, 1 x 50 mL vial (medicinal product pack)	Flolan (trade product)	• Flolan (epoprostenol (as sodium) 500 microgram) injection: powder for, vial (trade product unit of use) • Flolan (inert substance) diluent, vial (trade product unit of use)	• Flolan (epoprostenol (as sodium) 500 microgram) injection: powder for [1 x 500 microgram vial] (&) (inert substance) diluent [1 x 50 mL vial], 1 pack, composite pack (containered trade product pack) • Flolan (epoprostenol (as sodium) 500 microgram) injection: powder for, 1 x 500 microgram vial, vial (containered trade product pack) • Flolan (inert substance) diluent, 1 x 50 mL vial, vial (containered trade product pack)	Flolan (epoprostenol (as sodium) 500 microgram) injection: powder for [1 x 500 microgram vial] (&) (inert substance) diluent [1 x 50 mL vial], 1 pack (trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	CTPP FSN	TPP 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)	Haemaccel (trade product)	Haemaccel (calcium (as salt unspecified) 125 mg / 500 mL + chloride (as base unspecified) 2.574 g / 500 mL + polygeline 17.5 g / 500 mL + potassium (as salt unspecified) 99.71 mg / 500 mL + sodium (as salt unspecified) 1.67 g / 500 mL) injection: intravenous infusion, 500 mL bottle (trade product unit of use)	Haemaccel (calcium (as salt unspecified) 125 mg / 500 mL + chloride (as base unspecified) 2.574 g / 500 mL + polygeline 17.5 g / 500 mL + potassium (as salt unspecified) 99.71 mg / 500 mL + sodium (as salt unspecified) 1.67 g / 500 mL) injection: intravenous infusion, 1 x 500 mL bottle, bottle (containered trade product pack)	Haemaccel (calcium (as salt unspecified) 125 mg / 500 mL + chloride (as base unspecified) 2.574 g / 500 mL + polygeline 17.5 g / 500 mL + potassium (as salt unspecified) 99.71 mg / 500 mL + sodium (as salt unspecified) 1.67 g / 500 mL) injection: intravenous infusion, 1 x 500 mL bottle (trade product pack)
• peginterferon alfa-2b (medicinal product) • ribavirin (medicinal product) • inert substance (medicinal product)	• peginterferon alfa-2b 100 microgram injection, cartridge (medicinal product unit of use) • ribavirin 200 mg capsule (medicinal product unit of use) • inert substance diluent, cartridge (medicinal product unit of use)	• 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) • peginterferon alfa-2b 100 microgram injection, 4 x 100 microgram cartridges (medicinal product pack) • ribavirin 200 mg	• Rebetrol (trade product) • Peg-Intron Redipen Injector (trade product) • Pegatron Combinatio n Therapy (trade product)	• PEG-Intron Redipen Injector (peginterferon alfa-2b 100 microgram) injection: powder for, cartridge (trade product unit of use) • Rebetol (ribavirin 200 mg) capsule: hard, 1 capsule (trade product unit of use) • PEG-Intron Redipen Injector (inert substance) diluent, cartridge (trade product unit of use)	• Pegatron Combination Therapy (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 (containered trade product pack) • PEG-Intron Redipen Injector (inert substance) diluent, 4 x 0.5 mL	Pegatron Combination Therapy (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)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	CTPP FSN	TPP FSN
		capsule, 112 capsules (medicinal product pack) • inert substance diluent, 4 x 0.5 mL cartridges (medicinal product pack)			cartridges, cartridge (containered trade product pack) • Rebetol 200 mg capsule, 112 capsules, blister pack (containered trade product pack) • PEG-Intron Redipen Injector (peginterferon alfa-2b 100 microgram) injection: powder for, 4 x 100 microgram cartridges, cartridge (containered trade product pack)	
