nehta

Editorial Rules (v2 model)

Australian Medicines Terminology

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Table of contents

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Table of acronyms

AAN	Australian Approved Name
ACOM	Australian Catalogue of Medicines
AMDT	Australian Medicines and Devices Terminology
AMT	Australian Medicines Terminology
AO	Animal Origin
ARTG	Australian Register of Therapeutic Goods
AS	Availability Status
ATC	WHO Anatomical Therapeutic Chemical Classification
BD	Biotech Descriptor
BOSS	Basis Of Strength Substance
CDER	Centre for Drug Evaluation and Research
CT	Container Type
CTPP	Containered Trade Product Pack
dm+d	UK Dictionary of Medicines and Devices
EBNF	Extended Backus-Naur Form
F	Form
FSN	Fully Specified Name
HL7	Health Level 7
HTML	HyperText Markup Language
IANA	Internet Assigned Numbers Authority
IAS	Ingredient Activity Status
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

MHM	Medicinal Product Pack has Medicinal Product Unit of Use
MP	Medicinal Product
MPP	Medicinal Product Pack
MPUU	Medicinal Product Unit of Use
MPUUSAI	MPUU Specific Active Ingredient
MSP	Medication Sponsor
NEHTA	National E-Health Transition Authority
NHS	National Health Service (UK)
NPC	National Product Catalogue
ORG	Organisation
PBS	Pharmaceutical Benefits Scheme
PF	Proprietary Form
PI	Pharmaceutical Ingredient
PMI	Pack Manufacture Indicator
PP	Plant Part
PPN	Plant Preparation
PSI	Pack Size Indicator
PSRT	Preferred Strength Representation Type
PT	Preferred Term
R	Route
RA	Route of Administration
RPBS	Repatriation Pharmaceutical Benefits Scheme
SCTID	SNOMED Clinical Terms Identifier
SHPA	Society of Hospital Pharmacists of Australia
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
THT	Trade Product Pack has Trade Product Unit of Use
TP	Trade Product
TPG	Trade Product Group
TPP	Trade Product Pack
TPUU	Trade Product Unit of Use
TPUUPI	TPUU Pharmaceutical Ingredient
UDFI	Unit Dose Form Indicator
UML	Unified Modelling Language
UOM	Unit of Measure
UTF-8	Unicode Transformation Format (8-bit)
UUID	Universally Unique Identifier
WHO	World Health Organisation
XHTML	Extensible HyperText Markup Language

Notation

EBNF

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.

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.

Tables

Tables within this document have colour-coded heading rows for ease of recognition:

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 no less legible in greyscale print.

1 Introduction

1.1 Foreword

The National E-Health Transition Authority (NEHTA) Limited 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.

1.2 Opportunity for standardisation

Currently in Australia there are no agreed standard medication identifiers, which are necessary to enable sharing of 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 include:

- the Therapeutic Goods Administration (TGA);
- Australian Register of Therapeutic Goods (ARTG); 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.

NEHTA's aim is to ensure consistency and interoperability as required between these separate systems.

1.3 Aims of the AMT

The key aim of the Australian Medicines Terminology (AMT) project is to provide a consistent approach to the identification and naming of medicines, which can support medicines management and activity across the entire universal health domain. The project will develop a medicines terminology, which will be accessible to all.

To enable this to occur, the following objectives will need to be met:

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

NEHTA will work with industry and international experts to develop the specifications, standards and infrastructure necessary to achieve these aims.

1.4 Scope of the AMT

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

- medicines registered with the TGA; and
- medicines listed with the TGA.

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

- PBS information;
- standard medicines classifications (e.g. World Health Organisation (WHO) Anatomic Therapeutic and Chemical (ATC) Classification); and
- regulatory bodies in Australia including those organisations participating in the construction of the AMT, such as the TGA Australian Register of Therapeutic Goods.

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

Examples of knowledge-based information that is 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

1.5 AMT development process

The AMT model was developed initially based on work previously undertaken in this area, most notably by:

- The design for the Australian Catalogue of Medicines (ACOM) which was guided by input from the Medicines Coding Council of Australia (MCCA).
- A consultation draft of the Australia Medicines and Devices Terminology (AMDT) developed by the Department of Health and Ageing in conjunction with Health Level 7 (HL7) Australia and New Zealand.

The preliminary 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 Branch; 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 model.
- the complexity of many Australian products.
- Australian clinical practice.
- Potential safety issues, currently facing many Australian clinicians, that could be improved by the clear and consistent naming of medical products, especially when selection of these items is required in electronic systems.

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 terminology reference sets to support the NEHTA PCEHR work programme and eHealth solution specifications within the clinical contexts of eMedications Management (e.g. electronic transfer of prescriptions) and Continuity of Care (e.g. eDischarge Summaries and eReferrals).
- Publishing the new AMT v3 model release; a result of consultation with national stakeholders to simplify the AMT model in support of its approved use cases and aligning the release format with IHTSDO and SNOMED CT-AU.
- Developing an AMT v3 Implementation Guide which aims to provide guidance for technical audiences.
- Consultation with vendors and implementers to update the roadmap that forms part of the AMT Implementation Plan.

1.6 Purpose of this document

This document is one of a set of documents being developed by NEHTA to describe the scope, purpose, use, technical structures, governance, maintenance and quality assurance aspects of developing the AMT. The terminology is intended for use in computer systems for medication management[1] in both primary and secondary health care in Australia.

This document specifies the editorial rules for the AMT, which focuses on the naming conventions and rules associated with all description types for concepts in the AMT model.

This document may change according to stakeholder feedback, AMT model refinement and independent reviews of these rules.

The concept types and relationships types are defined in the:

- *Australian Medicines Terminology UML Class Diagram* v7.0 – 05/03/2008
- *Australian Medicines Terminology Technical Specifications* v3.0 – 02/04/2008

[1] Medication management in this context is limited to medicines and related devices that are prescribed, dispensed or administered in the Australian health care setting.

1.7 Feedback

Feedback on this document is being sought, particularly from health software vendors, public and private health institutions and government health jurisdictions. Input received will be incorporated, as appropriate, by NEHTA into the next release. The next version of the document will be published on NEHTA's website[2].

All comments should be directed to <terminologies@nehta.gov.au>.

1.8 Acknowledgements

In constructing this document, NEHTA would like to acknowledge the continuing contributions made by the NHS Dictionary of Medicines and Devices (dm+d) team.

This work builds on previous work by a number of groups and related initiatives including:

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

[2] The full URL is <http://www.nehta.gov.au/connecting-australia/terminology-and-information/clinical-terminology/australian-medicines-terminology>.

2 AMT model

2.1 Overview

The AMT data representation has been based on SNOMED CT, which is a comprehensive and precise clinical reference terminology. It provides a comprehensive list of clinical terms and identifiers that allows complex clinical concepts to be described in a way that can be interpreted by computers. SNOMED CT works at all levels of the health encounter, including history, examination, provisional diagnosis, test results and treatment. More information on SNOMED CT is available in the *SNOMED CT User Guide*.

NEHTA has developed SNOMED CT-AU, which is an extension of SNOMED CT to suit Australian healthcare requirements and to deliver the clinical information specifications that will be underpinned by SNOMED CT. A small portion of the data represented in the AMT does not fit into the standard SNOMED formats and data structures. These have been modified as described below. The AMT developers have chosen to represent this data in "SNOMED-like" format. The majority of this kind of data is represented by creating "additional description types".

2.2 AMT components

2.2.1 General constraints/Data definitions

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

Table 1: General Constraints/Data definitions rules

Rule ID	Data Element	Constraints/Data definitions	Constraint Source
AU-COMP-1	ComponentUUID	All Components must have exactly one ComponentUUID.	SNOMED CT-AU
AU-COMP-2	ComponentUUID	All ComponentUUIDs must be unique.	SNOMED CT-AU
AU-COMP-3	ComponentID	All Components must have exactly one ComponentID (i.e. SNOMED CT ID).	SNOMED CT
AU-COMP-4	ComponentID	All ComponentIDs must be unique.	SNOMED CT
AU-COMP-5	ComponentID	Each ComponentID is a SNOMED CT identifier (SCTID) that complies with the SNOMED data type format. The permitted characters for a SCTID are the digits 0-9. The minimum permitted length is 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".	SNOMED CT

Rule ID	Data Element	Constraints/Data definitions	Constraint Source
AU-COMP-6	ComponentStatusId	Each ComponentStatusId must be a ComponentUUID that identifies some concept in the "Australian concept ← Australian data representation concept ← Australian status type" hierarchy.	SNOMED CT-AU
AU-COMP-7	ComponentStatus	The valid values for ComponentStatus are: 0 (Current) • The component is in current use and is considered active. 1 (Retired) • The component has been withdrawn without a specified reason. 2 (Duplicate) • The component has been withdrawn from current use because it duplicates another component of the same type. 3 (Outdated) • The component has been withdrawn from current use because it is no longer recognised as valid, or is no longer in general clinical use. 4 (Ambiguous) • The component has been withdrawn from current use because it is inherently ambiguous. This status can only be used for concept components. 5 (Erroneous) • The component has been withdrawn from current use as it contains an error. 6 (Limited) • The component is of limited clinical value. Components with this status are still valid for current use. 7 (Inappropriate) • The (description) component has been withdrawn as it should not refer to the associated concept. This status applies only to description components. 8 (Concept Retired) • The (description) component is valid for the associated concept, but the concept has been made non-current (i.e.	SNOMED CT

Rule ID	Data Element	Constraints/Data definitions	Constraint Source
		the associated concept has ComponentStatus 1, 2, 3, 4, 5 or 10). 10 (Moved Elsewhere) • The component has been moved to an extension, to a different extension, or to the international release. If the component is a concept, a "moved to" relationship should be used to locate the namespace to which the concept has been moved. If the component is of any other type, a reference will indicate the namespace to which the component has been moved. 11 (Pending Move) • The component will be moved to an extension, to a different extension, or to the international release. Note that components with a ComponentStatus of 0, 6, 8 or 11 are considered to be active, while those with a ComponentStatus of 1, 2, 3, 4, 5, 7 or 10 are considered to be inactive.	
AU-COMP-8	EffectiveTime	The EffectiveTime date/time should be represented using ISO 8601 conventions, with no punctuation, and no letter "T" between date and time, with a granularity up to the level of seconds.	SNOMED CT-AU

2.2.2 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. ConceptIDs 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.

2.2.2.1 AMT notable concepts

The AMT includes the following AMT "notable concept" types.

Australian Product Concepts

These concepts 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 3.

Australian Substance Concepts

These concepts represent the ingredients within products. Additional details about the descriptions that describe these concepts are provided in Section 4.

Australian Qualifier Concepts

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 5.

Australian Relationship Details Concepts

These concepts will be used in the AMT to add more information about a relationship between two concepts. Additional details about the descriptions that describe these concepts are provided in Section 6.

Australian Data Representation Concepts

These concepts are used to assist in the representation of the AMT data in SNOMED-like format and currently include:

- Australian Characteristic Type Concepts.
- Australian Description Type Concepts.
- Australian Language Concepts.
- Australian Refinability Type Concepts.
- Australian Relationship Type Concepts.
- Australian Status Type Concepts.

Additional details about the descriptions that describe these concepts are provided in Section 7.

The concepts, attributes and relationships are further described in:

- *Australian Medicines Terminology UML Class Diagram v7.0* – 05/03/2008
- *Australian Medicines Terminology Technical Specifications* v3.0 – 02/04/2008

2.2.2.2 Concepts Constraints/Data definitions

Concept constraints relate to all concept types within the AMT model and are defined according to the table in Section 2.2.1.

2.2.3 Relationships

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

- Defining
- Qualifying
- Historical
- Additional

Every active SNOMED CT 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 SNOMED CT concepts. They are considered to be "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 SNOMED CT'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 for 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.

2.2.3.1 AMT Relationships

The AMT will include SNOMED CT relationships and Australian relationships which are used to:

- define a relationship between concepts; and
- add more information to a concept.

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. 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 is modified to display something that is clinically intuitive. The AMT represents the full list of ingredients within a Medicinal Product, using a set of "has ingredient" relationships between the Medicinal Product and its 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 descriptions, of type "Australian Description Type" (as described below).

Table 2: AMT relationship types

Name	Relationship Source
IS_A	SNOMED CT
MAY BE A	SNOMED CT
MOVED FROM	SNOMED CT
MOVED TO	SNOMED CT
REPLACED BY	SNOMED CT
SAME AS	SNOMED CT
WAS A	SNOMED CT
comes from plant part	AMT

Name	Relationship Source
has animal origin	AMT
has MPP	AMT
has MPUU	AMT
has Australian BOSS	AMT
has availability status	AMT
has base form strength denominator units	AMT
has base form strength numerator units	AMT
has base form strength units	AMT
has biotech descriptor	AMT
has BOSS	AMT
has container type	AMT
has dose form	AMT
has ingredient	AMT
has ingredient activity status	AMT
has ingredient strength denominator units	AMT
has ingredient strength numerator units	AMT
has ingredient strength units	AMT
has international BOSS	AMT
has manufactured dose form	AMT
has modification of	AMT
has pack	AMT
has pack manufacture indicator	AMT
has pack quantity units	AMT
has pack size indicator	AMT
has pharmaceutical ingredient	AMT
has plant part	AMT
has plant preparation	AMT
has preferred base form strength representation	AMT
has preferred salt form strength representation	AMT
has preferred strength representation	AMT
has proprietary dose form	AMT
has registered route	AMT
has route of administration	AMT
has salt form strength denominator units	AMT
has salt form strength numerator units	AMT

Name	Relationship Source
has salt form strength units	AMT
has specific active ingredient	AMT
has sponsor	AMT
has strength units	AMT
has subpack	AMT
has total unit of use quantity units	AMT
has total unit of use size units	AMT
has TPP	AMT
has TPUU	AMT
has trade product group	AMT
has unit dose form indicator	AMT
has unit dose form size units	AMT
has unit dose type units	AMT
has unit of measure	AMT
has unit of use	AMT
has unit of use quantity units	AMT
has unit of use size units	AMT
has units	AMT
hierarchical relationship type	AMT
historical relationship type	SNOMED CT

These relationships are further described in the following documents:

- *Australian Medicines Terminology UML Class Diagram* v7.0 – 05/03/2008
- *Australian Medicines Terminology Technical Specifications* v3.0 – 02/04/2008

2.2.3.2 Relationship constraints/Data definitions

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

Reciprocal relationships should not be explicitly 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 Relationships 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 and are not represented by rows in the Relationships 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 Relationships 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 rules apply.

Table 3: Relationship Constraints/Data definitions rules

Rule ID	Data Element	Constraints/Data definitions	Constraint Source
AU-REL-1	ComponentID	The ComponentID of each Relationship must have a partition-identifier of "2".	SNOMED CT
AU-REL-2	ComponentStatus	The valid values for the ComponentStatus of a relationship are: • 0 (Current) • 1 (Retired) • 2 (Duplicate) • 3 (Outdated) • 5 (Erroneous) • 6 (Limited) • 10 (Moved Elsewhere) • 11 (Pending Move) Refer to data rule AU-COMP-7 (Section 2.2.1) for a more complete definition of these statuses.	SNOMED CT-AU
AU-REL-3	ComponentStatus	The ComponentStatus of a Relationship can only be 0 (Current) if all associated Concepts are also current (i.e. ComponentStatus = 0).	SNOMED CT-AU
AU-REL-4	ConceptUUID1	All relationships must have exactly one ConceptUUID1.	SNOMED CT-AU
AU-REL-5	ConceptUUID1	The ConceptUUID1 must equal the ComponentUUID of some Concept.	SNOMED CT-AU
AU-REL-6	ConceptID1	All relationships must have exactly one ConceptID1.	SNOMED CT
AU-REL-7	ConceptID1	The ConceptID1 must equal the ComponentID of some Concept.	SNOMED CT
AU-REL-8	RelationshipTypeUUID	All relationships must have exactly one RelationshipTypeUUID.	SNOMED CT-AU
AU-REL-9	RelationshipTypeUUID	The RelationshipTypeUUID must equal the ComponentUUID of some Concept in the "Australian concept ← Australian data representation concept ← Australian relationship type" hierarchy.	SNOMED CT-AU
AU-REL-10	RelationshipType	All relationships must have exactly one RelationshipType.	SNOMED CT
AU-REL-11	RelationshipType	The RelationshipType must equal the ComponentID of some Concept in the "Australian concept ← Australian data representation concept ← Australian relationship type" hierarchy.	SNOMED CT

Rule ID	Data Element	Constraints/Data definitions	Constraint Source
AU-REL-12	ConceptUUID2	All relationships must have exactly one ConceptUUID2.	SNOMED CT-AU
AU-REL-13	ConceptUUID2	The ConceptUUID2 must equal the ComponentUUID of some Concept.	SNOMED CT-AU
AU-REL-14	ConceptID2	All relationships must have exactly one ConceptID2.	SNOMED CT
AU-REL-15	ConceptID2	The ConceptID2 must equal the ComponentID of some Concept.	SNOMED CT
AU-REL-16	CharacteristicTypeID	The CharacteristicTypeID must equal the ComponentUUID of some Concept in the "Australian concept ← Australian data representation concept ← Australian characteristic type" hierarchy.	SNOMED CT-AU
AU-REL-17	CharacteristicType	The valid values for the CharacteristicType of a relationship are: • 0 (Defining) • 1 (Qualifier) • 2 (Historical) • 3 (Additional)	SNOMED CT
AU-REL-18	RefinabilityId	The RefinabilityID must equal the ComponentUUID of some Concept in the "Australian concept ← Australian data representation concept ← Australian refinability type" hierarchy.	SNOMED CT-AU
AU-REL-19	Refinability	The valid values for the Refinability of a relationship are: • 0 (Not refinable) • 1 (Optional) • 2 (Mandatory)	SNOMED CT
AU-REL-20	RelationshipGroup	RelationshipGroup must be an integer value between 0 and 99.	SNOMED CT

2.2.4 Descriptions

The AMT has adopted the 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.

The AMT also has Additional Description Types that allow more information to be added to a concept than can be represented using relationships or descriptions with a core SNOMED CT description type. These Additional Descriptions are represented as a string of characters, but may contain data that is numeric, textual or temporal (i.e. including dates and times). Each Australian additional description type is described more fully under the type of concept that it describes.

2.2.4.1 AMT Description types

All AMT concepts will have the following descriptions:

- Fully Specified Name (FSN)
- Preferred Term (PT)

Additional descriptions are available for specific concepts in the AMT. A list of these additional descriptions by concept type is described in the table below. The definitions and rules for the concept-specific description types are listed under the Concept type that they describe.