calcium chloride dihydrate + potassium chloride + sodium chloride (medicinal product)	calcium 89.98 mg / 1000 mL | calcium chloride dihydrate 330 mg / 1000 mL + potassium 157.3 mg / 1000 mL | potassium chloride 300 mg / 1000 mL + sodium 3.83 g / 1000 mL | sodium chloride 8.6 g / 1000 mL injection, 1000 mL bag (medicinal product unit of use)	calcium 89.98 mg / 1000 mL | calcium chloride dihydrate 330 mg / 1000 mL + potassium 157.3 mg / 1000 mL | potassium chloride 300 mg / 1000 mL + sodium 3.83 g / 1000 mL | sodium chloride 8.6 g / 1000 mL injection, 1 x 1000 mL bag (medicinal product pack)	Ringer's (Pharmatel Fresenius Kabi) (trade product)	Ringer's (Pharmatel Fresenius Kabi) (calcium chloride dihydrate 330 mg / 1000 mL + potassium chloride 300 mg / 1000 mL + sodium chloride 8.6 g / 1000 mL) injection: intravenous infusion, 1000 mL bag (trade product unit of use)	Ringer's (Pharmatel Fresenius Kabi) (calcium chloride dihydrate 330 mg / 1000 mL + potassium chloride 300 mg / 1000 mL + sodium chloride 8.6 g / 1000 mL) injection: intravenous infusion, 1 x 1000 mL bag, bag (containered trade product pack)	Ringer's (Pharmatel Fresenius Kabi) (calcium chloride dihydrate 330 mg / 1000 mL + potassium chloride 300 mg / 1000 mL + sodium chloride 8.6 g / 1000 mL) injection: intravenous infusion, 1 x 1000 mL bag (trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	CTPP FSN	TPP FSN
• esomeprazole (medicinal product) • clarithromycin (medicinal product) • amoxycillin (medicinal product)	• esomeprazole 20 mg tablet (medicinal product unit of use) • clarithromycin 500 mg tablet (medicinal product unit of use) • amoxycillin 500 mg capsule (medicinal product unit of use)	amoxycillin 500 mg capsule [28 capsules] (&) clarithromycin 500 mg tablet [14 tablets] (&) esomeprazole 20 mg tablet [14 tablets], 1 pack (medicinal product pack)	• Nexium Hp7 (trade product) • Nexium (trade product) • Klacid (trade product) • Amoxil (trade product)	• Nexium (esomeprazole (as magnesium trihydrate) 20 mg) tablet: enteric, 1 tablet (trade product unit of use) • Klacid (clarithromycin 500 mg) tablet: film-coated, 1 tablet (trade product unit of use) • Amoxil (amoxycillin (as trihydrate) 500 mg) capsule: hard, 1 capsule (trade product unit of use)	• Nexium Hp7 (amoxycillin (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 (containered trade product pack) • Amoxil (amoxycillin (as trihydrate) 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 (as magnesium trihydrate) 20 mg) tablet: enteric, 14 tablets, blister pack (containered trade product pack)	Nexium Hp7 (amoxycillin (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 (trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	CTPP FSN	TPP FSN
mirtazapine (medicinal product)	mirtazapine 15 mg tablet (medicinal product unit of use)	mirtazapine 15 mg tablet, 30 tablets (medicinal product pack)	Avanza SolTab (trade product)	Avanza SolTab (mirtazapine 15 mg) tablet: orally disintegrating, 1 tablet (trade product unit of use)	Avanza SolTab (mirtazapine 15 mg) tablet: orally disintegrating, 30 tablets, blister pack (containered trade product pack)	Avanza SolTab (mirtazapine 15 mg) tablet: orally disintegrating, 30 tablets (trade product pack)
vinblastine (medicinal product)	vinblastine 8.92 mg / 10 mL | vinblastine sulfate 10 mg / 10 mL injection, 10 mL vial (medicinal product unit of use)	vinblastine 8.92 mg / 10 mL | 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, vial (containered trade product pack)	Vinblastine Sulfate (DBL) (vinblastine sulfate 10 mg / 10 mL) injection: solution, 5 x 10 mL vials (trade product pack)

Appendix O. Preferred Term (PT) examples

Table 122: Preferred Term examples

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	CTPP PT	TPP PT
amorolfine	amorolfine 5% (50 mg/mL) application	amorolfine 5% (50 mg/mL) application, 5 mL	Loceryl Nail Lacquer	Loceryl Nail Lacquer 5% (50 mg/mL) application	Loceryl Nail Lacquer 5% (50 mg/mL) application, 5 mL, bottle	Loceryl Nail Lacquer 5% (50 mg/mL) application, 5 mL
oestradiol	oestradiol 100 microgram/ 24 hours patch	oestradiol 100 microgram/ 24 hours patch, 8	Estraderm	Estraderm 100 microgram/ 24 hours patch	Estraderm 100 microgram/ 24 hours patch, 8, sachet	Estraderm 100 microgram/ 24 hours patch, 8
mesalazine	mesalazine 500 mg granules: modified release, sachet	mesalazine 500 mg granules: modified release, 100 x 500 mg sachets	Salofalk	Salofalk 500 mg granules: modified release, sachet	Salofalk 500 mg granules: modified release, 100 x 500 mg sachets	Salofalk 500 mg granules: modified release, 100 x 500 mg 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, sachet	Vitrasert 4.5 mg implant, 1
carboplatin	carboplatin 150 mg/15 mL injection, vial	carboplatin 150 mg/15 mL injection, 1 x 15 mL vial	Carboplatin (Ebewe)	Carboplatin (Ebewe) 150 mg/15 mL injection, vial	Carboplatin (Ebewe) 150 mg/15 mL injection, 1 x 15 mL vial	Carboplatin (Ebewe) 150 mg/15 mL injection, 1 x 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, bottle	Lasix 10 mg/mL oral liquid: solution, 30 mL
nystatin	nystatin 100 000 units pessary	nystatin 100 000 units pessary, 15	Nilstat Cream Pessaries	Nilstat Cream Pessaries 100 000 units, 1 pessary	Nilstat Cream Pessaries 100 000 units, 15 pessaries, bottle	Nilstat Cream Pessaries 100 000 units, 15 pessaries
ondansetron	ondansetron 4 mg wafer	ondansetron 4 mg wafer, 10	Zofran Zydis	Zofran Zydis 4 mg wafer	Zofran Zydis 4 mg wafer, 10, blister pack	Zofran Zydis 4 mg wafer, 10
amoxycillin	amoxycillin 500 mg capsule	amoxycillin 500 mg capsule, 20	Amoxil	Amoxil 500 mg capsule: hard, 1 capsule	Amoxil 500 mg capsule: hard, 20 capsules, blister pack	Amoxil 500 mg capsule: hard, 20 capsules