Table 4: Concept descriptions

Concept	Australian Additional Description Type Name	Reference
Medicinal Product Unit of Use (MPUU)	UnitDoseFormSizeValue	See Section 3.3.2.7
Medicinal Product Pack (MPP)	TotalUnitOfUseSizeValue	See Section 3.4.2.9
	TotalUnitOfUseQuantityValue	See Section 3.4.2.7
	TotalSubpackQuantity	See Section 3.4.2.8
Trade Product Unit of Use (TPUU)	OtherIdentifyingInformation	See Section 3.6.2.7
	TradeProductSuffix	See Section 3.6.2.8
Trade Product Pack (TPP)	TotalUnitOfUseSizeValue	See Section 3.7.2.10
	TradeProductSuffix	See Section 3.7.2.11
	OtherPackInformation	See Section 3.7.2.7
	TotalUnitOfUseQuantityValue	See Section 3.7.2.8
	TotalSubpackQuantity	See Section 3.7.2.9
Containered TPP (CTPP)	OtherContaineredPackInformation	See Section 3.8.2.7
	ARTG ID	See Section 3.8.2.8
MPP has MPUU (MHM)	RelationshipId	See Section 6.1.2.3
	UnitOfUseQuantityValue	See Section 6.1.2.4

Concept	Australian Additional Description Type Name	Reference
	UnitOfUseSizeValue	See Section 6.1.2.5
	PreferredComponentOrder	See Section 6.1.2.6
MPUU Specific Active Ingredient (MPUUSAI)	RelationshipId	See Section 6.2.2.3
	PreferredTermOrder	See Section 6.2.2.4
	BaseFormStrengthNumeratorValue	See Section 6.2.2.5
	BaseFormStrengthDenominatorValue	See Section 6.2.2.6
	SaltFormStrengthNumeratorValue	See Section 6.2.2.7
	SaltFormStrengthDenominatorValue	See Section 6.2.2.8
	BaseFormStrengthOtherRepresentation	See Section 6.2.2.9
	SaltFormStrengthOtherRepresentation	See Section 6.2.2.10
TPP has TPUU (THT)	RelationshipId	See Section 6.3.2.3
	UnitOfUseQuantityValue	See Section 6.3.2.4
	UnitOfUseSizeValue	See Section 6.3.2.5
TPUU Pharmaceutical Ingredient (TPUUPI)	BOSS OtherStrengthRepresentation	See Section 6.4.2.6
	RelationshipId	See Section 6.4.2.3
	IngredientStrengthNumeratorValue	See Section 6.4.2.4
	IngredientStrengthDenominatorValue	See Section 6.4.2.5

2.2.4.2 All 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 5: Description Constraints/Data definitions rules

Rule ID	Data Element	Constraints/Data definitions	Constraint Source
AU-DES-1	ComponentID	The ComponentID of each Description must have a partition-identifier of "1".	SNOMED CT

Rule ID	Data Element	Constraints/Data definitions	Constraint Source
AU-DES-2	ComponentStatus	The valid values for the ComponentStatus of a description are: • 0 (Current) • 1 (Retired) • 2 (Duplicate) • 3 (Outdated) • 5 (Erroneous) • 6 (Limited) • 7 (Inappropriate) • 8 (Concept Retired) • 10 (Moved Elsewhere) • 11 (Pending Move) Refer to data rule AU-COMP-7 (Section 2.2.1) for a more complete definition of these statuses.	SNOMED CT
AU-DES-3	ComponentStatus	The ComponentStatus of a Description can only be 0 (Current) if the associated Concept is also current (i.e. ComponentStatus = 0).	SNOMED CT
AU-DES-4	ComponentStatus	When the concept associated with a current Description (ComponentStatus = 0) is made "inactive" (i.e. ComponentStatus = 1, 2, 3, 4, 5, or 10), the Description's ComponentStatus is changed to 8 (Concept retired).	SNOMED CT
AU-DES-5	ComponentStatus	When the concept associated with a current Description (ComponentStatus = 0) is made "limited" (ConceptStatus 6), the Description's ComponentStatus must be changed to 6 (Limited).	SNOMED CT
AU-DES-6	ConceptUUID	All descriptions must have exactly one ConceptUUID.	SNOMED CT-AU
AU-DES-7	ConceptUUID	The ConceptUUID must equal the ComponentUUID for some Concept.	SNOMED CT-AU
AU-DES-8	ConceptID	All descriptions must have exactly one ConceptID.	SNOMED CT-AU
AU-DES-9	ConceptID	The ConceptID must equal the ComponentID for some Concept.	SNOMED CT
AU-DES-10	Term	All descriptions must have exactly one Term, which is valid in one or more languages or dialects.	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 Descriptions Table with the same text for each term but with different Description and Concept identifiers.	SNOMED CT

Rule ID	Data Element	Constraints/Data definitions	Constraint Source
AU-DES-12	Term	Each term is provided in XHTML fragment form (i.e. without an <html> header), encoded using UTF-8. The maximum length of a FSN is 32,000 characters.	SNOMED CT-AU
AU-DES-13	CaseSensitivity	All descriptions must have exactly one CaseSensitivity value (0=False, 1=True).	SNOMED CT-AU
AU-DES-14	InitialCapitalStatus	All descriptions must have exactly one InitialCapitalStatus value (0=False, 1=True).	SNOMED CT
AU-DES-15	DescriptionTypeID	All descriptions must have exactly one DescriptionTypeID in the hierarchy.	SNOMED CT-AU
AU-DES-16	DescriptionTypeID	Each DescriptionTypeID must equal the ComponentUUID of some concept in the "Australian concept ← Australian data representation concept ← Australian description type" hierarchy.	SNOMED CT-AU
AU-DES-17	DescriptionType	All descriptions must have exactly one DescriptionType.	SNOMED CT
AU-DES-18	DescriptionType	The valid values for DescriptionType are: 0 (Unspecified) 1 (Preferred) 2 (Synonym) 3 (Fully Specified Name)	SNOMED CT
AU-DES-19	LanguageId	Each LanguageId must equal the ComponentUUID of some concept in the "Australian concept ← Australian data representation concept ← Australian language" hierarchy.	SNOMED CT-AU
AU-DES-20	LanguageCode	Each LanguageCode consists of a two character ISO639-1 language code; and (optionally) a subcode – i.e. a string of uppercase letters that represents the dialect. The subcode is either an ISO3166 country code, or an IANA dialect representation. If the subcode is present, it is separated from the language code by a dash ("-").	SNOMED CT

2.2.4.3 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.

2.2.4.3.1 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. Disorder, Organism, Person, etc.). For example, amoxicillin (AU Product) is a FSN that describes a product that a clinician may choose to prescribe, whereas amoxicillin (AU Substance) is a FSN that describes an ingredient of a product. The table below summarises the specific Constraints/Data definitions for the FSN.

Table 6: Fully Specified Name rules

Rule ID	Constraints/Data definitions	Constraint Source
AMT-FSN-1	There must be exactly one FSN for each concept in SNOMED CT-AU.	SNOMED CT-AU
AMT-FSN-2	No two concepts in SNOMED CT-AU 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

2.2.4.3.2 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. If for example, the concept amoxicillin (AU 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.

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 an Ingredient. The table below summarises the specific Constraints/Data definitions for the term.

Table 7: Preferred Term rules

Rule ID	Constraints/Data definitions	Constraint Source
AMT-PT-1	There must be exactly one Australian PT for each SNOMED CT-AU concept.	SNOMED CT
AMT-PT-2	The PT of a concept can not be the same as the FSN.	SNOMED CT

2.3 Reference set

The SNOMED CT subset mechanism was provisionally adopted by the SNOMED International Editorial Board in late 2001. As originally planned, a revision of the mechanism has been undertaken based on comments and implementation experience. The original requirements were refined to address the increasing usage of SNOMED CT in a range of diverse applications and the need to advance the internationalisation of the core SNOMED CT design.

The current Reference Set specification (as defined by the IHTSDO in July 2007) is an evolution of the original subset mechanism, which enhances the ability to localise SNOMED CT to accommodate diverse user preferences and use cases. The Reference Set proposal also includes recommendations for the evolution of other SNOMED CT elements (including the Descriptions table and the history mechanism) that are either necessary for the Reference Set proposal or provide improvements to SNOMED CT that would be made possible by its adoption.

The AMT now includes seven reference sets:

1. Medicinal Product Reference Set
2. Medicinal Product Unit of Use Reference Set
3. Medicinal Product Pack Reference Set
4. Trade Product Reference Set
5. Trade Product Unit of Use Reference Set
6. Trade Product Pack Reference Set
7. Containered Trade Product Pack Reference Set.

Reference set content and constraints applied to data hierarchies may change due to the iterative process involving stakeholder and user feedback. For information on the scope, purpose and approach taken to develop the AMT reference sets refer to the *Development Approach to Reference Sets* document which is available to SNOMED licence holders as part of the release package.

2.4 History

A history mechanism has been developed and incorporated into the AMT to maintain a record of changes introduced by each release.

2.4.1 Introduction

The content of SNOMED CT evolves with each release. The types of changes made include the addition, update and retirement of components, such as concepts, descriptions and relationships. Drivers of these changes include changes in the understanding of health and disease processes; introduction of new drugs, investigations, therapies and procedures; and new threats to health, as well as proposals and work provided by SNOMED CT users.

It is important that the history of the SNOMED CT components is maintained, as any of these components may have been used directly in healthcare applications, patient records, data entry templates, decision support protocols, or reusable queries. A change in a terminology component may alter the interpretation of these records and tools. The proposed AMT history mechanisms allow legacy data to be mapped to current, equivalent concepts, and enable queries or protocols to include information represented using inactive concepts. The history mechanism is also used to track when the maintenance responsibility for one or more concepts is transferred between organisations (e.g. from an extension to the international release).

2.4.2 Principles

The evolution of SNOMED CT is based upon the following principles:

- Graceful evolution, rather than radical change.
- The meaning of a concept does not change.
- Concepts may become inactive, but are never deleted.
- Concept identifiers are persistent over time and are never reused.
- The link between a description and a concept is persistent.
- Redundancy is recognised by allowing information to be stated in two or more different ways, and by allowing duplicates to be inactivated.

2.4.3 Mechanisms

In order to support the evolution of the terminology, future releases of the AMT in Australia will include four major history management mechanisms:

- Component versioning;
- History reference set;
- Historical relationships; and
- ID mappings.

2.4.3.1 Component versioning

In keeping with the process for international release, all AMT components will continue to be distributed, even when they are no longer recommended for active use. This allows the current release to be used to interpret legacy data entered using an earlier release. In order to support this practical functionality, every component is versioned, using a Status and an EffectiveTime.

Significant changes to an SNOMED CT-AU component will require the component to have its status changed, and a replacement component to be added. Minor changes will only require the addition of a new version of the same component (with a new EffectiveTime).

The Status indicates whether or not the component is active or inactive, together with certain additional information about its usage or reason for being made inactive – for example, "current", "retired", "duplicate", "outdated", "ambiguous", "erroneous", "limited" etc.

The EffectiveTime is a time stamp, which serves as both a version number and a record of the date and time at which the given version of the component comes into effect – that is, the given component version can start to be used as a valid part of the terminology from the time specified in EffectiveTime. It is a text string in the format YYYYMMDD HH:MM:SS. For example, the EffectiveTime of a component may be set to "20070928 00:00:00".

Note: To support component-level versioning, these enhancements are aligned with the recommended enhancements to the overall SNOMED CT history mechanism, as referred to in the 2007 IHTSDO reference sets proposal.

2.4.3.2 History reference set

The AMT releases a History reference Set with each AMT release. This provides users with the ability to download a "History Reference Set" separately to the core data. The reference set contains the retired concepts together with their replacement concepts to provide history tracking.

2.4.3.3 Historical relationships

When a component is no longer in active use, or is replaced by or duplicates another component, this is indicated by an appropriate historical relationship. Historical relationships link inactive concepts into the current subtype hierarchy of SNOMED CT. There are a number of types of historical relationships, used for different purposes:

- An "erroneous" concept is related to the corrected concept that replaces it by a "REPLACED BY" relationship.
- A "duplicate" concept is related to the concept that it was found to duplicate by a "SAME AS" relationship.
- An "ambiguous" concept is related to the concept(s) that represent its possible disambiguated meanings by one or more "MAY BE A" relationships.
- Any inactive concept may be related to another concept that was previously considered to be its supertype, by a "WAS A" relationship. Note, "WAS A" relationships are only included where they add value.

For example, where a concept and its previously released subtypes are inactivated due to a similar ambiguity:

- A concept that has the status "Moved Elsewhere" or "Pending Move" is related to a Namespace Concept by a "MOVED TO" relationship. This identifies the namespace to which the concept has been moved or will be moved.
- A concept that replaces a concept moved from another namespace has a "MOVED FROM" relationship referring to the original concept in its original namespace.
- If the concept has been moved to the SNOMED CT international release namespace the "MOVED FROM" relationship should be maintained in the originating extension.

Refer to the *SNOMED CT Technical Reference Guide* for further information on historical relationships.

2.4.3.4 ID mappings

Once released, the unique identifiers of SNOMED CT components are persistent and their identifiers are not reused. However, there are a number of situations in which different identifiers actually refer to the same component. For example:

- Identifiers that have been created externally to SNOMED CT (e.g. organisational-specific identifiers, such as PBS codes), may require a mapping to be defined to a SNOMED CT concept.
- Components that are created in a local extension, and moved into the international release, may retain their UUID when moved, but require the allocation of a different SCTID, which more appropriately reflects the namespace to which it has been moved.

In these situations, an "ID Mapping" will be created that indicates the required mapping, along with the type and reason for the mapping. ID Mappings will be defined in more detail in future versions of this document.

2.5 Extensions

2.5.1 Overview

SNOMED CT is a deep and detailed clinical terminology with a broad scope. However, some groups of users will need additional components to support national, local or organisational needs.

The extension mechanism is a structure that enables authorised organisations (such as NEHTA) to add concepts, descriptions, relationships and other components to complement the content of the SNOMED CT International Release.

Goals of extensions are:

- To provide a structure where these extensions maintain unique identification across organisations for data transmission and information sharing, but share a common structure to simplify application development, so that reference sets can be constructed from a combination of International Release and extension content.
- To define a structure so that it is easy to submit, include, use, and migrate terminology developed as part of an extension into the International Release content.

An extension may contain components of various types (e.g. concepts, descriptions, relationships, reference sets etc.). The components of an extension have SNOMED CT identifiers which follow the same form used within the International release. However, these identifiers also include a partition-identifier indicating that the component is part of an extension, and a namespace-identifier specific to the responsible organisation.

3 Product concepts

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

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

These concepts are diagrammatically represented below.

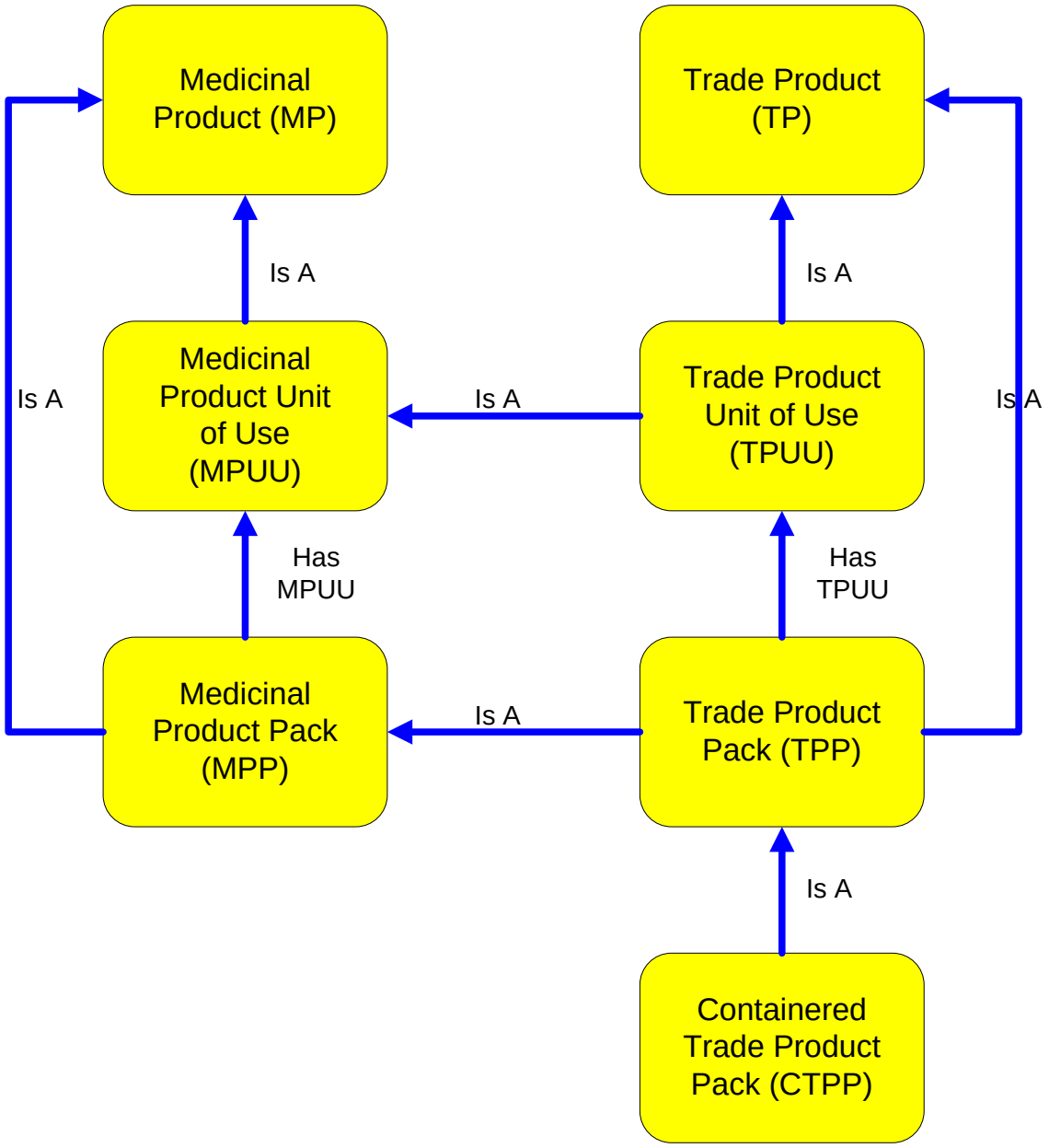

Figure 1: The AMT UML Model (Product Concepts)

3.1 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), strength, form, pack size and container type. This corresponds to the product concept of CTPP, which represents the product concept with the greatest level of granularity in the AMT model.

The model handles the following types of products:

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

Note that:

- MPs may be single ingredient, multi-ingredient and/or multi-component.
- MPUUs and TPUUs may be single ingredient or multi-ingredient, but may only be single-component.
- MPPs and TPPs may be single ingredient or multi-ingredient, multi-component and/or have subpacks.
- CTPPs may be single ingredient, multi-ingredient and/or multi-component.

The differences between multi-ingredient products, multi-component products and products with subpacks are explained in the following sub-sections.

3.1.1 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).

3.1.2 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 (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).

3.1.3 Multi-component

A multi-component product is one where two or more components are included in the same pack.

This includes both:

- Combination packs – where the one pack has different unit dose forms that are intended to be taken sequentially (e.g. Triphasil); and
- 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 Hp 7).

A multi-component product is one which contains multiple types of units of use (MPUUs or TPUUs).

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

- MP: esomeprazole (medicinal product).

  clarithromycin (medicinal product).

  amoxycillin (medicinal product).

  amoxycillin (&) clarithromycin (&) esomeprazole (medicinal product).

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

- TPP: Nexium Hp 7 (amoxycillin (as trihydrate) 500mg) capsule [28 capsules] (&) (clarithromycin 500 mg) tablet: film-coated [14 tablets] (&) (esomeprazole (as magnesium trihydrate)20 mg) tablet: enteric-coated [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, MPs, MPPs and TPs, TPPs and CTPPs may be multi-component.

If a multi-component product meets the following criteria, it will not be treated as a multi-component product, but will be treated as a multi-ingredient product. This allows the product to be represented by a single MPUU and TPUU instead of multiple MPUUs and TPUUs.

- Each of the components consists of at least one active ingredient.
- 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.
- The components are administered concurrently in a final combined form.

Examples of such products include: Vivaxim; Infanrix hexa.

3.1.4 Subpacks

When a product pack is composed of the same product packaged in smaller sized packs (e.g. multiple blister packs), then it is said to contain subpacks.

For example, for oral contraceptives, the top level pack may be a box, which contains four blister subpacks, each of which contains 21 (or 28) tablets.

Many oral contraceptives are multi-ingredient (because each tablet contains more than one active ingredient), multi-component (because a box contains tablets with different strength hormone combinations) and also multi-subpacks (because each box contains multiple blister packs).

Subpacks will be added when they are represented as subpacks in the Pharmaceutical Benefits Scheme (PBS) or are deemed to be required for consistency or for clinical reasons.

Table 8: Subpack examples

Pack Type	Fully Specified Name	Preferred Term
TPP (Superpack)	Triphasil (ethinyloestradiol 30 micrograms + levonorgestrel 125 microgram) tablet: sugar-coated [40 tablets] (&) (ethinyloestradiol 30 micrograms + levonorgestrel 50 micrograms) tablet: sugar-coated [24 tablets] (&) (ethinyloestradiol 40 micrograms + 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]
TPP (Subpack)	Triphasil (ethinyloestradiol 30 micrograms + levonorgestrel 125 microgram) tablet: sugar-coated [10 tablets] (&) (ethinyloestradiol 30 micrograms + levonorgestrel 50 micrograms) tablet: sugar-coated [6 tablets] (&) (ethinyloestradiol 40 micrograms + levonorgestrel 75 microgram) tablet: sugar-coated [5 tablets] (&) (inert substance) tablet: sugar-coated [7 tablets], 28 tablets (trade product pack)	Triphasil, 28 tablets

3.2 Medicinal Product (MP)

3.2.1 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.

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

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

All medicines with the same base active ingredient will be considered to be equivalent within the terminology (but they may not necessarily be physiologically equivalent) 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.

Note: All Medicinal Product concepts will have a relationship to each of their active ingredients, using one or more "has ingredient" relationships.

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

Table 9: 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
Combination product intended to be taken sequentially	ethinyloestradiol + levonorgestrel (medicinal product) inert substance (medicinal product)	levonorgestrel + ethinyloestradiol inert substance
Multi-component kit	esomeprazole (medicinal product) clarithromycin (medicinal product) amoxycillin (medicinal product) amoxycillin (&) clarithromycin (&) esomeprazole (medicinal product)	esomeprazole clarithromycin amoxycillin esomeprazole (&) clarithromycin (&) amoxycillin

3.2.2 Medicinal Product descriptions

3.2.2.1 Medicinal Product "Fully Specified Name" Brief Definition

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

```
MP FSN := ("inert substance" | Ingredient_Details)
          " (medicinal product)"
```

where the component parts are described as follows.