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	CTPP PT	TPP PT
salbutamol	salbutamol 100 microgram/actuation inhalation: pressurised	salbutamol 100 microgram/actuation inhalation: pressurised, 200 actuations	Airomir Inhaler	Airomir Inhaler 100 microgram/actuation inhalation: pressurised	Airomir Inhaler 100 microgram/actuation inhalation: pressurised, 200 actuations, metered dose aerosol can	Airomir Inhaler 100 microgram/actuation inhalation: pressurised, 200 actuations
ampicillin	ampicillin 500 mg injection, vial	ampicillin 500 mg injection, 5 x 500 mg vials	Austrapen	Austrapen 500 mg injection: powder for, vial	Austrapen 500 mg injection: powder for, 5 x 500 mg vials	Austrapen 500 mg injection: powder for, 5 x 500 mg 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	Ceclor 125 mg/5 mL oral liquid: powder for, 100 mL, bottle	Ceclor 125 mg/5 mL oral liquid: powder for, 100 mL
diclofenac	diclofenac sodium 50 mg tablet: enteric, 1 tablet	diclofenac sodium 50 mg tablet: enteric, 50 tablets	Voltaren	Voltaren 50 mg tablet: enteric, 1 tablet	Voltaren 50 mg tablet: enteric, 50 tablets, bottle	Voltaren 50 mg tablet: enteric, 50 tablets
terbinafine	terbinafine hydrochloride 1% (10 mg/g) cream	terbinafine hydrochloride 1% (10 mg/g) cream, 15 g	Lamisil	Lamisil 1% (10 mg/g) cream	Lamisil 1% (10 mg/g) cream, 15 g, tube	Lamisil 1% (10 mg/g) cream, 15 g
budesonide + eformoterol	budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for	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	Symbicort Turbuhaler 100/6 inhalation: powder for, 120 actuations, dry powder inhaler	Symbicort Turbuhaler 100/6 inhalation: powder for, 120 actuations
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, 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
sodium chloride	sodium chloride 0.9% (9 g/1000 mL) injection, bag	sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag	Sodium Chloride (Baxter)	Sodium Chloride (Baxter) 0.9% (9 g/1000 mL) injection: intravenous infusion, bag	Sodium Chloride (Baxter) 0.9% (9 g/1000 mL) injection: intravenous infusion, 1 x 1000 mL bag AHB 1324	Sodium Chloride (Baxter) 0.9% (9 g/1000 mL) injection: intravenous infusion, 1 x 1000 mL bag

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	CTPP PT	TPP PT
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, 1 tablet	Combivir tablet: film-coated, 60 tablets, bottle	Combivir tablet: film-coated, 60 tablets
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, 1 tablet	Caduet 10/20 tablet: film-coated, 30 tablets, blister pack	Caduet 10/20 tablet: film-coated, 30 tablets
antazoline + naphazoline	antazoline phosphate 0.5% (5 mg/mL) + naphazoline hydrochloride 0.05% (500 microgram/ mL) eye drops	antazoline phosphate 0.5% (5 mg/mL) + naphazoline hydrochloride 0.05% (500 microgram/ mL) 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, bottle	Albalon-A Liquifilm 0.5% / 0.05% eye drops: solution, 15 mL
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, 1 tablet	Panadeine Forte tablet: uncoated, 20 tablets, blister pack	Panadeine Forte tablet: uncoated, 20 tablets

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	CTPP PT	TPP PT
• levonorgestrel + ethinyloestradiol • inert substance	• levonorgestrel 50 microgram + ethinyloestradiol 30 microgram tablet • levonorgestrel 75 microgram + ethinyloestradiol 40 microgram tablet • levonorgestrel 125 microgram + ethinyloestradiol 30 microgram tablet • inert substance tablet	• levonorgestrel 50 microgram + ethinyloestradiol 30 microgram tablet [24 tablets] (&) levonorgestrel 75 microgram + ethinyloestradiol 40 microgram tablet [20 tablets] (&) levonorgestrel 125 microgram + ethinyloestradiol 30 microgram tablet [40 tablets] (&) inert substance tablet [28 tablets], 112 [4 x 28 tablets] • ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet [10 tablets] (&) ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [6 tablets] (&) ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [5 tablets] (&) inert substance tablet [7 tablets], 28 tablets	Triphasil	• Triphasil (levonorgestrel 50 microgram + ethinyloestradiol 30 microgram) tablet: sugar-coated, 1 tablet • Triphasil (levonorgestrel 75 microgram + ethinyloestradiol 40 microgram) tablet: sugar-coated, 1 tablet • Triphasil (levonorgestrel 125 microgram + ethinyloestradiol 30 microgram) tablet: sugar-coated, 1 tablet • Triphasil (inert substance) tablet: sugar-coated, 1 tablet	• Triphasil, 112 tablets [4 x 28 tablets], blister pack • Triphasil, 28 tablets, blister pack	Triphasil, 112 tablets [4 x 28 tablets]