Table 10: Medicinal Product "Fully Specified Name" description

Description Component	Description
inert substance	Used to indicate an MP in which no active ingredients are recorded. This applies to those products in which inactive (inert) ingredients are part of sequential multi-component products or diluents provided for the preparation of the actual administrable form of a product.
Ingredient_Details	An alphabetical list of the PTs of each of the MP's ingredients, with: • ingredients of the same MP component separated by a " + " and grouped together; • ingredients from different MP components separated by a " (&) "; and • MP components, which contain exactly the same ingredients, shown only once.
(medicinal product)	The semantic tag used in the FSN of all Medicinal Product concepts.

3.2.2.2 Medicinal Product "Fully Specified Name" full definition

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

Table 11: Medicinal Product "Fully Specified Name" full definition

Description Component	Definition
Medicinal Product FSN	("inert substance"[1] | MP_Ingredient_Details[2]) " (medicinal product)" 1: "inert substance" is used to represent the Medicinal Product in which no active ingredients are recorded. 2: MP_Ingredient_Details is used for Medicinal Products which contain one or more active ingredients.
MP_Ingredient_Details	MP_Component { " (&) " MP_Component } [1 2] 1: An MP_Component is included for each distinct component of the MP. 2: MP_Components are ordered alphabetically.
MP_Component	Ingredient_Name { " + " Ingredient_Name } [1 2] 1: An Ingredient_Name is included for each ingredient in the given MP_Component. 2: Ingredient_Names are ordered alphabetically within each MP_Component.
Ingredient_Name	MP.has ingredient.PT where MP has Ingredient, and the Ingredient is in the given component.
(medicinal product)	The semantic tag used in the FSN of all Medicinal Product concepts.

3.2.2.3 Medicinal Product "Fully Specified Name" rules

Table 12: Medicinal Product "Fully Specified Name" rules

Rule ID	Description
AMT–MP-FSN-1	All rules in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply.
AMT–MP–FSN-2	The Medicinal Product FSN will be derived from the Australian Approved Name (AAN)[3], followed by other approved or clinically intuitive names as specified in the Australian Register of Therapeutic Goods.
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: • Clinically significant physiological salts; • Clinically distinct complexes; • Discernible therapeutic differences to the base; • Enantiomers; or • Micronised and macrocrystal formulations. • See Appendix B: for further information.
AMT–MP-FSN-4	The MP FSN will include all active ingredients for each multi-ingredient preparation or component of a multi-component product. The MP FSN will also include the description "inert substance" 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.

3.2.2.4 Medicinal Product "Preferred Term" brief definition

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

```
MP PT := "inert substance" | Ingredient_Details
```

where the component parts are described as follows.

[3] Note: NEHTA is currently investigating the use of an international terminology standard for ingredient names.

Table 13: Medicinal Product "Preferred Term" description

Description Component	Description
inert substance	Used to indicate an MP in which no active ingredients are recorded. This applies to those products in which inactive (inert) ingredients are part of sequential multi-component products or diluents provided for the preparation of the actual administrable form of a product.
Ingredient_Details	A list (alphabetical by default) of the PTs of each of the MP's ingredients, with: • ingredients of th7.3e same MP component separated by a " + " and grouped together; • ingredients from different MP components separated by a " (&) "; and • MP components, which contain exactly the same ingredients, only shown once. Note that by default, the order of this list is alphabetical. However, if every MPUU associated with one of the components of the MP (either through the "MPUU Is A MP" relationship, or through the two relationships "MPP Is A MP" and "MPP has MPUU") has the same "PreferredTermOrder" for the corresponding ingredients, then this order is used instead.

Note that variation to this syntax may occur to meet the requirements of clinical practice. In particular, the PT of MPs with more than three active ingredients per component will in most cases be manually created (refer to rule AMT-MP-PT-4 in Section 3.2.2.6 for more details).

3.2.2.5 Medicinal Product "Preferred Term" full definition

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

Table 14: Medicinal Product "Preferred Term" full definition

Description Component	Definition
Medicinal Product PT	("inert substance" [1] | MP_Ingredient_Details [2]) 1: "inert substance" is used to represent the Medicinal Product in which no active ingredients are recorded. 2: MP_Ingredient_Details is used for Medicinal Products which contain one or more active ingredients.
MP_Ingredient_Details	MP_Component { " (&) " MP_Component } [1 2] 1: An MP_Component is included for each distinct component of the MP. 2: MP_Components are ordered by their preferred component order.
MP_Component	Ingredient_Name { " + " Ingredient_Name } [1 2] 1: An Ingredient_Name is included for each ingredient in the given MP_Component. 2: Ingredient_Names are ordered by their preferred term order within the given component.
Ingredient_Name	MP.has ingredient.PT Where MP has Ingredient, and the Ingredient is in the given component.

3.2.2.6 Medicinal Product "Preferred Term" rules

Table 15: Medicinal Product "Preferred Term" rules

Rule ID	Description
AMT-MP-PT-1	All rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply. EXCEPTION Where Tall Man Letters are required to improve safety as defined in Appendix A:.
AMT-MP-PT-2	The Medicinal Product Preferred Term will be derived from the TGA active ingredient name (as defined in the TGA Approved Terminology for Medicines). EXCEPTION This may, however, differ to meet requirements of clinical practice. Current exceptions are listed in Appendix C: and will be added to on a case-by-case basis.
AMT-MP-PT-3	The Medicinal Product Preferred Term 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: • Clinically significant physiological salts; • Clinically distinct complexes; • Discernible therapeutic differences to the base; • Enantiomers; or • Micronised and macrocrystal formulations. See Appendix B: for further information.
AMT-MP-PT-4	The Medicinal Product Preferred Term will include up to three active ingredients per product or component of a multi-component product. For Medicinal Products with greater than three active ingredients, the AMT editors will create a clinically intuitive name based on the review of each individual product. EXCEPTION Items that may use 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 (not only those included in the FSN) is available from the Medicinal Product (MP) "has ingredient" relationship with Ingredient (ING). The current exception list is attached as Appendix D:. The Medicinal Product will also include the description "inert substance" 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.

Rule ID	Description
AMT-MP-PT-5	The sequence of ingredients in the Medicinal Product Preferred Term will, by default, be based on the alphabetic order of the ingredient names. However, if every MPUU associated with one of the components of the MP (either through the "MPUU is a MP" relationship, or through the two relationships "MPP is a MP" and "MPP has MPUU") has the same "PreferredTermOrder" 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 C:. This will be developed on a case-by-case basis. The complete list of exceptions may be found in Appendix C:, Section C.6. Example: MP FSN is codeine + paracetamol — MP PT is paracetamol + codeine MP FSN is clavulanic acid + ticarcillin — MP PT is ticarcillin + clavulanic acid

3.3 Medicinal Product Unit of Use (MPUU)

3.3.1 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. Equivalent TPUUs are those that have the same base active ingredient (or the same precise active ingredients, where the salt is therapeutically necessary), as well as the same strength, dose form, and administrable unit type, and where the TPUUs are considered as quantitatively equivalent. The MPUU will be represented by the associated MP's ingredient name(s), strength(s), form(s) and unit dose(s) (where appropriate). An MPUU will include single dose units of inactive (inert) ingredients (where these are part of sequential multi-component products) or diluents (provided for the preparation of the actual administrable form of a product).

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

The MPUU may represent the name of a salt or modified form for safety reasons or where this is the clinically relevant representation of the active ingredient. For example:

- Where the salt or modified salt is not clinically significant but is clinically relevant (i.e. the Basis of Strength Substance is the salt). 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 clinically relevant to decisions concerning dose.

  Example: perindopril arginine 5 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: All MPUU concepts will also have relationships to all of their active ingredients, as identified by the "has specific active ingredient" relationship.

Table 16: Examples of Medicinal Product Unit of Use 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 (see Appendix B:)	• diclofenac 46.54 mg tablet (medicinal product unit of use) • diclofenac 46.54 mg | diclofenac sodium 50 mg tablet (medicinal product unit of use)	• diclofenac 46.54 mg tablet • diclofenac sodium 50 mg tablet
Single ingredient – clinically significant salt (see Appendix B:)	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
Multi-ingredient	• codeine 23.43 mg + paracetamol 500 mg tablet (medicinal product unit of use) • codeine 23.43 mg | codeine phosphate 30 mg + paracetamol 500 mg tablet (medicinal product unit of use)	• paracetamol 500 mg + codeine 23.43 mg tablet • paracetamol 500 mg + codeine phosphate 30 mg tablet

Type of Product	Fully Specified Name	Preferred Term
• 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	• etidronic acid 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 powder – dual chamber	• hydrocortisone 100 mg | hydrocortisone sodium succinate 134 mg injection, vial (medicinal product unit of use) • inert substance diluent, vial (medicinal product unit of use	• hydrocortisone (as sodium succinate) 100 mg injection, vial • inert substance diluent, vial
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

Type of Product	Fully Specified Name	Preferred Term
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

3.3.1.1 Examples of Medicinal Product Unit of Use FSNs and PTs that include Unit Dose Form Indicators

Table 17: Examples of Medicinal Product Unit of Use FSNs and PTs that include Unit Dose Form Indicators

Type of Product	Fully Specified Name	Preferred Term
granules in single use sachet	mesalazine 500 mg granules: modified release, 500 mg sachet (medicinal product unit of use)	mesalazine 500 mg granules: modified release, sachet
injection solution vial	carboplatin 150 mg/15 mL injection, 15 mL vial (medicinal product unit of use)	carboplatin 150 mg/15 mL injection, vial
powder for injection vial	ampicillin 500 mg injection, 500 mg vial (medicinal product unit of use)	ampicillin 500 mg injection, vial

3.3.1.2 Examples of Medicinal Product Unit of Use FSNs and PTs for all different strength representation rules

Table 18: 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 tablet (medicinal product unit of use) diclofenac 46.54 mg | diclofenac sodium 50 mg tablet (medicinal product unit of use)	diclofenac 46.54 mg tablet diclofenac sodium 50 mg 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

Type of product	Fully Specified Name	Preferred Term
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

3.3.2 Medicinal Product Unit of Use descriptions

3.3.2.1 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 := ("inert substance" | Ingredients_With_Strength) " "
            Form [", " Unit_Dose_Form_Details]
            " (medicinal product unit of use)"
```

where the component parts are described as follows.

Table 19: Medicinal Product Unit of Use "Fully Specified Name" description

Description Component	Description
inert substance	Used to indicate an MPUU in which no active ingredients are recorded. This applies to those products in which inactive (inert) ingredients are part of sequential multi-component products or diluents provided for the preparation of the actual administrable form of a product.
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. • The name and strength pairs for different ingredients are separated by a "+". • If the ingredient is a base, then the ingredient name used is the FSN (without the semantic tag) of the ingredient and the strength is a valid representation of the base strength of that ingredient in the MPUU. • If the ingredient is a salt, then the name used includes the FSN (without the semantic tag) and strength of the base of the ingredient in the MPUU, followed by a "|" (vertical bar), and then the FSN (without the semantic tag) and strength of the salt ingredient.
Form	The dose formulation of the MPUU for prescribing, dispensing or administration, defined in a non-proprietary way. This is the PT of the Form (F) from the relationship "MPUU has manufactured dose form F".

Description Component	Description
Unit_Dose_Form_Details	A list of the unit dose form details (UDFS) (if populated), which may include: • Unit Dose Form Size: The size of the unit dose form. This includes the value of the "UnitDoseFormSizeValue" description and the units (UOM) from the relationship "MPUU has unit dose form size units UOM". • Unit Dose Type: The unit dose item that can be physically handled. This is the UOM from the relationship "MPUU has unit dose type UOM". When these values are shown, the first of these is preceded by a comma followed by a space. Note that the unit dose form 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). Also note that the unit dose type is not shown when it matches the UDFS units, or 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: The FSN of MPUUs with more than three active ingredients will be manually created in most cases (refer to rule AMT-MP-FSN-4 in Section 3.2.2.3 and Appendix D: for more details).

3.3.2.2 Medicinal Product Unit of Use "Fully Specified Name" full definition

The Fully Specified Name of a Medicinal Product Unit of Use can be more fully defined as follows.

Table 20: Medicinal Product Unit of Use "Fully Specified Name" description

Description Component	Definition
Medicinal Product Unit of Use FSN	("inert substance" | Ingredients_With_Strength) [1] " " Form ["," Unit_Dose_Form_Details] [2] " (medicinal product unit of use)" 1: "inert substance" is used when no active ingredients exist. Otherwise, "Ingredients_With_Strength" is used. 2: Unit_Dose_Form_Details are included if they exist, based on the definition below
Ingredients_With_Strength	Ingredient_Strength {" + " Ingredient_Strength} [1 2] 1: One Ingredient_Strength is included for each "MPUU has specific active Ingredient" relationship that exists for the given MPUU. 2: The Ingredient_Strengths are ordered alphabetically based on the Preferred Term of the MPUU's specific active Ingredient.

Description Component	Definition
Ingredient_Strength	Base_Ingredient " " Base_Strength [" | " Salt_Ingredient " " Salt_Strength] [1] 1: Include Salt_Ingredient and Salt_Strength when the specific active ingredient is a modification of some other ingredient.
Base_Ingredient	MPUU.has specific active ingredient.is a modification of.PT (i.e. the Preferred Term of the ingredient of which the MPUU's specific active ingredient is a modification)
Base_Strength	MPUUSAI.base strength numerator value " " MPUUSAI.has base strength numerator units.PT [1] [" / " MPUUSAI.base strength denominator value " " MPUUSAI.has base strength denominator units.PT] [1 2] where MPUUSAI has MPUU for the given MPUU. 1: If strength value > 1 then use plural units if the units are expressed in full and not as an abbreviation (To be implemented in future releases.) 2: Include denominator details if values are not null
Salt_Ingredient	MPUU.has specific active ingredient.PT
Salt_Strength	MPUUSAI.salt strength numerator value " " MPUUSAI.has salt strength numerator units.PT [1] [" / " MPUUSAI.salt strength denominator value " " MPUUSAI.has salt strength denominator units.PT] [1 2] where MPUUSAI has MPUU for the given MPUU. 1: If strength value > 1 then use plural units if the units are expressed in full and not as an abbreviation (To be implemented in future releases.) 2: Include denominator details if values are not null
Form	MPUU.has manufactured dose form.PT
Unit_Dose_Form_Details	[" " Unit_Dose_Form_Size] [1] " " Unit_Dose_Type] [2] 1: Do not include Unit_Dose_Form_Size if either: • MPUU.unit_dose_form_size is null or • MPUU.unit_dose_form_size_value = 1 and MPUU.has unit dose form size units equals MPUU.has manufactured dose form (or one of its parents in the Form hierarchy). 2: Include Unit_Dose_Type if: • MPUU.has unit dose type exists and • MPUU.has unit dose type does not equal MPUU.has manufactured dose form (or one of its parents in the Form hierarchy) and • MPUU.has unit dose type does not equal MPUU.has unit dose form size units.
Unit_Dose_Form_Size	MPUU.unit_dose_form_size_value " " MPUU.has unit dose form size units.PT
Unit_Dose_Form_Type	MPUU.has unit dose type units.PT
(medicinal product unit of use)	The semantic tag used in the FSN of all Medicinal Product Unit of Use concepts.

3.3.2.3 Medicinal Product Unit of Use "Fully Specified Name" rules

Table 21: Medicinal Product Unit of Use "Fully Specified Name" rules

Rule ID	Description
AMT-MPUU-FSN-1	All rules in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply.
AMT-MPUU-FSN-2	The Medicinal Product Unit of Use will be derived from the base or salt of the active ingredients, as defined for MP FSN. 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). The MPUU will also include the description "inert substance" 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-MPUU-FSN-3	Strength expression. The MPUU FSN will include strength expression (if available). The strength expression general rules and application to specific medication forms is outlined in Appendix E:. EXCEPTIONS See AMT-APP-STR-9 in Appendix E.1.
AMT-MPUU-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 (e.g. injection: intrathecal, tablet: modified release).

3.3.2.4 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 := ("inert substance" | Ingredients_With_Strength) " "
           Form [", " Unit_Dose_Form_Details]
```

where the component parts are described as follows.

Table 22: Medicinal Product Unit of Use "Preferred Term" description

Description Component	Description
inert substance	Used to indicate an MPUU in which no active ingredients are recorded. This applies to those products in which inactive (inert) ingredients are part of sequential multi-component products or diluents provided for the preparation of the actual administrable form of a product.
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. • The name and strength pairs for different ingredients are separated by a "+". • The list, by default, is in alphabetical order of the ingredient names. However, when the "PreferredTermOrder" description of the associated MPUUSAI 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): – If the ingredient is a base, then the ingredient name used is the PT of the ingredient and the strength is a valid representation of the base form strength of that ingredient in the MPUU. – If the ingredient is a salt, and the Australian BOSS for that ingredient in the MPUU is the base of the ingredient, then the ingredient name used is the PT of the base form of the ingredient, and the strength is a valid representation of the base form strength of that ingredient in the MPUU. – If the ingredient is a clinically significant salt or a clinically relevant salt (refer Section B.1) and the Australian BOSS for that ingredient in the MPUU is a salt, then the ingredient name used is the PT of the ingredient, and the strength is a valid representation of the salt form strength of that ingredient in the MPUU. – If the ingredient is a clinically significant salt (refer Section B.1 and the Australian BOSS for that ingredient in the MPUU is the base of the ingredient, then the ingredient name used is the PT of the base form of the ingredient, followed by the text "(as SaltMinusBase)" in brackets – where SaltMinusBase is the PT of the ingredient, with the name of the base removed, and the strength is a valid representation of the base form strength of that ingredient in the MPUU. Note that SaltMinusBase name may not always be the salt name minus the base portion of the name – see Appendix C.3).
Form	The dose formulation of the MPUU for prescribing, dispensing or administration, defined in a non-proprietary way. This is the PT of the Form (F) from the relationship "MPUU has manufactured dose form F".

Description Component	Description
Unit_Dose_Form_Details	A list of the unit dose form details (when populated), which may include: • Unit Dose Form Size: The size of the unit dose form. This includes the value of the "UnitDoseFormSizeValue" description and the units (UOM) from the relationship "MPUU has unit dose form size units UOM". • Unit Dose Type: The unit dose item that can be physically handled. This is the UOM from the relationship "MPUU has unit dose type UOM". When these values are shown, the first of these is preceded by a comma and space. Note that the unit dose form size (value and units) is not shown when it is the same as the strength denominator (value and units) for all of its ingredients. The unit dose form size is also 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). Also note that the unit dose type is not shown when it matches the UDFS units, or the PT of the MPUU's Form (or one of this Form's parents in the "Form is a Form" hierarchy).

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

Table 23: Examples of different ingredient types and their associated MPUU representations

Ingredient type	Boss	MP	MPUU
base • abciximab	base • abciximab	base • abciximab	base • abciximab
salt (non-relevant) • ranitidine hydrochloride	base • ranitidine	base • ranitidine	base • ranitidine
clinically significant salt • flupenthixol decanoate	salt • flupenthixol decanoate	salt • flupenthixol decanoate	salt • flupenthixol decanoate
clinically relevant salt • rabeprazole sodium	salt • rabeprazole sodium	base • rabeprazole	salt • rabeprazole sodium
clinically significant salt • erythromycin ethylsuccinate	base • erythromycin	salt • erythromycin ethylsuccinate	base • erythromycin (as ethylsuccinate)

Note: Variation to this syntax may occur to meet the requirements of clinical practice. In particular, the PT of MPUUs with more than three active ingredients will be manually created in most cases (refer to rule AMT-MP-PT-4 in Section 3.2.2.6 for more details).

3.3.2.5 Medicinal Product Unit of Use "Preferred Term" full definition

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

Table 24: Medicinal Product Unit of Use "Preferred Term" description

Description Component	Definition
Medicinal Product Unit of Use PT	("inert substance" | Ingredients_With_Strength) [1] " " Form [", " Unit_Dose_Form_Details] [2] 1: "inert substance" is used when no active ingredients exist. Otherwise, "Ingredients_With_Strength" is used. 2: Unit_Dose_Form_Details are included if they exist, based on the definition below.
Ingredients_With_Strength	Ingredient_Strength {" + " Ingredient_Strength} [1 2] 1: One Ingredient_Strength is included for each "MPUU has specific active Ingredient" relationship (and MPUUSAI concept) that exists for the given MPUU. 2: The Ingredient_Strengths are ordered based on the MPUUSAI.preferred term order, of the associated MPUUSAI concept.

Ingredient_Strength	IF MPUUSAI.has Australian BOSS.is modification of EXISTS THEN
	Salt_Ingredient " " Salt_Strength
	ELSIF MPUUSAI.has Australian BOSS = MPUUSAI.has ingredient THEN
	Base_Ingredient " " Base_Strength
	ELSE
	Base_Ingredient " (as " Salt_Ingredient_Minus_Base ") " Base_Strength
	ENDIF

Salt_Ingredient	MPUUSAI.has ingredient.PT

Salt_Strength	IF MPUUSAI.has salt form strength preferred representation.PT = "N" or not exists THEN
	Salt_Strength_N
	ELSIF MPUUSAI.has salt form strength preferred representation.PT = "NA" THEN
	Salt_Strength_N " (" Salt_Strength_A ")"
	ELSIF MPUUSAI.has salt form strength preferred representation.PT = "A"
	Salt_Strength_A
	ELSIF MPUUSAI.has salt form strength preferred representation.PT = "AN"
	Salt_Strength_A " (" Salt_Strength_N ")"
	ENDIF

Description Component	Definition
Salt_Strength_N	MPUUSAI.salt form strength numerator value " " MPUUSAI.has salt form strength numerator units.PT ["/" [MPUUSAI.salt form strength denominator value " "] 1 MPUUSAI.has salt form strength denominator units.PT] 2 1: Include salt strength denominator value if not equal to 1. 2: Include salt strength denominator if denominator units exists.
Salt_Strength_A	MPUUSAI.salt form strength other representation

Base_Ingredient	IF MPUUSAI.has ingredient.is modification of EXISTS THEN
	MPUUSAI.has ingredient.is modification of.PT
	ELSIF
	MPUUSAI.has ingredient.PT
	ENDIF

Base_Strength	IF MPUUSAI.has base form strength preferred representation.PT = "N" or not exists THEN
	Base_Strength_N
	ELSIF MPUUSAI.has base form strength preferred representation.PT = "NA" THEN
	Base_Strength_N " (" Base_Strength_A ")"
	ELSIF MPUUSAI.has base form strength preferred representation.PT = "A"
	Base_Strength_A
	ELSIF MPUUSAI.has base form strength preferred representation.PT = "AN"
	Base_Strength_A " (" Base_Strength_N ")"
	ENDIF

Base_Strength_N	MPUUSAI.base form strength numerator value " " MPUUSAI.has base form strength numerator units.PT ["/" [MPUUSAI.base form strength denominator value " "] 1 MPUUSAI.has base form strength denominator units.PT] 2 1: Include base strength denominator value if not equal to 1. 2: Include base strength denominator if denominator units exists.
Base_Strength_A	MPUUSAI.base form strength other representation
Salt_Ingredient_Minus_Base	MPUUSAI.has ingredient.salt minus base name. (Note: "salt minus base name" is not a description of Substance in the terminology.)
Form	MPUU.has manufactured dose form.PT

Description Component	Definition
Unit_Dose_Form_Details	[" " Unit_Dose_Form_Size] [1] [" " Unit_Dose_Type] [2] 1: Do not include Unit_Dose_Form_Size if either: • MPUU.unit_dose_form_size is null; or • MPUU.unit_dose_form_size_value = 1 and MPUU.has unit dose form size units equals MPUU.has manufactured dose form (or one of its parents in the Form hierarchy). There exists a BV, such that BV = MPUUSAI.base ingredient strength denominator value (for all MPUUSAIs that "has a MPUU" to the given MPUU) and there exists a BU, such that BU = MPUUSAI.has base strength denominator units (for all MPUUSAIs that "has a MPUU" to the given MPUU) and BV = MPUU.unit dose form size value and BU = MPUU.has unit dose form size units (where BV = base value and BU = base units). MPUU has exactly one specific active ingredient, and for that MPUUSAI, MPUUSAI.base denominator strength value does not exist and MPUUSAI.base strength numerator value = MPUU.unit dose form size value and MPUUSAI.has base strength numerator units = MPUU.has unit dose form size units. 2: Include Unit_Dose_Type if: • MPUU.has unit dose type exists; and • MPUU.has unit dose type equals MPUU.has manufactured dose form (or one of its parents in the Form hierarchy); and • Unit_Dose_Type.PT ≠ "measure"
Unit_Dose_Form_Size	MPUU.unit_dose_form_size_value " "MPUU.has unit dose form size units.PT
Unit_Dose_Form_Type	MPUU.has unit dose type units.PT

3.3.2.6 Medicinal Product Unit of Use "Preferred Term" rules

Table 25: Medicinal Product Unit of Use "Preferred Term" rules

Rule ID	Description
AMT-MPUU-PT-1	All rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply. EXCEPTION Where Tall Man Letters are required to improve safety as defined in Appendix A:.
AMT-MPUU-PT-2	The MPUU will be derived from the base or salt of the active ingredient, as defined for MP PT. 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). The MPUU will also include the description "inert substance" 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-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 E:. EXCEPTIONS See AMT-APP-STR-9 in Appendix E.1.
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 (e.g. injection: intrathecal, tablet: modified release).

3.3.2.7 Medicinal Product Unit of Use "Unit Dose Form Size Value" definition and rules

Definition

The MPUU Unit Dose Form Size Value is the numerical value that represents the Unit Dose Form Size. This will be displayed as part of the MPUU where the dosage form is insufficient to fully describe the product.

Table 26: MPUU Unit Dose Form Size Value Rules

Rule ID	Description
AMT-MPUU-UDFSV-1	This term is only to be populated with decimal numbers (e.g. 0.25, 6.0).
AMT-MPUU-UDFSV-2	This value is optional.

3.4 Medicinal Product Pack (MPP)

3.4.1 Medicinal Product Pack definition

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

Note: For every TPP, a corresponding MPP will exist which will have one to many TPPs linked to it.

Table 27: Examples of Medicinal Product Pack 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 (see Appendix B:)	diclofenac 46.54 mg | diclofenac sodium 50 mg tablet, 50 tablets (medicinal product pack)	diclofenac sodium 50 mg tablet, 50
Single ingredient – clinically significant salt (see Appendix B:)	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
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)	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]
Multi-component Sequential	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)	etidronate disodium 200 mg tablet [28 tablets] (&) calcium (as carbonate) 500 mg tablet [76 tablets], 104

Type of Product	Fully Specified Name	Preferred Term
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)	esomeprazole 20 mg tablet [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxycillin 500 mg capsule [28 capsules], 1 pack
patch	oestradiol 100 microgram / 24 hours patch, 8 patches (medicinal product pack)	oestradiol 100 microgram/24 hours patch, 8
injection powder – dual chamber	hydrocortisone 100 mg | hydrocortisone sodium succinate 134 mg injection [1 x 100 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack (medicinal product pack)	hydrocortisone (as sodium succinate) 100 mg injection [1 x 100 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack
injection solution less than 1 mL	fluphenazine 9.24 mg / 0.5 mL | fluphenazine decanoate 12.5 mg / 0.5 mL injection, 5 x 0.5 mL 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)	lantreotide 30 mg injection; modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack

3.4.2 Medicinal Product Pack descriptions

3.4.2.1 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 28: Medicinal Product Pack "Fully Specified Name" description

Description Component	Description
MPUU_Details	The details about an individual MPUU that is contained within the MPP, including: • The list of ingredients and strengths (formatted as per MPUU 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. • The quantity of this MPUU in the given MPP, placed inside square brackets. This component is defined by the description "unit of use quantity value" in the associated MHM concept, and the "MHM has unit of use quantity units" relationship. • 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 FSNs (e.g. those containing more than three active ingredients), the MPUU's FSN (without the semantic tag) will be used here instead. Unit of use quantity is only shown for multi-component MPPs.
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 "MPP has total unit of use quantity units". (e.g. "25 tablets"). 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 has a number of subpacks (i.e. the description "total subpack quantity" is populated) then the string is followed by subpack quantity details in square brackets. The subpack quantity details includes the description "total subpack quantity", followed by the multiplication symbol (i.e. " x "), followed by the total number of units of uses in each subpack (i.e. "total unit of use quantity value" ÷ "total subpack quantity", together with the unit of measure from "MPP has total unit of use quantity units").
(medicinal product pack)	The semantic tag used in the FSN of all Medicinal Product Pack concepts.

3.4.2.2 Medicinal Product Pack "Fully Specified Name" full definition

The default Fully Specified Name of an MPP can be more fully defined as follows.

Table 29: Medicinal Product Pack "Fully Specified Name" 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 concept that exists, such that MPP has MPUU, for the given MPP. 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 such that MPP has MPUU M THEN
	MPUU_ISFO " [" MPUU_Qty_Size "]"
	ELSE
	MPUU_ISFO
	ENDIF

MPUU_ISFO	["inert substance" [1] | " " Ingredient_Strength {" + " Ingredient_Strength} [2] [3]] " " Form 1: "inert substance" is included when "MPUU has specific active ingredient" does not exist, for the given MPUU. 2: Ingredient_Strength is included for each "MPUU has specific active ingredient" relationship that exists, for the given MPUU. 3: Ingredient_Strengths are ordered alphabetically.
Ingredient_Strength	Ingredient_Strength, as defined for the given MPUU's FSN.
Form	Form, as defined for the given MPUU's FSN.
MPUU_Qty_Size	MHM.unit of use quantity value [" × " MHM.unit of use size value " " MHM.has unit of use size units.PT] [1] [" " MHM.has unit of use quantity units.PT] [2] Where MHM is the relationship details concept where MHM.has MPP is the given MPP, and MHM.has MPUU is the given MPUU. 1: Size value and size units are included when MHM.unit of use size value exists. 2: Unit of use quantity units is included when MHM.has unit of use quantity units.PT ≠ MPUU.has manufactured dose form.PT and MHM.has unit of use quantity units.PT ≠ MPUU.has proprietary dose form.PT (or one of the parents of these forms).
Total_Quantity_Size_Details	Total_Quantity_Size [" [" Subpack_Details "]"] [1] 1: Subpack_Details are included when MPP.total subpack quantity exists.
Total_Quantity_Size	MPP.total unit of use quantity value [" × " MPP.total unit of use size value " " MPP.has total unit of use size units.PT] [1] " " MPP.has total unit of use quantity units.PT 1: Size value and size units is included when MPP.total unit of use size value is not null.

Description Component	Definition
Subpack_Details	MPP.total subpack quantity " × " (MPP.total unit of use quantity value ÷ MPP.total subpack quantity) " " 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.

3.4.2.3 Medicinal Product Pack "Fully Specified Name" rules

Table 30: Medicinal Product Pack "Fully Specified Name" rules

Rule ID	Description
AMT-MPP-FSN-1	All rules in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply.
AMT-MPP-FSN-2	The MPP will be derived from the base or salt of the active ingredients, as defined for MP FSN. EXCEPTION Where a salt is not clinically significant but the representation of the salt is required for safety reasons then the MPUU will be represented as a salt. See Appendix B:. Example: • haloperidol decanoate Note the associated Medicinal Product will still retain the base representation for that ingredient. Example: • haloperidol The MPUU will also include the description "inert substance" 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-FSN-3	The MPP FSN naming convention for exceptions that require the representation of a salt will include both base and salt strength separated by " | ". Example: • calcium (as carbonate) 600 mg | calcium carbonate 1500 mg tablet
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 MPP level, the form is expressed as the specific form (e.g. injection: intrathecal, tablet: modified release).

Rule ID	Description
AMT-MPP-FSN-5	Pack_Units: If the Pack_Units is greater than one, then the Pack QTY units will be expressed as a plural form. See Appendix I: 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 Hp 7 contains 14 tablets + 28 capsules + 14 tablets Pack size = 1 pack If the pack consists of a discrete and continuous (or not applicable) unit dose forms, the pack size = x components. e.g. Canesoral Duo (1 x 150 mg capsule, 1 x 10 g cream) Pack size = 1 pack

3.4.2.4 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 31: Medicinal Product Pack "Preferred Term" 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 MHM.preferred component order (if this exists – otherwise alphabetically, as per the MPP.FSN). • The dose formulation of the MPUU, for prescribing, dispensing or administration, as defined for the corresponding MPUU. • The quantity of this MPUU in the given MPP, placed inside square brackets. This component is defined by the description "unit of use quantity value" in the associated MHM concept, and the "MHM has unit of use quantity units" relationship. • 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 FSNs (e.g. those containing more than three active ingredients), 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 usually includes the description "total unit of use quantity value" and the PT of the unit of measure from MPP "has total unit of use quantity units" UOM (e.g. "25 tablets"). 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 total quantity units may be omitted. 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 has a number of subpacks (i.e. the description "total subpack quantity" is populated), then the string is replaced by subpack quantity details. The subpack quantity details includes the description "total subpack quantity", followed by the multiplication symbol (i.e. " x "), followed by the total number of units of uses in each subpack (i.e. "total unit of use quantity value" ÷ "total subpack quantity", together with the unit of measure from MPP "has total unit of use quantity units").

Note: Variation to this syntax may occur to meet the requirements of clinical practice.

3.4.2.5 Medicinal Product Pack "Preferred Term" full definition

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

Table 32: Medicinal Product Pack "Preferred Term" full 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 concept U that exists, such that MPP has MPUU U. 2: The MPUU_Details are ordered, based on the associated MHM.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.
MPUU_ISFO	("inert substance" [1] | " " Ingredient_Strength { " + " Ingredient_Strength} [2 3]) " " Form 1: "inert substance" is included when no MPUU concept U exists such that MPP has MPUU U (i.e. it has no active ingredients). 2: Ingredient_Strength is included for each MPUUSAI that exists, such that MPUUSAI.has MPUU equals some MPP.has MPUU for the given MPP. 3: Ingredient_Strengths are ordered by MPUUSAI.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	MHM.unit of use quantity value [" × " MHM.unit of use size value " " MHM.has unit of use size units.PT] [1] [" " MHM.has unit of use quantity units.PT] [2] Where MHM is the relationship details concept where MHM.has MPP is the given MPP and MHM.has MPUU is the given MPUU. 1: Size value and size units are included when MHM.unit of use size value exists. 2: Unit of use quantity units is included when MHM.has unit of use quantity units.PT ≠ MPUU.has manufactured dose form.PT and MHM.has unit of use quantity units.PT ≠ MPUU.has proprietary dose form.PT (or one of the parents of these forms).
Total_Quantity_Size_Details	Total_Quantity_Size [" [" Subpack_Details "]"] [1] 1: Subpack_Details are included when MPP.total subpack quantity exists.

Description Component	Definition
Total_Quantity_Size	MPP.total unit of use quantity value [" × " MPP.total unit of use size value " " MPP.has total unit of use size units .PT] [1] [" " MPP.has total unit of use quantity units.PT] [2] 1: Size value and size units are included when MPP.total unit of use size value is not null. 2: Total unit of use quantity units is included when MPP.has total unit of use quantity units.PT ≠ U.has manufactured dose form.PT (or one of its parents in the form hierarchy) for all Us, such that MPP has MPUU U.
Subpack_Details	MPP.total subpack quantity " × " (MPP.total unit of use quantity value ÷ MPP.total subpack quantity) " " MPP.has total unit of use quantity units.PT

3.4.2.6 Medicinal Product Pack "Preferred Term" rules

Table 33: Medicinal Product Pack "Preferred Term" rules

Rule ID	Description
AMT-MPP-PT-1	All rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply. EXCEPTION Where Tall Man Letters are required to improve safety as defined in Appendix A:.
AMT-MPP-PT-2	The MPP will be derived from the base of the active ingredient, as defined for MP PT. EXCEPTION Where a salt is not clinically significant but the representation of the salt is required for safety reasons, then the MPP will be represented as a salt. See Appendix B:. Example: • haloperidol decanoate Note the associated Medicinal Product will still retain the base representation. Example: • haloperidol The MPUU will also include the description "inert substance" 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 E:. EXCEPTION There are occasions when this is not applicable. Examples of this include Calamine lotion, Vitamin B compound tablets, Aqueous cream. Note: The addition to the exceptions list will be reviewed on a case-by-case basis. Refer to Appendix E:.

Rule ID	Description
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 MPP level, the form is expressed as the specific form (e.g. injection: intrathecal, tablet: modified release).
AMT-MPP-PT-5	Pack_Units: If the Pack_Units is greater than one, then the Pack QTY units will be expressed as a plural form. See Appendix I: 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 Hp 7 contains 14 tablets + 28 capsules + 14 tablets Pack size = 1 pack If the pack consists of discrete and continuous (or not applicable) unit dose forms, the pack size = x components. e.g. Canesoral Duo (1 x 150 mg capsule, 1 x 10 g cream) Pack size = 1 pack

3.4.2.7 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.

Table 34: Total Unit of Use Quantity Value Rules

Rule ID	Rule
AMT-MPP-TUUQV-1	This term is only to be populated with decimal numbers (e.g. 0.25, 6.0).
AMT-MPP-TUUQV-2	This value is optional.

3.4.2.8 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.

Table 35: Total Subpack Quantity example

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)	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]

In the above example, the superpack MPP will have a "TotalSubpackQuantity" description with a value of "4". This indicates that it has four subpacks, which are defined by the "MPP (superpack) has subpack MPP (subpack)" relationship.

Table 36: 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.
AMT-MPP-TSQ-3	This will only be populated when the subpack exists or is required by the PBS.

3.4.2.9 Medicinal Product Pack "TotalUnitOfUseSizeValue" definition and rules

Definition

This is the numeric value of the size (weight or volume) of each entity comprising the pack size in a given MPP, e.g. if the MPP total quantity size details are "5 x 300 mg vials", then the TotalUnitOfUseSizeValue is "300".

Table 37: Total Unit Of Use Size Value rules

Rule ID	Rule
AMT-MPP-TUUSV-1	This term can only to be populated with an integer value greater than 1.

3.5 Trade Product (TP)

3.5.1 Trade Product definition

The Trade Product (TP) represents the product brand name or the grouping of products into a "family", for either single component products that contain the same base of an active ingredient or components of multi-component products which contain the same combination of bases of the active ingredients. Grouping at the Trade Product level occurs only at the base level of the ingredients, regardless of whether the salts are discernibly therapeutically different or not. For example the Trade Product name of Clopixol groups together products which have zuclopenthixol dihydrochloride (a non significant salt) zuclopenthixol acetate or zuclopenthixol decanoate (both of which are discernibly therapeutically different modifications to the base) as their active ingredient. This concept allows the recording of medications where only incomplete information is available. It will also allow the grouping of products for analysis. For example, a patient may be aware that they were previously prescribed "Amoxil", but cannot be more specific about the form and strength. The Trade Product name will exclude suffixes that further define the item.

Table 38: 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 (trade product)	Panadeine
Combination product	Triphasil (trade product)	Triphasil
Multi-component kit	Nexium Hp 7 (trade product) Nexium (trade product) Klacid (trade product) Amoxil (trade product)	Nexium Hp 7 Nexium Klacid Amoxil
Single ingredient exception	Canesten Clotrimazole (trade product)	Canesten Clotrimazole
Single ingredient exception	Canesten Bifonazole (trade product)	Canesten Bifonazole

3.5.2 Trade Product descriptions

3.5.2.1 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 39: Trade Product "Fully Specified Name" 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.
(trade product)	The semantic tag used in the FSN of all Trade Product concepts.

3.5.2.2 Trade Product "Fully Specified Name" full definition

The Fully Specified Name of a Trade Product can be more fully defined as follows.

Table 40: Trade Product "Fully Specified Name" full description

Description Component	Definition
Trade Product FSN	TF_Name ["(" TF_Supplier ")"] [1] " (trade product)" 1: TD_Supplier is included for generic medicines
TF_Name	TPUU.is a (TP).PT (* without the TF_Supplier, where relevant *)
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.

3.5.2.3 Trade Product "Fully Specified Name" rules

Table 41: Trade Product "Fully Specified Name" rules

Rule ID	Description
AMT-TP-FSN-1	All rules in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply.
AMT-TP-FSN-2	TF_Name will be populated with the product brand name with any suffixes that define the product, strength or presentation excluded. Each Trade Product will consist of products with the same Medicinal Product. EXCEPTION Where Trade Products exist with the same Brand Family name but different active ingredients, a suffix will be included to create a unique unambiguous name, e.g. Canesten Clotrimazole and Canesten Bifonazole will be created as two trade families.