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	CTPP PT	TPP PT
norethisterone + ethinyloestradiol	norethisterone 500 microgram + ethinyloestradiol 35 microgram tablet	• norethisterone 500 microgram + ethinyloestradiol 35 microgram tablet, 84 [4 x 21 tablets] • ethinyloestradiol 35 microgram + norethisterone 500 microgram tablet, 21	Brevinor 21 Day	Brevinor 21 Day tablet: uncoated, 1 tablet	• Brevinor 21 Day tablet: uncoated, 84 tablets [4 x 21 tablets], blister pack • Brevinor 21 Day tablet: uncoated, 21 tablets, blister pack	Brevinor 21 Day tablet: uncoated, 84 tablets [4 x 21 tablets]
• norethisterone acetate + oestradiol • oestradiol	• oestradiol 2 mg tablet • norethisterone acetate 1 mg + oestradiol 2 mg tablet • oestradiol 1 mg tablet	oestradiol 2 mg tablet [12 tablets] (&) norethisterone acetate 1 mg + oestradiol 2 mg tablet [10 tablets] (&) oestradiol 1 mg tablet [6 tablets], 28	Trisequens	• Trisequens 2 mg tablet: film-coated, 1 tablet • Trisequens tablet: film-coated, 1 tablet • Trisequens 1 mg tablet: film-coated, 1 tablet	Trisequens, 28 tablets, dial dispenser pack	Trisequens, 28 tablets
• calcium carbonate • etidronate disodium	• etidronate disodium 200 mg tablet • calcium (as carbonate) 500 mg tablet	• etidronate disodium 200 mg tablet [28 tablets] (&) calcium (as carbonate) 500 mg tablet [76 tablets], 104 • calcium (as carbonate) 500 mg tablet, 76 • etidronate disodium 200 mg tablet, 28	• Didronel • Calcium Carbonate (Sanofi-Aventis) • Didrocal	• Didronel 200mg tablet: uncoated, 1 tablet • Calcium Carbonate (Sanofi-Aventis) 500 mg tablet: film-coated, 1 tablet	• Didrocal, 104 tablets, blister pack • Calcium Carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg tablet), 76 tablets, blister pack • Didronel 200 mg tablet, 28 tablets, blister pack	Didrocal, 104 tablets

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	CTPP PT	TPP PT
• risperidone • inert substance	• risperidone 25 mg injection: modified release, vial • inert substance diluent, syringe	• risperidone 25 mg injection: modified release [1 x 25 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack • risperidone 25 mg injection: modified release, 1 x 25 mg vial • inert substance diluent, 1 x 2 mL syringe	Risperdal Consta	• Risperdal Consta (risperidone 25 mg) injection: modified release, vial • Risperdal Consta diluent, syringe	• Risperdal Consta (1 x 25 mg vial), 1 pack, composite pack • Risperdal Consta 25 mg injection: modified release, 1 x 25 mg vial • Risperdal Consta diluent, 1 x 2 mL syringe	Risperdal Consta (1 x 25 mg vial), 1 pack
• lantreotide • inert substance	• lantreotide 30 mg injection: modified release, vial • inert substance diluent, ampoule	• lantreotide 30 mg injection; modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack • lanreotide 30 mg injection: modified release, 1 x 30 mg vial • inert substance diluent, 1 x 2 mL ampoule	Somatuline LA	• Somatuline LA 30 mg injection: modified release, vial • Somatuline LA diluent, ampoule	• Somatuline LA (1 x 30 mg vial), 1 pack, composite pack • Somatuline LA 30 mg injection: modified release, 1 x 30 mg vial • Somatuline LA diluent, 1 x 2 mL ampoule	Somatuline LA (1 x 30 mg vial), 1 pack