Rule ID	Description
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 ")" (parentheses). For example: • Simvastatin (GenRx) Where a generic product includes the sponsor/manufacturer/house brand name as a suffix, the TF_Name will consist of the generic name followed by a " " and the sponsor/manufacturer/house brand name. In this case "(" and ")" will not be used. For example: • Methotrexate Ebewe Where a generic product name includes an abbreviation for sponsor/manufacturer/house brand name as a hyphenated suffix, the TF_Name will consists of the generic name and the hyphenated suffix. 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 Trade Product Name will consist of both names, for example, Blackmores Magmin.
AMT-TP-FSN-5	The Trade Product Name will not include details of strength, pack size or container type.

3.5.2.4 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 42: Trade Product "Preferred Term" 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.

Note: Variation to this syntax may occur to meet the requirements of clinical practice.

3.5.2.5 Trade Product "Preferred Term" full definition

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

Table 43: Trade Product "Preferred Term" full description

Description Component	Definition
Trade Product FSN	TF_Name ["(" TF_Supplier ")"] [1] 1: TF_Supplier is included for generic medicines
TF_Name	TPUU.is a (TP).PT (* without the TF_Supplier, where relevant *)
TF_Supplier	TPUU.is a (TP).PT (* without the TF_Name *)

3.5.2.6 Trade Product "Preferred Term" rules

Table 44: Trade Product "Preferred Term" rules

Rule ID	Description
AMT-TP-PT-1	All rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply. EXCEPTION Where Tall Man Letters are required to improve safety as defined in Appendix A:.
AMT-TP-PT-2	Trade_Product_Term will be populated with the product brand name with any suffixes that define the product, strength or presentation excluded. Each Trade Product will consist of products with the same active ingredients. EXCEPTION Where Trade Products exist with the same Brand Family name but different active ingredients, a suffix will be included to create a unique unambiguous name, e.g. Canesten Clotrimazole and Canesten Bifonazole will be created as two trade families.

Rule ID	Description
AMT-TP-PT-3	For generic products, the Trade_Product_Term will be populated with generic name followed by a " " and the sponsor/manufacturer/house brand name surrounded by "(" and ")". For example: • Simvastatin (GenRx) Where a generic product includes the sponsor/manufacturer/house brand name as a suffix, the Trade_Product_Term will consist of the generic name followed by a " " and the sponsor/manufacturer/house brand name. In this case "(" and ")" will not be used. For example: • Methotrexate Ebewe Where a generic product name includes an abbreviation for sponsor/manufacturer/house brand name as a hyphenated suffix, the Trade_Product_Term will consist of the generic name and the hyphenated suffix. 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 Trade Product Name will consist of both names, for example, Blackmores Magmin.
AMT-TP-PT-5	The Trade Product Name will not include details of strength, pack size or container type.

3.6 Trade Product Unit of Use (TPUU)

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

Table 45: Examples of Trade Product Unit of Use 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 (amoxycillin (as trihydrate) 500 mg) capsule: hard, 1 capsule
Single ingredient – clinically relevant salt (see Appendix B:)	Voltaren 50 (diclofenac sodium 50 mg) tablet: enteric-coated, 1 tablet (trade product unit of use)	Voltaren (diclofenac sodium 50 mg) tablet: enteric-coated, 1 tablet

Type of product	Fully Specified Name	Preferred Term
Single ingredient – clinically significant salt (see Appendix B:)	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) (sodium chloride 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 (paracetamol 500 mg + codeine phosphate 30 mg) 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 (etidronate disodium 200mg) tablet: uncoated, 1 tablet • Calcium carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg) tablet: film-coated, 1 tablet
Multi-component kit	• Nexium (esomeprazole (as magnesium trihydrate) 20 mg) tablet: enteric-coated, 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 (trade product unit of use)	• Nexium (esomeprazole (as magnesium trihydrate) 20 mg) tablet: enteric-coated, 1 tablet • Klacid (clarithromycin 500 mg) tablet: film-coated, 1 tablet • Amoxil (amoxycillin (as trihydrate) 500 mg) capsule

Type of product	Fully Specified Name	Preferred Term
patch	Estraderm 100 (oestradiol 100 microgram / 24 hours) patch (trade product unit of use)	Estraderm (oestradiol 100 microgram/24 hours) patch
injection powder – dual chamber	• Solu-Cortef ACT-O-VIAL (hydrocortisone (as sodium succinate) 100 mg) injection: powder for, vial (trade product unit of use) • Solu-Cortef ACT-O-VIAL (inert substance) diluent, vial (trade product unit of use)	• Solu-Cortef ACT-O-VIAL (hydrocortisone (as sodium succinate) 100 mg) injection: powder for, vial • Solu-Cortef ACT-O-VIAL diluent, vial
injection solution less than 1 mL	Modecate (fluphenazine decanoate 12.5 mg / 0.5 mL) injection: solution for, 0.5 mL ampoule (trade product unit of use)	Modecate (fluphenazine decanoate 12.5 mg/0.5 mL) injection: solution for, 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 (lanreotide (as acetate) 30 mg) injection: modified release, vial • Somatuline LA diluent, ampoule

3.6.2 Trade Product Unit of Use descriptions

3.6.2.1 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_Suffix] [ " (" TF_Supplier ")" ]
            [ " " Other_Identifying_Information ]
            [ " (inert substance)" | " (" Ingredient_Strength
            { " + " Ingredient_Strength } ")" ] " "
            Generic_or_Proprietary_Form
            ["," Unit_Dose_Form_Details]
            " (trade product unit of use)"
```

where the component parts are described as follows.

Table 46: Trade Product Unit of Use "Fully Specified Name" 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_Suffix	The suffix appended to the TF_Name to add extra meaning.
TF_Supplier	The supplier name for products available as unbranded generic medicines.

Description Component	Description
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").
inert substance	Used to indicate a TPUU in which no active ingredients are recorded. This applies to those products in which inactive (inert) ingredients are part of sequential multi-component products or diluents provided for the preparation of the actual administrable form of a product.
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". This component is mandatory in the FSN of those TPUUs with three or less active ingredients. Inert substances are included where the TPUU is not associated with any TPUUPI concept (i.e. it has no active ingredients) and the TPUU is in a TPP that has another TPUU that is associated with a TPUUPI concept (i.e. another component of the same pack does have active ingredients) and the TPUU manufactured dose form is not "Diluent".
Generic_Or_Proprietary_Form	If the ProprietaryDoseForm is populated, then this is used here. Otherwise the ManufacturedDoseForm is shown.
Unit_Dose_Form_Details	A list of the unit dose form details (if populated), which may include: • Unit Dose Form Size (UDFS): The size of the unit dose form. This includes the value of the "UnitDoseFormSizeValue" description and the units (unit of measure) from the relationship "MPUU has unit dose form size units" unit of measure. • Unit Dose Type: The unit dose item that can be physically handled. This is the unit of measure from the relationship "MPUU has unit dose type" unit of measure. When these values are shown, the first of these is preceded by a comma and space. Note that the unit dose form size (value and units) is not shown when it is the same as the strength denominator (value and units) for all of its ingredients. The unit dose form size is also not shown when it has a value of "1" and a unit that matches the PT of the MP's Form (or one of this Form's parents in the "Form is a Form" hierarchy). Also note that the unit dose type is not shown when it matches the UDFS units, or the PT of the MP's Form (or one of this Form's parents in the "Form is a Form" hierarchy).
(trade product unit of use)	The semantic tag used in the FSN of all Trade Product Unit of Use concepts.

3.6.2.2 Trade Product Unit of Use "Fully Specified Name" full definition

The Fully Specified Name of a Trade Product Unit of Use can be more fully defined as follows.

Table 47: Trade Product Unit of Use "Fully Specified Name" full description

Description Component	Definition
Trade Product Unit of Use FSN	TF_Name [TF_Suffix] [1] [" (" TF_Supplier ")"] [2] [" " Other_Identifying_Information] [3] [" (inert substance)" [4] | " (" Ingredient_Strength { " + " Ingredient_Strength } [5] ")" [6 7]] " " Generic_or_Proprietary_Form [", " Unit_Dose_Form_Details] [8] " (trade product unit of use)" 1: TF_Suffix is included if it exists. 2: TF_Supplier is included only if the TF_Name is a Generic name. 3: Other_Identifying_Information is included if it exists. 4: "inert substance" is included if the TPUU does not participate in a "TPUU has pharmaceutical ingredient" relationship (i.e. it has no active ingredients) and the TPUU is part of some multicomponent TPP that contains a different unit of use that does contain an active ingredient (i.e. there exists some TPP T, such that T participates in a "has TPUU" relationship with the given TPUU, and there exists some U such that T "has TPUU" U, and there exists some I such that U "has pharmaceutical ingredient" I. 5: Ingredient_Strength is included if the TPUU participates in at least one "has pharmaceutical ingredient" relationship. 6: One Ingredient_Strength is included for each "has pharmaceutical ingredient" relationship (TPUUPI) that the TPUU participates in. 7: The Ingredient_Strengths are included in alphabetical order of the BOSS ingredient of the associated TPUUPI concept. 8: Unit Dose Form Details are included if they are not null (based on the conditions in their definition below).
TF_Name	TPUU.is a (TP).PT (* without the Supplier, where relevant *)
TF_Suffix	TPUU.trade product suffix
TF_Supplier	TPUU.is a (TP).PT (* without the TF_Name *)
Other_Identifying_Information	TPUU.other identifying information

Ingredient_Strength	IF TPUUPI.has BOSS = TPUUPI.has ingredient (for the associated TPUUPI) THEN
	
	BOSS_Ingredient " " BOSS_Strength
	
	ELSE
	
	BOSS_Ingredient " (as " PI_Ingredient_Minus_Base ") " BOSS_Strength

BOSS_Ingredient	TPUUPI.has BOSS.PT

Description Component	Definition

BOSS_Strength	IF not exists TPUUPI.has BOSS.is modification of THEN
	Base_Strength
	ELSE
	Salt_Strength

PI_Ingredient_Minus_Base	TPUUPI.has ingredient.ingredient minus base (* Note, this is not part of the terminology, but can be recorded for each ingredient *)
Base_Strength	MPUUSAI.base form strength numerator value " " MPUUSAI.has base form strength numerator units.PT [1] [" / " MPUUSAI.base form strength denominator value " " MPUUSAI.has base form strength denominator units.PT [1]] [2] where TPUUPI.has ingredient = MPUUSAI.has ingredient and TPUU "is a" MPUUSAI.has MPUU. 1: If strength value > 1 then use plural units if the units are expressed in full and not as an abbreviation (To be implemented in future releases.) 2: Denominator value and units are included if they exist
Salt_Strength	MPUUSAI.salt form strength numerator value " " MPUUSAI.has salt form strength numerator units.PT [1] [" / " MPUUSAI.salt form strength denominator value " " MPUUSAI.has salt form strength denominator units.PT [1]] [2] where TPUUPI.has ingredient = MPUUSAI.has ingredient and TPUU "is a" MPUUSAI.has MPUU. 1: If strength value > 1 then use plural units if the units are expressed in full and not as an abbreviation (To be implemented in future releases). 2: Denominator value and units are included if they exist

Generic_or_Proprietary_Form	IF TPUU.has proprietary dose form EXISTS then
	TPUU.has proprietary dose form.PT
	ELSE
	TPUU.has manufactured dose form.PT

Description Component	Definition
Unit_Dose_Form_Details	[" " Unit_Dose_Form_Size] [1] [" " Unit_Dose_Type] [2] 1: Do not include Unit_Dose_Form_Size if either: • TPUU.is a (MPUU).unit_dose_form_size does not exist or • TPUU.is a (MPUU).unit_dose_form_size_value = 1 and TPUU.is a (MPUU).has unit dose form size units equals TPUU.has manufactured dose form (or one of its parents in the Form hierarchy). 2: Include Unit_Dose_Type if: • TPUU.is a (MPUU).has unit dose type exists and • TPUU.is a (MPUU).has unit dose type does not equal TPUU.has manufactured dose form (or one of its parents in the Form hierarchy) and • TPUU.is a (MPUU).has unit dose type does not equal TPUU.is a (MPUU).has unit dose form size units.
Unit_Dose_Form_Size	TPUU.is a (MPUU).unit dose form size value " " TPUU.is a (MPUU).has unit dose form size units.PT
Unit_Dose_Form_Type	TPUU.is a (MPUU).has unit dose type units.PT
(trade product unit of use)	The semantic tag used in the FSN of all Trade Product Unit of Use concepts.

3.6.2.3 Trade Product Unit of Use "Fully Specified Name" rules

Table 48: Trade Product Unit of Use "Fully Specified Name" rules

Rule ID	Description
AMT-TPUU-FSN-1	All rules in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply.
AMT-TPUU-FSN–2	If a Suffix was excluded from the Trade Product Name which defines the product, strength, form or presentation, this will be included as a TradeProductSuffix. If the TradeProductSuffix represents different strengths then the following strength expressions may not be populated. A strength component of a suffix for a single ingredient product will be omitted and strength will be defined using the strength expression. Trade Product Names with a suffix 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_Suffix will include a representation of the strength, e.g. Caduet 10/10 and Caduet 5/20. Strength representation in the TF_Suffix may be omitted for multi-ingredient products when only one strength is currently marketed in Australia, e.g. Moduretic tablets.

Rule ID	Description
AMT-TPUU-FSN–3	Strength expression. The TPUU FSN will include strength expression (if available). The strength expression general rules and application to specific medication forms are outlined in Appendix E:. EXCEPTIONS See AMT-APP-STR-9 in Appendix E.1.
AMT-TPUU-FSN–4	Form 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–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 (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)
AMT-TPUU-FSN–6	ProprietaryDoseForm (e.g. Minims) will be sourced from TGA data, sponsor's Product Information and/or Consumer Medicine Information or the NPC when it becomes available. This will be expressed as a singular form. EXCEPTION Where ProprietaryDoseForm is not available, Form will be derived from the TGA Approved Terminology of Medicines, Dosage Forms. The form will be expressed as a singular form (e.g. tablet, ampoule). These forms will be consistent with the Form (AU qualifier) hierarchy and that associated in the TPUU relationship "has manufactured dose form" with Form.

3.6.2.4 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_Suffix] [ " (" TF_Supplier ")" ]
           [ " " Other_Identifying_Information ]
           [ " (inert substance)" | " (" Ingredient_Strength
           { " + " Ingredient_Strength } ")" ] " "
           Generic_or_Proprietary_Form
           ["," Unit_Dose_Form_Details]
```

where the component parts are described as follows.

Table 49: Trade Product Unit of Use "Preferred Term" 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_Suffix	The suffix appended to the TF_Name to add extra meaning. EXCEPTION Single ingredient products will use TF_Suffix with the strength details omitted.
TF_Supplier	The supplier name for products available as an unbranded generic medicine.
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").
inert substance	Used to indicate a Trade Product Unit of Use in which no active ingredients are recorded. This applies to those products in which inactive (inert) ingredients are part of sequential multi-component products or diluents provided for the preparation of the actual administrable form of a product.
Ingredient_Strength	A 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". This list is alphabetical by default, however, when the Preferred Term order is populated for the associated ingredients then this order is used instead. This component is mandatory in the PT of those TPUUs with three or less active ingredients. Inert substances are included where the TPUU is not associated with any TPUUPI concept (i.e. it has no active ingredients) and the TPUU is in a TPP that has another TPUU that is associated with a TPUUPI concept (i.e. another component of the same pack does have active ingredients) and the TPUU manufactured dose form is not "Diluent".
Generic_Or_Proprietary_Form	If the ProprietaryDoseForm is populated, then this is used here. Otherwise the ManufacturedDoseForm is shown.

Description Component	Description
Unit_Dose_Form_Details	A list of the unit dose form details (if populated), which may include: • Unit Dose Form Size (UDFS): The size of the unit dose form. This includes the value of the "UnitDoseFormSizeValue" description and the units (unit of measure) from the relationship "MPUU has unit dose form size units" unit of measure. • Unit Dose Type: The unit dose item that can be physically handled. This is the unit of measure from the relationship "MPUU has unit dose type" unit of measure. When these values are shown, the first of these is preceded by a comma and space. Note that the unit dose form size (value and units) is not shown when it is the same as the strength denominator (value and units) for all of its ingredients. The unit dose form size is also not shown when it has a value of "1" and a unit that matches the PT of the MP's Form (or one of this Form's parents in the "Form is a Form" hierarchy). Also note that the unit dose type is not shown when it matches the UDFS units, or the PT of the MP's Form (or one of this Form's parents in the "Form is a Form" hierarchy).

Note: Variation to this syntax may occur to meet the requirements of clinical practice.

3.6.2.5 Trade Product Unit of Use "Preferred Term" full definition

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

Table 50: Trade Product Unit of Use "Preferred Term" full description

Description Component	Definition
Trade Product Unit of Use FSN	TF_Name [TF_Suffix] [1] [" (" TF_Supplier ")"] [2] [" " Other_Identifying_Information] [3] [" (inert substance)" [4] | " (" Ingredient_Strength { " + " Ingredient_Strength } [5] ")" [6 7]] [" " Generic_or_Proprietary_Form] [8] ["," Unit_Dose_Form_Details] [9] 1: TF_Suffix is included if it exists 2: TF_Supplier is included only if the TF_Name is a Generic name 3: Other_Identifying_Information is included if it exists 4: "inert substance" is included if: • The TPUU does not participate in a "TPUU has pharmaceutical ingredient" relationship (i.e. it has no active ingredients); and • The TPUU is part of some multicomponent TPP that contains a different unit of use that does contain an active ingredient (i.e. there exists some TPP T, such that T participates in a "has TPUU" relationship with the given TPUU, and there exists some U such that T "has TPUU" U, and there exists some I such that U "has pharmaceutical ingredient" I; and • TPUU.has manufactured dose form.PT ≠ "diluent". 5: Ingredient_Strength is included if the TPUU participates in at least one "has pharmaceutical ingredient" relationship. 6: One Ingredient_Strength is included for each "has pharmaceutical ingredient" relationship (TPUUPI) that the TPUU participates in. 7: The Ingredient_Strengths are ordered based on the value of TPUUPI.preferred term order (if this exists) – otherwise in alphabetical order or the TPUUPI.has BOSS.PT. 8: Generic_or_Proprietary_Form is not included if TPUU.is a (TP).PT or TPUU.trade product suffix includes the form. 9: Unit Dose Form Details are included if they are not null (based on the conditions in their definition below).
TF_Name	TPUU.is a (TP).PT (* without the Supplier, where relevant *)
TF_Suffix	TPUU.trade product suffix (* without any strength representation for single-ingredient TPUUs *)
TF_Supplier	TPUU.is a (TP).PT (* without the TF_Name *)
Other_Identifying_Information	TPUU.other identifying information

Description Component	Definition

Ingredient_Strength	IF TPUUPI.has BOSS = TPUUPI.has ingredient (for the associated TPUUPI) THEN
	BOSS_Ingredient " " BOSS_Strength
	ELSE
	BOSS_Ingredient " (as " PI_Ingredient_Minus_Base ") " BOSS_Strength

BOSS_Ingredient	TPUUPI.has BOSS.PT
BOSS_Strength	IF TPUUPI.has preferred strength representation.PT = "N" or TPUUPI.has preferred strength representation does not exist THEN BOSS_Strength_N ELSIF TPUU.has preferred strength representation.PT = "NA" THEN BOSS_Strength_N " (" BOSS_Strength_A ")" ELSIF TPUU.has preferred strength representation.PT = "AN" THEN BOSS_Strength_A " (" BOSS_Strength_N ")" ELSIF TPUU.has preferred strength representation.PT = "A" THEN BOSS_Strength_A

BOSS_Strength_N	IF not exists TPUUPI.has BOSS.is modification of THEN
	Base_Strength
	ELSE
	Salt_Strength

BOSS_Strength_A	TPUUPI.BOSS other strength representation
PI_Ingredient_Minus_Base	TPUUPI.has ingredient.ingredient minus base (* Note, this is not part of the terminology, but can be recorded for each ingredient *)
Base_Strength	MPUUSAI.base form strength numerator value " " MPUUSAI.has base form strength numerator units.PT [1] ["/" [MPUUSAI.base form strength denominator value " "] [2] MPUUSAI.has base form strength denominator units.PT [1]] [3] where TPUUPI.has ingredient = MPUUSAI.has ingredient and TPUU "is a" MPUUSAI.has MPUU. 1: If strength value > 1 then use plural units 2: Include base strength denominator value if ≠ 1 3: Denominator value and units is included if it exists

Description Component	Definition
Salt_Strength	MPUUSAI.salt form strength numerator value " " MPUUSAI.has salt form strength numerator units.PT [1] ["/" [MPUUSAI.salt form strength denominator value " "] [2] MPUUSAI.has salt strength form denominator units.PT [1]] [3] where TPUUPI.has ingredient = MPUUSAI.has ingredient and TPUU "is a" MPUUSAI.has MPUU. 1: If strength value > 1 then use plural units 2: Include salt strength denominator value if ≠ 1 3: Denominator value and units is included if it exists