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	CTPP PT	TPP PT
• epoprostenol • inert substance	• epoprostenol 500 microgram injection, vial • inert substance diluent, vial	• epoprostenol 500 microgram injection [1 x 500 microgram vial] (&) inert substance diluent [1 x 50 mL vial], 1 pack • epoprostenol 500 microgram injection, 1 x 500 microgram vial • inert substance diluent, 1 x 50 mL vial	Flolan	• Flolan 500 microgram injection: powder for, vial • Flolan diluent, vial	• Flolan (1 x 500 microgram vial), 1 pack, composite pack • Flolan 500 microgram injection: powder for, 1 x 500 microgram vial • Flolan diluent, 1 x 50 mL vial	Flolan (1 x 500 microgram vial), 1 pack
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, 1 x 500 mL bottle	Haemaccel	Haemaccel injection: intravenous infusion, bottle	Haemaccel intravenous infusion, 1 x 500 mL bottle	Haemaccel intravenous infusion, 1 x 500 mL bottle

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	CTPP PT	TPP PT
• peginterferon alfa-2b • ribavirin • inert substance	• peginterferon alfa-2b 100 microgram injection, cartridge • ribavirin 200 mg capsule • inert substance diluent, cartridge	• 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 • peginterferon alfa 2b 100 microgram injection, 4 x 100 microgram cartridges • ribavirin 200 mg capsule, 112 • inert substance diluent, 4 x 0.5 mL cartridges	• Rebetol • Peg-Intron Redipen Injector • Pegatron Combination Therapy	• PEG-Intron Redipen Injector 100 microgram injection: powder for, cartridge • Rebetol 200 mg capsule: hard, 1 capsule • PEG-Intron Redipen Injector diluent, cartridge	• Pegatron Combination Therapy (4 x 100 microgram cartridges, 112 x 200 mg capsules), 1 pack, composite pack • PEG-Intron Redipen Injector 100 microgram injection: powder for, 4 x 100 microgram cartridges • PEG-Intron Redipen Injector diluent, 4 x 0.5 mL cartridges • Rebetol 200 mg capsule: hard, 112, blister pack	Pegatron Combination Therapy (4 x 100 microgram cartridges, 112 x 200 mg capsules), 1 pack
sodium chloride + potassium chloride + calcium chloride dihydrate	sodium chloride 8.6 g/1000 mL + potassium chloride 300 mg/1000 mL + calcium chloride dihydrate 330 mg/1000 mL injection, bag	sodium chloride 8.6 g/1000 mL + potassium chloride 300 mg/1000 mL + calcium chloride dihydrate 330 mg/1000 mL injection, 1 x 1000 mL bag	Ringer's (Pharmatel Fresenius Kabi)	Ringer's (Pharmatel Fresenius Kabi) injection: intravenous infusion, bag	Ringer's (Pharmatel Fresenius Kabi) intravenous infusion, 1 x 1000 mL bag	Ringer's (Pharmatel Fresenius Kabi) intravenous infusion, 1 x 1000 mL bag

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	CTPP PT	TPP PT
• esomeprazole • clarithromycin • amoxycillin	• esomeprazole 20 mg tablet • clarithromycin 500 mg tablet • amoxycillin 500 mg capsule	• esomeprazole 20 mg tablet [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxycillin 500 mg capsule [28 capsules], 1 pack • clarithromycin 550 mg tablet, 14 • esomeprazole 20 mg tablet, 14 • amoxycillin 500 mg capsule, 28	• Nexium • Klacid • Amoxil • Nexium Hp7	• Nexium 20 mg tablet: enteric, 1 tablet • Klacid 500 mg tablet: film-coated, 1 tablet • Amoxil 500 mg capsule: hard, 1 capsule	• Nexium Hp7, 1 pack, composite pack • Amoxil 500 mg capsule: hard, 28 capsules, blister pack • Klacid 500 mg tablet: film-coated, 14 tablets, blister pack • Nexium 20 mg tablet, 14, blister pack	Nexium Hp7, 1 pack
mirtazapine	mirtazapine 15 mg tablet	mirtazapine 15 mg tablet, 30	Avanza SolTab	Avanza SolTab 15 mg tablet: orally disintegrating, 1 tablet	Avanza SolTab 15 mg tablet: orally disintegrating, 30 tablets, blister pack	Avanza SolTab 15 mg tablet: orally disintegrating, 30 tablets
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, 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