Generic_or_Proprietary_Form	IF TPUU.has proprietary dose form EXISTS then
	TPUU.has proprietary dose form.PT
	ELSE
	TPUU.has manufactured dose form.PT

Unit_Dose_Form_Details	[" " Unit_Dose_Form_Size] [1] [" " Unit_Dose_Type] [2] 1: Do not include Unit_Dose_Form_Size if either: • TPUU.is a (MPUU).unit_dose_form_size does not exist; or • TPUU.is a (MPUU).unit_dose_form_size_value = 1 and TPUU.is a (MPUU).has unit dose form size units equals TPUU.has manufactured dose form (or one of its parents in the Form hierarchy); or • There exists a BV, such that BV = BOSS_Strength denominator value (for all TPUUPIs that "has a TPUU" to the given TPUU) and there exists a BU, such that BU = BOSS_Strength denominator units (for all TPUUPIs that "has a TPUU" to the given TPUU) and BV = TPUU.is a (MPUU).unit dose form size value and BU = TPUU.is a (MPUU).has unit dose form size units TPUU has exactly one pharmaceutical ingredient, and for that ingredient BOSS_Strength has no denominator and the BOSS_Strength numerator value equals TPUU.is a (MPUU).has unit dose form size value and the BOSS_Strength numerator units equals TPUU.is a (MPUU).has unit dose form size units. 2: Include Unit_Dose_Type if: • TPUU.is a (MPUU).has unit dose type exists and • TPUU.is a (MPUU).has unit dose type does not equal TPUU.has manufactured dose form (or one of its parents in the Form hierarchy) and • TPUU.is a (MPUU).has unit dose type does not equal TPUU.is a (MPUU).has unit dose form size units and • Unit_Dose_Type.PT ≠ "measure"
Unit_Dose_Form_Size	TPUU.is a (MPUU).unit dose form size value " " TPUU.is a (MPUU).has unit dose form size units.PT [1] 1: If unit dose form size value > 1 then use plural units
Unit_Dose_Form_Type	TPUU.is a (MPUU).has unit dose type units.PT

3.6.2.6 Trade Product Unit of Use "Preferred Term" rules

Table 51: Trade Product Unit of Use "Preferred Term" rules

Rule ID	Description
AMT-TPUU-PT–1	All rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply. EXCEPTION Where Tall Man Letters are required to improve safety as defined in Appendix A:.
AMT-TPUU-PT–2	If a Suffix was excluded from the Trade Product Name which defines the product, strength, form or presentation, this will be included as a TradeProductSuffix. If the TradeProductSuffix represents different strengths then the following strength expressions may not be populated. A strength component of a suffix for a single ingredient product will be omitted and strength will be defined using the strength expression. Trade Product Names with a suffix 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_Suffix will include a representation of the strength, e.g. Caduet 10/10 and Caduet 5/20. Strength representation in the TF_Suffix may be omitted for multi-ingredient products when only one strength is currently marketed in Australia, e.g. Moduretic tablets.
AMT-TPUU-PT-3	Strength expression. The TPUU FSN/PT will include strength expression (if available). The strength expression general rules and application to specific medication forms is outlined in Appendix E:. EXCEPTIONS See AMT-APP-STR-9 in Appendix E.1.
AMT-TPUU-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".
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 (paracetamol 1 g) oral liquid: powder for, 1 sachet • Dimetapp 12 Hour refill (oxymetazoline hydrochloride 0.05% (500 microgram/mL)) nasal spray

Rule ID	Description
AMT-TPUU-PT-6	ProprietaryDoseForm (e.g. Minims) will be sourced from TGA data, sponsor's Product Information and/or Consumer Medicine Information or the NPC when it becomes available. This will be expressed as a singular form. EXCEPTION Where ProprietaryDoseForm is not available Form will be derived from the TGA Approved Terminology of Medicines, Dosage Forms. The form will be expressed as a singular form, e.g. tablet, ampoule. These forms will be consistent with the Form (AU qualifier) hierarchy and that associated in the TPUU relationship "has Manufactured dose form" with Form. However, this may differ to meet requirements of clinical practice. See Appendix G: and Appendix H:.

3.6.2.7 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 or the NPC when it becomes available.

Table 52: Trade Product Unit of Use "Other Identifying Information" rules

Rule ID	Rule
AMT-TPP-OPI-1	All rules defined in Section 2.2.4.2 (All Description Constraints/Data definitions) apply.
AMT-TPP-OPI-2	A TPUU may not have more than one Other_Identifying_Information descriptor.

3.6.2.8 Trade Product Unit of Use "Trade Product Suffix" definition and rules

Definition

The Trade Product Suffix is an extension to a Trade Product name that further defines the commercial product in terms of strength, form or presentation (e.g. for the product name Adalat Oros, "Adalat" is the Trade Product name and "Oros" is the Trade Product Suffix). This may be sourced from the TGA ARTG Label Name, sponsor's Product Information and/or Consumer Medicine Information, or the product label.

The suffix associated with the Trade Product Unit of Use can either be the same as the suffix associated with the Trade Product Pack (if the product is single component) or different to the pack (i.e. unique to that unit of use) for certain multi-component products e.g. for "Pegatron Combination Therapy (4 x 100 microgram cartridges, 112 x 200 mg capsules), 1 pack" the suffix at the TPUU level for one of its active components is "Redipen Injector" while the suffix at the TPP level is "Combination Therapy".

Table 53: Trade Product Unit of Use "Trade Product Suffix" rules

Rule ID	Rule
AMT-TPUU-TPS-1	All rules in Section 2.2.4.2 (All Description Constraints/Data definitions) apply.
AMT-TPUU-TPS-2	Forms will be included as part of Trade Product Suffix where this is required to prevent ambiguity.
AMT-TPUU-TPS-3	The population of this term is optional.

3.7 Trade Product Pack (TPP)

3.7.1 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: The TPP does not contain details of Container Type. This information is included in the Containered Trade Product Pack (CTPP).

Table 54: Examples of 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 (trade product pack)	Amoxil 500 mg capsule: hard, 20 capsules
Single ingredient – clinically relevant salt (see Appendix B:)	Voltaren 50 (diclofenac sodium 50 mg) tablet: enteric-coated, 50 tablets (trade product pack)	Voltaren 50 mg tablet: enteric-coated, 50 tablets
Single ingredient – clinically significant salt (see Appendix B:)	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

Type of product	Fully Specified Name	Preferred Term
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
Multi-component kit	Nexium Hp 7 (amoxycillin (as trihydrate) 500 mg) capsule [28 capsules] (&) (clarithromycin 500 mg) tablet: film-coated [14 tablets] (&) (esomeprazole (as magnesium trihydrate) 20 mg) tablet: enteric-coated [14 tablets], 1 pack (trade product pack)	Nexium Hp 7, 1 pack
patch	Estraderm 100 (oestradiol 100 microgram / 24 hours) patch, 8 patches (trade product pack)	Estraderm 100 microgram/24 hours patch, 8
injection powder – dual chamber	Solu-Cortef ACT-O-VIAL (hydrocortisone (as sodium succinate) 100 mg) injection: powder for [1 x 100 mg vial] (&) (inert substance) diluent [1 x 2 mL vial], 1 pack (trade product pack)	Solu-Cortef ACT-O-VIAL (1 x 100 mg vial), 1 pack
injection solution less than 1 mL	Modecate (fluphenazine decanoate 12.5 mg / 0.5 mL) injection: solution for, 5 x 0.5 mL ampoules (trade product pack)	Modecate 12.5 mg/0.5 mL injection: solution for, 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

3.7.2 Trade Product Pack descriptions

3.7.2.1 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_Suffix] [ " (" 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 55: Trade Product Pack "Fully Specified Name" 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_Suffix	The suffix appended to the TF_Name to add extra meaning.
TF_Supplier	The supplier name for products available as an unbranded generic medicine.
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").
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 (proprietary or manufactured) 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 is only included when it is 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.

Description Component	Description
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 the TPP has a number of subpacks (i.e. the description "total subpack quantity" is populated) then the string is followed by subpack quantity details in square brackets. The subpack quantity details includes the description "total subpack quantity", followed by the multiplication symbol (i.e. " x "), followed by the total number of units of uses in each subpack (i.e. "total unit of use quantity value" ÷ "total subpack quantity", together with the unit of measure from "TPP has total unit of use quantity units").
(trade product pack)	The semantic tag used in the FSN of all Trade Product Pack concepts.

3.7.2.2 Trade Product Pack "Fully Specified Name" full definitions

The Fully Specified Name of a Trade Product Pack can be more fully defined as follows.

Table 56: Trade Product Pack "Fully Specified Name" full description

Description Component	Definition
Trade Product Pack FSN	TPP FSN := TF_Name [TF_Suffix] [1] [" (" TF_Supplier ")"] [2] [" " Other_Pack_Information] [3] TPUU_Details { " (&) " TPUU_Details } [4 5] ", " Total_Quantity_Size_Details " (trade product pack)" 1: TF_Suffix is included if it exists 2: TF_Supplier is included only if the TF_Name is a Generic name 3: Other_Pack_Information is included if it exists 4: TPUU_Details are included if there exists a TPUU such that TPP.has TPUU.has pharmaceutical ingredient exists (i.e. if one of its component TPUUs has an active ingredient) 5: One TPUU_Details is included for each THT that exists, where THT.has TPP is the given TPP. These are ordered alphabetically on Ingredient_Strength.
TF_Name	TPP.is a (TP).PT (* without the Supplier, where relevant *)
TF_Suffix	TPP.trade product suffix
TF_Supplier	TPP.is a (TP).PT (* without the TF_Name *)
Other_Pack_Information	TPP.other pack information

Description Component	Definition
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.
TPUU_ISF	[" (inert substance)" [1] | " (" Ingredient_Strength { " + " Ingredient_Strength } ")" [2 3]] Generic_Or_Proprietary_Form 1: "inert substance" is used when the given TPUU has no active ingredients (i.e. has no associated TPUUPI concepts), but another TPP.has TPUU exists that does have an active ingredient (i.e. there exists some TPP.has TPUU.has pharmaceutical ingredient). 2: Ingredient_Strength is included for each TPUU.has pharmaceutical ingredient (i.e. TPUUPI concept) that exists. 3: Ingredient_Strengths are ordered alphabetically on ingredient name.
Ingredient_Strength	Ingredient_Strength, as defined for the given TPUU's FSN.
Generic_Or_Proprietary_Form	Generic_Or_Proprietary_Form, as defined for the given TPUU's FSN.
TPUU_Qty	THT.unit of use quantity value [" × " THT.unit of use size value " " THT.has unit of use size units.PT [1]] [2] [" " THT.has unit of use quantity units.PT [3]] [4] where THT.has TPP is the given TPP, and THT.has TPUU is the given TPUU 1: If unit of use size value > 1 then use plural size units 2: Size value and units is included when THT.unit of use size value exists 3: If unit of use quantity value > 1 then use plural quantity units 4: Unit of use quantity units is included when THT.has unit of use quantity units ≠ TPUU.has manufactured dose form (or one of its parents in the Form hierarchy) and THT.has unit of use quantity units ≠ TPUU.has proprietary dose form (or one of its parents in the Form hierarchy)
Total_Quantity_Size_Details	Total_Quantity_Size [" [" Subpack_Details "]"] [1] 1: Subpack_Details are included when TPP.total subpack quantity exists.
Total_Quantity_Size	TPP.total unit of use quantity value [" × " TPP.total unit of use size value " " TPP.has total unit of use size units.PT] [1] " " TPP.has total unit of use quantity units.PT 1: Size value and size units is included when TPP.total unit of use size value is not null
Subpack_Details	TPP.total subpack quantity " × " (TPP.total unit of use quantity value ÷ TPP.total subpack quantity) " " 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.

3.7.2.3 Trade Product Pack "Fully Specified Name" rules

Table 57: Trade Product Pack "Fully Specified Name" rules

Rule ID	Description
AMT-TPP-FSN-1	All rules in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply.
AMT-TPP-FSN-2	If a Suffix was excluded from the Trade Product Name which defines the product, strength, form or presentation, this will be included as TradeProductSuffix. If the TradeProductSuffix represents different strengths then the following strength expressions will not be populated. Trade Product Names with a suffix will differentiate between different available strengths, e.g. Panadeine and Panadeine Forte.
AMT-TPP-FSN–3	Strength expression The strength expression general rules and application to specific medication forms is outlined in Appendix E:. For multi ingredient products when the constructed description does not include a representation of strength (either trade product 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	ProprietaryDoseForm (e.g. Minims) will be sourced from TGA data, sponsor's Product Information and/or Consumer Medicine Information or the NPC when it becomes available. This will be expressed as a singular form. EXCEPTION Where ProprietaryDoseForm is not available Form will be derived from the TGA Approved Terminology of Medicines, Dosage Forms. The form will be expressed as a singular form (e.g. tablet, ampoule). These forms will be consistent with the Form (AU qualifier) hierarchy and that associated in the TPUU relationship "has manufactured dose form" with Form.

Rule ID	Description
AMT-TPP-FSN-6	Pack_Units: If the Pack_Units is greater than one, then the Pack QTY units will be expressed as a plural form. See Appendix I: 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 Hp 7 contains 14 tablets + 28 capsules + 14 tablets Pack size = 1 pack If the pack consists of a discrete and continuous (or not applicable) unit dose forms, the pack size = x components. e.g. Canesoral Duo (1 x 150 mg capsule, 1 x 10 g cream) Pack size = 1 pack

3.7.2.4 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_Suffix] [ " (" TF_Supplier ")" ]
          [ " " Other_Pack_Information ] [ " " BOSS_Strength ]
          [ " " Generic_Or_Proprietary_Form]
          [ " " PT_Other_Identifying_Information] ", "
         Total_Quantity_Size_Details
```

where the component parts are described as follows.

Table 58: Trade Product Pack "Preferred Term" 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.

Description Component	Description
TF_Suffix	The suffix appended to the TF_Name to add extra meaning. EXCEPTIONS: Single ingredient products will use TF_Suffix with the strength details omitted. To avoid ambiguity for multi-ingredient products with multiple strengths available, the TF_Suffix at the TPP level will include a representation of the strength, e.g. Caduet 10/10 and Caduet 5/20. Where this still does not disambiguate two or more products, each of the ingredients will be included in the suffix. The ingredients shall appear in the same order in which they are referred to in the suffix, and shall be enclosed within a single bracket, with each of the ingredients separated by a "/" with no spacing around it. Each ingredient shall be represented as the BOSS without hydration. For example: Coveram 5 mg/10 mg tablet: uncoated, 30 tablets is ambiguous as it is not possible to distinguish it from Coveram 10 mg/5 mg tablet: uncoated, 30 tablets. Disambiguation as described above results in the creation of the following unambiguous descriptions: • Coveram 5 mg/10 mg (perindopril arginine/amlodipine) tablet: uncoated, 30 tablets; and • Coveram 10 mg/5 mg (perindopril arginine/amlodipine) tablet: uncoated, 30 tablets.
TF_Supplier	The supplier name for products available as an unbranded generic medicine.
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). This is only populated if the TPP has a single TPUU component with only one active ingredient.
Generic_Or_Proprietary_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 proprietary dose form, where available, otherwise it is the manufactured dose form.
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.

Description Component	Description
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 the TPP has a number of subpacks (i.e. the description "total subpack quantity" is populated), then the string is followed by subpack quantity details in square brackets. The subpack quantity details includes the description "total subpack quantity", followed by the multiplication symbol (i.e. " x "), followed by the total number of units of use in each subpack (i.e. "total unit of use quantity value ÷ "total subpack quantity", together with the unit of measure from "TPP has total unit of use quantity units").

3.7.2.5 Trade Product Pack "Preferred Term" full definition

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

Table 59: Trade Product Pack "Preferred Term" full description

Description Component	Definition
Trade Product Pack PT	TF_Name [TF_Suffix] [1] [" (" TF_Supplier ")"] [2] [" " Other_Pack_Information] [3] [" " BOSS_Strength] [4] [" " Generic_Or_Proprietary_Form] [5] [" " PT_Other_Identifying_Information] [6] ", " Total_Quantity_Size_Details 1: TF_Suffix is included if it exists 2: TF_Supplier is included only if the TF_Name is a Generic name 3: Other_Pack_Information is included if it exists 4: BOSS_Strength is included when exactly one TPP.has TPUU.has pharmaceutical ingredient exists (i.e. there is exactly one active ingredient in the TPP) 5: Generic_Or_Proprietary_Form is included when the TPP has exactly one TPUU and the TPP.is a (TP).TF_Name or TPP.trade product suffix does not include the Form 6: PT_Other_Identifying_Information is included if the TPP has more than one TPUU
TF_Name	TPP.is a (TP).PT (* without the Supplier, where relevant *)

TF_Suffix	IF TPP has exactly one TPUU and that TPUU has exactly one pharmaceutical ingredient THEN
	TPP.trade product suffix (* with strength expression omitted *)
	ELSE
	TPP.trade product suffix

TF_Supplier	TPP.is a (TP).PT (* without the TF_Name *)
Other_Pack_Information	TPP.other pack information
BOSS_Strength	BOSS_Strength, as defined for the given TPUU and its pharmaceutical ingredient (TPUUPI)
Generic_Or_Proprietary_Form	Generic_Or_Proprietary_Form, as defined for the given TPUU's FSN
PT_Other_Identifying_Information	TPP.Other_Identifying_Information (* This is not part of the terminology, but can be recorded for each TPP *)
Total_Quantity_Size_Details	Total_Quantity_Size [" [" Subpack_Details "]"] [1] 1: Subpack_Details are included when TPP.total subpack quantity exists.

Description Component	Definition
Total_Quantity_Size	TPP.total unit of use quantity value [" × " TPP.total unit of use size value " " TPP.has total unit of use size units.PT] [1] " " TPP.has total unit of use quantity units.PT 1: Size value and size units is included when TPP.total unit of use size value is not null
Subpack_Details	TPP.total subpack quantity " × " (TPP.total unit of use quantity value ÷ TPP.total subpack quantity) " " TPP.has total unit of use quantity units.PT

3.7.2.6 Trade Product Pack "Preferred Term" rules

Table 60: Trade Product Pack "Preferred Term" rules

Rule ID	Description
AMT-TPP-PT-1	All rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply. EXCEPTION Where Tall Man Letters are required to improve safety as defined in Appendix A:.
AMT-TPP-PT–2	If a Suffix was excluded from the Trade Product Name which defines the product, strength, form or presentation, this will be included as TradeProductSuffix. If the TradeProductSuffix represents different strengths then the following strength expressions will not be populated. Trade Product Names with a suffix will differentiate between different available strengths, e.g. Panadeine and Panadeine Forte.
AMT-TPP-PT-3	Strength expression The strength expression general rules and application to specific medication forms is outlined in Appendix E:. For multi ingredient products when the constructed description does not include a representation of strength (either trade product 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 specific 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.

Rule ID	Description
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
AMT-TPP-PT–6	ProprietaryDoseForm (e.g. Minims) will be sourced from TGA data, sponsor's Product Information and/or Consumer Medicine Information or the NPC when it becomes available. This will be expressed as a singular form. EXCEPTION Where ProprietaryDoseForm is not available, Form will be derived from the TGA Approved Terminology of Medicines, Dosage Forms. The form will be expressed as a singular form, e.g. tablet, ampoule. However, this may differ to meet requirements of clinical practice. See Appendix H: for the associated Preferred Term Form.
AMT-TPP-PT-7	Pack_Units: If the Pack_Units is greater than one, then the Pack QTY units will be expressed as a plural form. See Appendix I: 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 Hp 7 contains 14 tablets + 28 capsules + 14 tablets Pack size = 1 pack If the pack consists of a discrete and continuous (or not applicable) unit dose forms, the pack size = x components. e.g. Canesoral Duo (1 x 150 mg capsule, 1 x 10 g cream) Pack size = 1 pack

3.7.2.7 Trade Product Pack "OtherPackInformation" 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 or the NPC when it becomes available.

Table 61: Trade Product Pack "OtherPackInformation" rules

Rule ID	Rule
AMT-TPP-OPI-1	All rules defined in Section 2.2.4.2 (All Description Constraints/Data definitions) apply.
AMT-TPP-OPI-2	A TPP may not have more than one Other_Pack_Information descriptor.

3.7.2.8 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.

Table 62: Trade Product Pack "Total Unit of Use Quantity Value" rules

Rule ID	Rule
AMT-TPP-TUUQV-1	This term is only to be populated with decimal numbers (e.g. 1.25, 6.0).
AMT-TPP-TUUQV-2	This value is optional.

3.7.2.9 Trade Product Pack "Total Subpack Quantity" definition and rules

Definition

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

This is the numeric value of the quantity of the TPP which is the Subpack (TPPSubpack).

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

Table 63: Trade Product Pack "Total Subpack Quantity" example

Trade Product Preferred Term	Fully Specified Name	Preferred Term
Triphasil	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]

Table 64: Trade Product Pack "Total Subpack Quantity" rules

Rule ID	Rule
AMT-TPP-TSQ-1	This term can only be populated with an integer greater than one.
AMT-TPP-TSQ-2	This value is optional.
AMT-TPP-TSQ-3	This will only be populated when the subpack exists or is required by the PBS.

3.7.2.10 Trade Product Pack "TotalUnitOfUseSizeValue" definition and rules

Definition

This is the numeric value of the size (weight or volume) of each entity comprising the pack size in a given TPP e.g. if the TPP total quantity size details are "5 x 300 mg vials", then the TotalUnitOfUseSizeValue is "300".

Table 65: Trade Product Pack "TotalUnitOfUseSizeValue" rule

Rule ID	Rule
AMT-TPP-TUUSV-1	This term can only to be populated with an integer value greater than 1.

3.7.2.11 Trade Product Pack "TradeProductSuffix" definition and rules

Definition

The Trade Product Suffix is an extension to a Trade Product name that further defines the commercial product in terms of strength, form or presentation (e.g. for the product name Adalat Oros, "Adalat" is the Trade Product name and "Oros" is the Trade Product Suffix). This may be sourced from the TGA ARTG Label Name, the sponsor's Product Information and/or Consumer Medicine Information or product label.

The Suffix associated with the Trade Product Pack may be different to the Suffix associated with the Trade Product Unit of Use for certain multi-component products e.g. for "Pegatron Combination Therapy (4 x 100 microgram cartridges, 112 x 200 mg capsules), 1 pack" the Suffix at TPP level is "Combination Therapy" while the Suffix at TPUU level for one of its active components is "Redipen Injector".

Table 66: Trade Product Pack "TradeProductSuffix" rule

Rule ID	Rule
AMT-TPP-TPS-1	All rules defined in Section 2.2.4.2 (All Description Constraints/Data definitions) apply.
AMT-TPP-TPS-2	A TPP may not have more than one Trade_Product_Suffix.
AMT-TPP-TPS-3	Population of this term is optional.

3.8 Containered TPP (CTPP)

3.8.1 Containered TPP definition

The Containered Trade Product Pack (CTPP) is the packaged product that is supplied for direct patient use and includes details of the container type. The Container Type defines the type of containers that immediately cover the medicine at the Trade Product Pack level. 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 67: Examples of Containered 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 (containered trade product pack)	Amoxil 500 mg capsule: hard, 20 capsules, blister pack
Single ingredient – clinically relevant salt (see Appendix B:)	Voltaren 50 (diclofenac sodium 50 mg) tablet: enteric-coated, 50 tablets, bottle (containered trade product pack)	Voltaren 50 mg tablet: enteric-coated, 50 tablets, bottle
Single ingredient – clinically significant salt (see Appendix B:)	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) 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

Type of product	Fully Specified Name	Preferred Term
• 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, 112 tablets [4 x 28 tablets], blister pack
• 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)	Didrocal, 104 tablets, blister pack
Multi-component kit	Nexium Hp 7 (amoxycillin (as trihydrate) 500 mg) capsule [28 capsules] (&) (clarithromycin 500 mg) tablet: film-coated [14 tablets] (&) (esomeprazole (as magnesium trihydrate) 20 mg) tablet: enteric-coated [14 tablets], 1 pack, composite pack (containered trade product pack)	Nexium Hp 7, 1 pack, composite 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 powder – dual chamber	Solu-Cortef ACT-O-VIAL (hydrocortisone (as sodium succinate) 100 mg) injection: powder for [1 x 100 mg vial] (&) (inert substance) diluent [1 x 2 mL vial], 1 pack, dual chamber composite pack (containered trade product pack)	Solu-Cortef ACT-O-VIAL (1 x 100 mg vial), 1 pack, dual chamber composite pack
injection solution less than 1 mL	Modecate (fluphenazine decanoate 12.5 mg / 0.5 mL) injection: solution for, 5 x 0.5 mL ampoules, ampoule (containered trade product pack)	Modecate 12.5 mg/0.5 mL injection: solution for, 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 (1 x 30 mg vial), 1 pack, composite pack

3.8.2 Containered TPP Pack descriptions

3.8.2.1 Containered TPP "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 68: Containered TPP "Fully Specified Name" description

Description Component	Description
TPP_FSN_Details	The details included in the FSN of the parent TPP.
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.

3.8.2.2 Contained TPP "Fully Specified Name" full definition

The Fully Specified Name of a Contained Trade Product Pack can be more fully defined as follows:

Table 69: Contained TPP "Fully Specified Name" full description

Description Component	Definition
Contained Trade Product Pack FSN	TPP_FSN_Details ", " Container [" (" Other_Contained_Pack_Information ")"] [1] " (contained trade product pack)" 1: Other_Contained_Pack_Information is included if it exists and if CTPP.other contained pack information ≠ CTPP.is a (TPP).other pack information
TPP_FSN_Details	CTPP.is a (TPP).FSN, as defined for the parent TPP's FSN, but without the semantic tag (i.e. without " (trade product pack)")
Container	CTPP.has container type.PT
Other_Contained_Pack_Information	CTPP.other contained pack information
(contained trade product pack)	The semantic tag used in the FSN of all Contained Trade Product Pack concepts.

3.8.2.3 Contained TPP "Fully Specified Name" rules

Table 70: Contained TPP "Fully Specified Name" rules

Rule ID	Description
AMT-CTPP-FSN-1	All rules in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply.
AMT-CTPP-FSN-2	If a Suffix was excluded from the Trade Product Name which defines the product, strength, form or presentation, then this will be included as TradeProductSuffix. If the TradeProductSuffix represents different strengths, then the following strength expressions will not be populated. Trade Product Names with a suffix will differentiate between different available strengths, e.g. Panadeine and Panadeine Forte.
AMT-CTPP-FSN-3	Strength expression The strength expression general rules and application to specific medication forms is outlined in Appendix E:. For multi ingredient products when the constructed description does not include a representation of strength (either trade product suffix or strength expression), then the missing details may be added to produce the description and prevent ambiguity. EXCEPTION Strength may be omitted for multi-ingredient products when only one strength is currently marketed in Australia. For example, Moduretic tablets.

Rule ID	Description
AMT-CTPP-FSN-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”.
AMT-CTPP-FSN-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_Containered_Pack_Information (e.g. pack includes applicator). For example: At present there are no products which have information which is unique to this field.
AMT-CTPP-FSN-6	ProprietaryDoseForm (e.g. Minims) will be sourced from TGA data, sponsor’s Product Information and/or Consumer Medicine Information or the NPC when it becomes available. This will be expressed as a singular form. EXCEPTION Where ProprietaryDoseForm is not available Form will be derived from the TGA Approved Terminology of Medicines, Dosage Forms. The form will be expressed as a singular form (e.g. tablet, ampoule).
AMT-CTPP-FSN-7	Pack_Units: If the Pack_Units is greater than one, then the Pack QTY units will be expressed as a plural form. See Appendix I: 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 Hp 7 contains 14 tablets + 28 capsules + 14 tablets Pack size = 1 pack If the pack consists of a discrete and continuous (or not applicable) unit dose forms, the pack size = x components. e.g. Canesoral Duo (1 x 150 mg capsule, 1 x 10 g cream) Pack size = 1 pack
AMT-CTPP-FSN-8	ContainerType Container type will always be populated, as defined by the TGA. See Appendix K:.

3.8.2.4 Containered TPP “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 71: Contained TPP "Preferred Term" description

Description Component	Description
TPP_PT_Details	The details included in the PT of the parent TPP.
Container	The PT of the container type of the CTPP, as defined by the relationship CTPP "has container type".
Other_Contained_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 contained 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.

3.8.2.5 Contained TPP "Preferred Term" full definition

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

Table 72: Contained TPP "Preferred Term" full description

Description Component	Definition
Contained Trade Product Pack PT	TPP_PT_Details ", " Container [" (" Other_Contained_Pack_Information ")"] [1] [Manufacturers_Code] 1: Other_Contained_Pack_Information is included if it exists and if CTPP.other contained pack information ≠ CTPP.is a (TPP).other pack information
TPP_PT_Details	CTPP.is a (TPP).PT, as defined for the parent TPP's PT
Container	CTPP.has container type.PT
Other_Contained_Pack_Information	CTPP.other contained pack information
Manufacturers_Code	CTPP.manufacturers code

3.8.2.6 Containered TPP "Preferred Term" rules

Table 73: Containered TPP "Preferred Term" rules

Rule ID	Description
AMT-CTPP-PT-1	All rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply. EXCEPTION Where Tall Man Letters are required to improve safety as defined in Appendix A:.
AMT-CTPP-PT-2	If a Suffix was excluded from the Trade Product Name which defines the product, strength, form or presentation. This will be included as TradeProductSuffix. If the TradeProductSuffix represents different strengths then the following strength expressions will not be populated. Trade Product Names with a suffix will differentiate between different available strengths, e.g. Panadeine and Panadeine Forte.
AMT-CTPP-PT-3	Strength expression The strength expression general rules and application to specific medication forms is outlined in Appendix E:. For multi-ingredient products when the constructed description does not include a representation of strength (either trade product 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 when only one strength is currently marketed in Australia. For example, Moduretic tablets.
AMT-CTPP-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 may be excluded.
AMT-CTPP-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_Containered_Pack_Information (e.g. pack includes applicator). For example: At present there are no products which have information which is unique to this field.

Rule ID	Description
AMT-CTPP-PT-6	ProprietaryDoseForm (e.g. Minims) will be sourced from TGA data, sponsor's Product Information and/or Consumer Medicine Information or the NPC when it becomes available. This will be expressed as a singular form. EXCEPTION Where ProprietaryDoseForm is not available, Form will be derived from the TGA Approved Terminology of Medicines, Dosage Forms. The form will be expressed as a singular form, e.g. tablet, ampoule. These units will be consistent with the Form (AU qualifier) reference set and that associated in the TPUU relationship "has Manufactured dose form" with Form. However, this may differ to meet requirements of clinical practice. See Appendix G: and Appendix H:.
AMT-CTPP-PT-7	Pack_Units: If the Pack_Units is greater than one, then the Pack QTY units will be expressed as a plural form. See Appendix I: 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 Hp 7 contains 14 tablets + 28 capsules + 14 tablets Pack size = 1 pack If the pack consists of a discrete and continuous (or not applicable) unit dose forms, the pack size = x components. e.g. Canesoral Duo (1 x 150 mg capsule, 1 x 10 g cream) Pack size = 1 pack
AMT-CTPP-PT-8	ContainerType Container type will always be populated as defined by the TGA.

3.8.2.7 Containered TPP "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 or the NPC when it becomes available.

Table 74: Contained TPP "Other Contained Pack Information" rules

Rule ID	Rule
AMT-CTPP-OPI-1	All rules defined in Section 2.2.4.2 (All Description Constraints/Data definitions) apply.
AMT-CTPP-OPI-2	A CTPP may not have more than one Other_Contained_Pack_Information descriptor.

3.8.2.8 Contained TPP "ARTG ID" definition and rules

Definition

The ARTG ID is the primary identifier used to identify therapeutic goods as included in the Australian Register of Therapeutic Goods (ARTG).

Note: The ARTG ID has been renamed Licence ID recently in the ARTG data.

Table 75: Contained TPP "ARTG ID" rules

Rule ID	Rule
AMT-CTPP-AI-1	This term can only to be populated with an integer value.

4 Substance concepts

These concepts represent the ingredients within products.

4.1 Ingredient (ING)

4.1.1 Ingredient 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.
- Excipients are not included in 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 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 76: Examples of Ingredient FSNs and PTs

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

4.1.2 Ingredient descriptions

4.1.2.1 Ingredient "Fully Specified Name" definition

The Fully Specified Name of an Ingredient follows the syntax:

```
ING FSN := Ingredient_Name " (AU substance)"
```

where the component parts are described as follows.

Table 77: Ingredient "Fully Specified Name" description

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

4.1.2.2 Ingredient "Fully Specified Name" rules

Table 78: Ingredient "Fully Specified Name" rules

Rule ID	Description
AMT-ING-FSN-1	All rules in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply.
AMT-ING-FSN-2	The ingredient fully specified name is derived from the Australian Approved Name (AAN)[4] or clinically intuitive names as specified in the Australian Register of Therapeutic Goods. The base form of the ingredient as well as the salt will be represented.
AMT-ING-FSN-3	No additional name segments will be added to the Ingredient 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.

4.1.2.3 Ingredient "Preferred Term" definition

The Preferred Term of an Ingredient follows the syntax:

```
ING PT := Ingredient_Name
```

where the component parts are described as follows.

Table 79: Ingredient "Preferred Term" description

Description Component	Description
Ingredient_Name	The name of the ingredient.

4.1.2.4 Ingredient "Preferred Term" rules

Table 80: Ingredient "Preferred Term" rules

Rule ID	Description
AMT-ING-PT-1	All rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply. Capitalisation rules as defined in Appendix A: apply. EXCEPTION Where Tall Man Letters are required to improve safety as defined in Appendix A:.
AMT-ING-PT-2	The Ingredient Preferred Term will be derived from the TGA active ingredient name (as defined in the TGA Approved Terminology for Medicines).

[4] Note: NEHTA is currently investigating the use of an international terminology standard for ingredient names.

Rule ID	Description
AMT-ING-PT-3	No additional name segments will be added to the Ingredient 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.

5 Australian Qualifier concepts

5.1 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 81: Australian Qualifier Concepts

Concept Name	Definition	Source of Data
Animal Origin (AO)	This qualifier concept defines the animal origin for an ingredient.	The name is derived from the TGA Approved Terminology for Medicines.
Availability Status (AS)	This qualifier relationship links the Containered Trade Product Unit of Use to a reference set defining the availability of the product. Allowable values are: • not available • available only as a component or subpack • available	This will be sourced from the NPC when it becomes available, and/or from other relevant data sources.
Biotech Descriptor (BD)	This qualifier concept represents a product or pharmaceutical ingredient derived from a genetically engineered cell line which has been developed in order to express a therapeutically recombinant protein.	This data is sourced from the TGA or supplier Product Information (where data was missing from the TGA).
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 manufactured dose form. Manufactured dose forms are the forms in which the product is manufactured and transported (i.e. the dose form created by the manufacturer, e.g. powder for reconstitution as suspension). 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
Ingredient Activity Status (IAS)	This qualifier concept indicates whether an ingredient is an active ingredient or an excipient. At this stage Proprietary Ingredients are not included. Allowable values are: • active ingredient • excipient ingredient Note that excipients have not yet been implemented in AMT.	This data is sourced from the TGA.
Medication Sponsor (MSP)	A sponsor is an organisation that supplies some medicinal product. The sponsor may or may not also be the manufacturer of the product.	This data is sourced from the TGA.
Organisation (ORG)	To be defined.	To be defined.
Pack Manufacture Indicator (PMI)	This concept is used to describe whether the pack is in its original form or if the product has been re-packaged. Allowable values are: • original manufacture pack • re-packaged pack	Currently will not be populated in the AMT.
Pack Size Indicator (PSI)	This concept qualifier indicates if the medicinal product pack contains a single administrable dose or multiple unit doses. Allowable values are: • multiple unit dose pack • unit dose pack	To be defined.
Plant Part (PP)	This defines the part of a plant that is the source of the ingredient, for example, fruit or root.	Plant Part descriptions are derived from the TGA Approved Terminology for Medicines.
Plant Preparation (PPN)	This defines the preparation technique used to prepare a substance from plant origin for medicinal use, for example, extract or infusion.	Plant Preparation descriptions are derived from the TGA Approved Terminology for Medicines.
Preferred Strength Representation Type (PSRT)	This is the strength representation which is to be used in the PT of a given concept. It may or may not correspond to the FSN strength representation.	To be defined.
Proprietary Form (PF)	This defines forms that are privately owned and controlled by a product sponsor. (e.g. Minims, Filmtab)	This will be sourced from the TGA ARTG Label Name, sponsor's Product Information and/or Consumer Medicine Information or the NPC when it becomes available.

Concept Name	Definition	Source of Data
Route of Administration (RA)	Route is used to describe the set of registered routes of administration for medicinal products in the AMT (e.g. oral, intravenous).	These routes are derived from the TGA Approved Terminology for Medicines.
Trade Product Group (TPG)	This qualifier concept allows for trade products sharing a common root trade product name to be grouped. Trade products grouped under this concept may not share the same active ingredients. For example, Canesten is the Trade Product Group description and provides links to Canesten Clotrimazole and Canesten Bifonazole, both of which are Trade Product concepts. As such, Trade Families containing non-identical active ingredients can be grouped. The Trade Product Group name is the root of the Trade name without suffixes that defines a Trade Product based on common active ingredients. If a range of products under one Trade Product name do not have any suffixes, the Trade Product Group name is identical to the Trade Product Name. Generically named products (e.g. Terry White Amoxycillin) or products with general descriptions (e.g. Chemmart Cold and Flu) do not have a root trade name and as such they are not assigned a TF group.	Derived from TGA ARTG Label name.
Unit Dose Form Indicator (UDFI)	The unit dose form indicator (UDFI) identifies if an MPUU describes a discrete unit dose form, e.g. tablet or capsule; a continuous substance where a consistent physically measurable unit or sub-unit cannot be identified, e.g. cream or eye drops; or a product where a unit dose form is not applicable. Allowable values are: • unit dose form not applicable • discrete • continuous	To be defined.

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 • Salt form strength numerator units • Salt form strength denominator units • Ingredient strength numerator units • Ingredient strength denominator units • Total unit of use quantity units • Total unit of use size units • Pack quantity units • Unit dose form size units • Unit dose type units • Unit of use quantity units • Unit of use size units	This data is sourced from the TGA.

Examples of these Australian Qualifier Concepts are displayed in the following table.

Table 82: Examples of Australian Qualifier Concepts

Concept Name	Fully Specified Name	Preferred Term
Animal Origin (AO)	bovine (AU qualifier)	bovine
Availability Status (AS)	available (AU qualifier)	available
Biotech Descriptor (BD)	rys (AU qualifier)	rys
Container Type (CT)	vial (AU qualifier)	vial
Form (F)	tablet: enteric-coated (AU qualifier)	tablet: enteric-coated
Ingredient Activity Status (IAS)	active ingredient (AU qualifier)	active ingredient
Medication Sponsor (MSP)	AstraZeneca Pty Ltd (AU qualifier)	AstraZeneca Pty Ltd
Organisation (ORG)	TBC	TBC
Pack Manufacture Indicator (PMI)	original manufactured pack (AU qualifier)	original manufactured pack
Pack Size Indicator (PSI)	unit dose pack (AU qualifier)	unit dose pack
Plant Part (PP)	leaf (AU qualifier)	leaf
Plant Preparation (PPN)	tincture (AU qualifier)	tincture
Preferred Strength Representation Type (PSRT)	numerator/denominator strength (AU qualifier)	numerator/denominator strength
Proprietary Form (PF)	Minims (AU qualifier)	Minims
Route of Administration (RA)	intravenous (AU qualifier)	intravenous

Concept Name	Fully Specified Name	Preferred Term
Trade Product Group (TPG)	Nurofen (AU qualifier)	Nurofen
Unit Dose Form Indicator (UDFI)	discrete (AU qualifier)	discrete
Unit of Measure (UOM)	microgram (AU qualifier)	microgram

5.2 Australian Qualifier descriptions

5.2.1 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 83: Australian Qualifier "Fully Specified Name" 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

The rules defined in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply.

5.2.2 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 84: Australian Qualifier "Preferred Term" rules

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

Table 85: Australian Qualifier "Preferred Term" rules

Rule ID	Description
AMT-AQ-PT-1	In addition to the rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules), the following also apply. **Note:** The Form PT will be the same as the Form FSN without the word "dose form" and the semantic tag of "(AU qualifier)". For example, where the FSN is "injection: solution dose form (AU qualifier)" the PT will be "injection: solution". See Appendix G: for Preferred Term Forms. **Exception** If required, the route description may be altered to meet clinical practice.

6 Relationship Details concepts

These concepts will be used in the AMT to add more information about a relationship between two concepts. These concepts include:

- MPP has MPUU (MHM)
- MPUU Specific Active Ingredient (MPUUSAI)
- TPP has TPUU (THT)
- TPUU Pharmaceutical Ingredient (TPUUPI)

6.1 MPP has MPUU (MHM)

6.1.1 MPP has MPUU definition

MPP has MPUU describes the relationship between a particular Medicinal Unit of Use and a particular Medicinal Product Pack. For each distinct type of component within a Product Pack (i.e. with distinct active ingredients, strength, form) an MPP has MPUU will record the quantity of that Unit of Use component within that Pack.

Note: This will only be populated for Multi-component packs.

6.1.2 MPP has MPUU descriptions

6.1.2.1 MPP has MPUU "Fully Specified Name" definition and rules

Definition

The Fully Specified Name of an "MPP has MPUU" follows the syntax:

```
MHM FSN := MPP_PT " HAS MPUU " MPUU_PT " (Relationship id: "
           Relationship_id ") (relationship details)"
```

where the component parts are described as follows.

Table 86: MPP has MPUU "Fully Specified Name" description

Description Component	Description
MPP_PT	The PT of the MPP concept defined by MHM.has MPP.
HAS MPUU	Text used to join the MPP PT and the MPUU PT.
MPUU_PT	The PT of the MPUU concept defined by MHM.has MPUU.
Relationship_Id	The numeric value of the SNOMED Relationship ID to which this information applies.
(relationship details)	The semantic tag included in the FSN of all Relationship Details concepts.

Table 87: MPP has MPUU "Fully Specified Name" rules

Rule ID	Rule
AMT-MHM-FSN-1	Rules defined in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply.

6.1.2.2 MPP has MPUU "Preferred Term" definition and rules

Definition

The Preferred Term of an "MPP has MPUU" follows the syntax:

```
MHM PT := MPP_PT " HAS MPUU " MPUU_PT
```

where the component parts are described as follows.

Table 88: MPP has MPUU "Preferred Term" description

Description Component	Description
MPP_PT	The PT of the MPP concept defined by MHM.has MPP.
HAS MPUU	Text used to join the MPP PT and the MPUU PT.
MPUU_PT	The PT of the MPUU concept defined by MHM.has MPUU.

Table 89: MPP has MPUU "Preferred Term" rules

Rule ID	Rule
AMT-MHM-PT-1	Rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply

6.1.2.3 MPP has MPUU "RelationshipId" definition and rules

Definition

This is the numeric value of the SNOMED Relationship ID to which this information applies.

Table 90: MPP has MPUU "RelationshipId" rules

Rule ID	Rule
AMT-MHM-RI-1	This term can only be populated with an integer value greater than zero.

6.1.2.4 MPP has MPUU "UnitOfUseQuantityValue" definition and rules

Definition

The numeric value of the quantity of the "UnitOfUseQuantityUnits" in the given MPUU in the given MPP AMT Concept Type.

Where "UnitOfUseQuantityUnit" is the unit of measure associated with the quantity of the given MPUU in the given MPP.

Table 91: MPP has MPUU "UnitOfUseQuantityValue" rules

Rule ID	Rule
AMT-MHM-UUQV-1	This term is only to be populated with decimal numbers (e.g. 0.25, 6.0).
AMT-MHM-UUQV-2	This value is optional.

6.1.2.5 MPP has MPUU "UnitOfUseSizeValue" definition and rules

Definition

This is the numeric value of the size (weight or volume) of each entity comprising the pack size in a given MPP has MPUU component e.g. the multi-component product "Sandostatin LAR (1 x 10 mg vial), 1 pack, composite pack" has two MHM concepts. The MHM component associated with the active component is "octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack HAS MPUU octreotide 10 mg injection: modified release, vial" and has UnitOfUseSizeValue of "10". The MHM component associated with the inert component is "octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack HAS MPUU inert substance diluent, syringe" and has UnitOfUseSizeValue of "2.5".

Table 92: MPP has MPUU "UnitOfUseSizeValue" rules

Rule ID	Rule
AMT-MHM-UUSV-1	This term can only to be populated with an integer value greater than 1.

6.1.2.6 MPP has MPUU "PreferredComponentOrder" definition and rules

Definition

This describes the order in which a component is displayed within a term (such as MP or MPP) if there are multiple components relating to a multi-component product and a therapeutically relevant order of the components is required e.g. the multi-component product "Aredia (1 x 60 mg vial), 1 pack, composite pack" has two MHM concepts. The MHM component associated with the active component is "pamidronate disodium 60 mg injection [1 x 60 mg vial] (&) inert substance diluent [1 x 10 mL ampoule], 1 pack HAS MPUU pamidronate disodium 60 mg injection, vial" and has PreferredComponentOrder of "1". The MHM component associated with the inert component is "pamidronate disodium 60 mg injection [1 x 60 mg vial] (&) inert substance diluent [1 x 10 mL ampoule], 1 pack HAS MPUU inert substance diluent, ampoule" and has PreferredComponentOrder of "2".

Table 93: MPP has MPUU "PreferredComponentOrder" rules

Rule ID	Rule
AMT-MHM-PCO-1	This term can only to be populated with an integer value greater than 1.
AMT-MHM-PCO -2	Population of this term is optional.

6.2 MPUU Specific Active Ingredient (MPUUSAI)

6.2.1 MPUU Specific Active Ingredient definition

MPUU Specific Active Ingredient (MPUUSAI) records the active ingredient information of the associated MPUU, its strength, basis of strength substance (BOSS) and BOSS strength.

6.2.1.1 Additional notes

The active ingredient is the substance in the medication formulation that is pharmaceutically active and is responsible for the medication's therapeutic effect defined by its identifying name and the strength per dose unit.

The Active Ingredient Information of an MPUU records only the base of each active ingredient, except in those cases in which:

- the salt represents a chemical complex that has been defined as discernibly therapeutically different from the base concept;
- the salt is a chemical modification to the base that is a physiological salt;
- there are overriding clinical reasons why the salt must be individually represented in the Medicinal Product;
- the salt represents the active enantiomer of a racemic mixture in which the opposite enantiomer is inactive;
- the active ingredient has been formulated in a micronised form; or
- the salt is required to improve patient safety.

The "strength" is the representation of the amount of active ingredient present in a single dose unit of a medicinal product (or concentration, in the case of products which do not have a defined administrable unit, known as "continuous"). It should be noted that the strength of a particular medication may be represented in terms of:

- the active moiety (or salt);
- the basic ingredient;
- another salt of the active moiety; or
- a different active ingredient.

Each medicine therefore has a "basis of strength substance (BOSS)" which may be different to the actual active ingredient.

Table 94: BOSS examples

MPUU	Pharmaceutical Ingredient	Pharmaceutical Ingredient Strength	Basis of Strength Substance (BOSS)	BOSS Strength
trandolapril 1 mg capsule	trandolapril	1 mg	trandolapril	1 mg
oestrone sulfate sodium 1.25 mg tablet	oestrone piperazine sulfate	1.46 mg	oestrone sulfate sodium	1.25 mg
amitriptyline hydrochloride 10 mg tablet	amitriptyline hydrochloride	10 mg	amitriptyline hydrochloride	10 mg
amoxycillin 250 mg capsule	amoxycillin trihydrate	272 mg	amoxycillin (base)	250 mg

6.2.2 MPUU Specific Active Ingredient descriptions

6.2.2.1 MPUU Specific Active Ingredient "Fully Specified Name" definition and rules

Definition

The Fully Specified Name of an MPUU Specific Active Ingredient follows the syntax:

```
MPUUSAI FSN := MPUU_PT " HAS SPECIFIC ACTIVE INGREDIENT "
               Ingredient_PT " (Relationship id: "
               Relationship_id ") (relationship details)"
```

where the component parts are described as follows.

Table 95: MPUU Specific Active Ingredient "Fully Specified Name" description

Description Component	Description
MPUU_PT	The PT of the MPUU concept defined by MPUUSAI.has MPUU.
HAS SPECIFIC ACTIVE INGREDIENT	Text used to join the MPUU PT and the Ingredient PT.
Ingredient_PT	The PT of the Ingredient concept defined by MPUUSAI.has ingredient.
Relationship_Id	The numeric value of the SNOMED Relationship ID to which this information applies.
(relationship details)	The semantic tag included in the FSN of all Relationship Details concepts.

Table 96: MPUU Specific Active Ingredient "Fully Specified Name" rules

Rule ID	Rule
AMT-MSAI-FSN-1	All rules defined in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply.

6.2.2.2 MPUU Specific Active Ingredient "Preferred Term" definition and rules

Definition

The Preferred Term of an MPUU Specific Active Ingredient follows the syntax:

```
MPUUSAI PT := MPUU_PT " HAS SPECIFIC ACTIVE INGREDIENT "
              Ingredient_PT
```

where the component parts are described as follows.

Table 97: MPUU Specific Active Ingredient "Preferred Term" description

Description Component	Description
MPUU_PT	The PT of the MPUU concept defined by MPUUSAI.has MPUU.
HAS SPECIFIC ACTIVE INGREDIENT	Text used to join the MPUU PT and the Ingredient PT.
Ingredient_PT	The PT of the Ingredient concept defined by MPUUSAI.has ingredient.

Table 98: MPUU Specific Active Ingredient "Preferred Term" rules

Rule ID	Rule
AMT-MSAI-PT-1	Rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply.

6.2.2.3 MPUU Specific Active Ingredient "RelationshipId" definition and rules

Definition

This is the numeric value of the SNOMED Relationship ID to which this information applies.

Table 99: MPUU Specific Active Ingredient "RelationshipId" rules

Rule ID	Rule
AMT-MSAI-RI-1	This term can only be populated with an integer greater than zero.

6.2.2.4 MPUU Specific Active Ingredient "PreferredTermOrder" definition and rules

Definition

Identifies the order that this specific ingredient name appears in the MPUU Preferred term. This is only applicable for multi-ingredient products.

Table 100: MPUU Specific Active Ingredient "PreferredTermOrder" rules

Rule ID	Rule
AMT-MSAI-PTO-1	This term can only be populated with an integer greater than zero.
AMT-MSAI-PTO-2	This value is optional.

6.2.2.5 MPUU Specific Active Ingredient "BaseFormStrengthNumeratorValue" definition and rules

Definition

The numeric value of the numerator of the strength of the given base form of the active ingredient, i.e. the quantity of Base Form Strength Numerator Units.

Table 101: MPUU Specific Active Ingredient "BaseFormStrengthNumeratorValue" rules

Rule ID	Rule
AMT-MSAI-BFSNV-1	This term is only to be populated with decimal numbers (e.g. 0.25, 6.0).
AMT-MSAI-BFSNV-2	This value is optional.

6.2.2.6 MPUU Specific Active Ingredient "BaseFormStrengthDenominatorValue" definition and rules

Definition

The numeric value of the denominator of the strength of the given base form of the active ingredient, i.e. the quantity of Base Form Strength Denominator Units.

Table 102: MPUU Specific Active Ingredient "BaseFormStrengthDenominatorValue" rules

Rule ID	Rule
AMT-MSAI-BFSDV-1	This term is only to be populated with decimal numbers (e.g. 0.25, 6.0).
AMT-MSAI-BFSDV-2	This value is optional.

6.2.2.7 MPUU Specific Active Ingredient "SaltFormStrengthNumeratorValue" definition and rules

Definition

The numeric value of the numerator of the strength of the given salt form of the active ingredient, i.e. the quantity of Salt Form Strength Numerator Units.

Table 103: MPUU Specific Active Ingredient "SaltFormStrengthNumeratorValue" rules

Rule ID	Rule
AMT-MSAI-SFSNV-1	This term is only to be populated with decimal numbers (e.g. 0.25, 6.0).
AMT-MSAI-SFSNV-2	This value is optional.

6.2.2.8 MPUU Specific Active Ingredient "SaltFormStrengthDenominatorValue" definition and rules

Definition

The numeric value of the denominator of the strength of the given salt form of the active ingredient, i.e. the quantity of Salt Form Strength Denominator Units.

Table 104: MPUU Specific Active Ingredient "SaltFormStrengthDenominatorValue" rules

Rule ID	Rule
AMT-MSAI-SFSDV-1	This term is only to be populated with decimal numbers (e.g. 0.25, 6.0).
AMT-MSAI-SFSDV-2	This value is optional.

Table 105: Strength Numerator/Denominator examples

Strength Example	Numerator Value	Denominator Value
10 mg	10	none
10 mg/mL	10	1

6.2.2.9 MPUU Specific Active Ingredient "BaseFormStrengthOtherRepresentation" definition and rules

Definition

This describes an alternate strength representation to the numerator/denominator strength representation of the base ingredient currently recorded as the MPUU's specific active ingredient. This description only exists if an alternate strength representation is required and the BOSS is the base ingredient.

Table 106: MPUU Specific Active Ingredient "BaseFormStrengthOtherRepresentation" rules

Rule ID	Rule
AMT-MSAI-BFSOR-1	All rules defined in Section 2.2.4.2 (All Description Constraints/Data definitions) apply.
AMT-MSAI-BFSOR-2	This may be a text string or a numerical value (e.g. a percentage, a ratio, etc).
AMT-MSAI-BFSOR-3	Population of this term is optional.

6.2.2.10 MPUU Specific Active Ingredient "SaltFormStrengthOtherRepresentation" definition and rules

Definition

This describes an alternate strength representation to the numerator/denominator strength representation of the salt ingredient currently recorded as the MPUU's specific active ingredient. This description only exists if an alternate strength representation is required and the BOSS is the salt ingredient.

Table 107: MPUU Specific Active Ingredient "SaltFormStrengthOtherRepresentation" rules

Rule ID	Rule
AMT-MSAI-SFSOR-1	All rules defined in Section 2.2.4.2 (All Description Constraints/Data definitions) apply.
AMT-MSAI-SFSOR-2	This may be a text string or a numerical value (e.g. a percentage, a ratio, etc).
AMT-MSAI-SFSOR-3	Population of this term is optional.

6.3 TPP Has TPUU (THT)

6.3.1 TPP has TPUU definition

TPP has TPUU describes the relationship between a particular Trade Unit of Use and a particular Trade Product Pack. For each distinct type of component within a Product Pack (i.e. with distinct active ingredients, strength, form), a TPP has TPUU Component will record the quantity of that Unit of Use component within that Pack.

6.3.2 TPP has TPUU descriptions

6.3.2.1 TPP has TPUU "Fully Specified Name" definition and rules

Definition

The Fully Specified Name of a "TPP has TPUU" follows the syntax:

```
THT FSN := TPP_PT " HAS TPUU " TPUU_PT " (Relationship id: "
           Relationship_id ") (relationship details)"
```

where the component parts are described as follows.

Table 108: TPP has TPUU "Fully Specified Name" description

Description Component	Description
TPP_PT	The PT of the TPP concept defined by THT.has TPP.
HAS TPUU	Text used to join the TPP PT and the TPUU PT.
TPUU_PT	The PT of the TPUU concept defined by TPP.has TPUU.
Relationship_Id	The numeric value of the SNOMED Relationship ID to which this information applies.
(relationship details)	The semantic tag used in the FSN of all Relationship Details concepts.

Table 109: TPP has TPUU "Fully Specified Name" rules

Rule ID	Rule
AMT-THT-FSN-1	Rules defined in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply.

6.3.2.2 TPP has TPUU "Preferred Term" definition and rules

Definition

The Preferred Term of a "TPP has TPUU" follows the syntax:

```
THT PT := TPP_PT " HAS TPUU " TPUU_PT
```

where the component parts are described as follows.

Table 110: TPP has TPUU "Preferred Term" description

Description Component	Description
TPP_PT	The PT of the TPP concept defined by THT.has TPP.
HAS TPUU	Text used to join the TPP PT and the TPUU PT.
TPUU_PT	The PT of the TPUU concept defined by TPP.has TPUU.

Table 111: TPP has TPUU "Preferred Term" rules

Rule ID	Rule
AMT-THT-PT-1	Rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply.

6.3.2.3 TPP has TPUU "RelationshipId" definition and rules

Definition

This is the numeric value of the SNOMED Relationship ID to which this information applies.

Table 112: TPP has TPUU "RelationshipId" rules

Rule ID	Rule
AMT-THT-RI-1	This term can only be populated with an integer greater than zero.

6.3.2.4 TPP has TPUU "UnitOfUseQuantityValue" definition and rules

Definition

This is the numeric value of the quantity of the UnitOfUseQuantityUnits in the given TPUU in the given TPP AMT Concept Type, where the UnitOfUseQuantityUnit is the unit of measure associated with the quantity of the given TPUU in the given TPP.

Table 113: TPP has TPUU "UnitOfUseQuantityValue" rules

Rule ID	Rule
AMT-THT-UUQV-1	This term is only to be populated with decimal numbers (e.g.0.25, 6.0).
AMT-THT-UUQV-2	This value is optional.

6.3.2.5 TPP has TPUU "UnitOfUseSizeValue" definition and rules

Definition

This is the numeric value of the size (weight or volume) of each entity comprising the pack size in a given TPP has TPUU component e.g. the multi-component product "Sandostatin LAR (1 x 10 mg vial), 1 pack, composite pack" has two THT concepts. The THT component associated with the active component is "Sandostatin LAR (inert substance) diluent [1 x 2.5 mL syringe] (&) (octreotide (as acetate) 10 mg) injection: modified release [1 x 10 mg vial], 1 pack HAS TPUU Sandostatin LAR (octreotide (as acetate) 10 mg) injection: modified release, vial" and has UnitOfUseSizeValue of "10". The THT component associated with the inert component is "Sandostatin LAR (inert substance) diluent [1 x 2.5 mL syringe] (&) (octreotide (as acetate) 10 mg) injection: modified release [1 x 10 mg vial], 1 pack HAS TPUU Sandostatin LAR (inert substance) diluent, syringes" and has UnitOfUseSizeValue of "2.5".

Table 114: TPP has TPUU "UnitOfUseSizeValue" rules

Rule ID	Rule
AMT-THT-UUSV-1	This term can only to be populated with an integer value greater than 1.

6.4 TPUU Pharmaceutical Ingredient (TPUUPI)

6.4.1 TPUU Pharmaceutical Ingredient definition

This is used to provide information about actual active ingredients and excipients contained in the Trade Product Unit of Use.

Excipient ingredients are the inactive or inert substances that are combined with the active ingredients of the medication at the time of manufacture to improve formulation characteristics like stability, solubility, spreadability, and are also used as a "filling agent" to give form or consistency appropriate for administration, but which do not add materially to the effectiveness of the medication.

Note: The excipient information is not guaranteed to be complete. The absence of excipient information does not imply the absence of all or any excipients.

6.4.2 TPUU Pharmaceutical Ingredient descriptions

6.4.2.1 TPUU Pharmaceutical Ingredient "Fully Specified Name" definition and rules

Definition

The Fully Specified Name of a TPUU Pharmaceutical Ingredient follows the syntax:

```
TPUUPI FSN := TPUU_PT " HAS PHARMACEUTICAL INGREDIENT "
              Ingredient_PT " (Relationship id: "
              Relationship_id ") (relationship details)"
```

where the component parts are described as follows.

Table 115: TPUU Pharmaceutical Ingredient "Fully Specified Name" description

Description Component	Description
TPUU_PT	The PT of the TPUU concept defined by TPUUPI.has TPUU.
HAS PHARMACEUTICAL INGREDIENT	Text used to join the TPUU PT and the Ingredient PT.
Ingredient_PT	The PT of the Ingredient concept defined by TPUUPI.has ingredient.
Relationship_Id	The numeric value of the SNOMED Relationship ID to which this information applies.
(relationship details)	The semantic tag used in the FSN of all Relationship Details concepts.

Table 116: TPUU Pharmaceutical Ingredient "Fully Specified Name" rules

Rule ID	Rule
AMT-TPI-FSN-1	Rules defined in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply.

6.4.2.2 TPUU Pharmaceutical Ingredient "Preferred Term" definition and rules

Definition

The Preferred Term of a TPUU Pharmaceutical Ingredient follows the syntax:

```
TPUUPI PT := TPUU_PT " HAS PHARMACEUTICAL INGREDIENT "
             Ingredient_PT
```

where the component parts are described as follows.

Table 117: TPUU Pharmaceutical Ingredient "Preferred Term" description

Description Component	Description
TPUU_PT	The PT of the TPUU concept defined by TPUUPI.has TPUU.
HAS PHARMACEUTICAL INGREDIENT	Text used to join the TPUU PT and the Ingredient PT.
Ingredient_PT	The PT of the Ingredient concept defined by TPUUPI.has ingredient.

Table 118: TPUU Pharmaceutical Ingredient "Preferred Term" rules

Rule ID	Rule
AMT-TPI-PT-1	Rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply.

6.4.2.3 TPUU Pharmaceutical Ingredient "RelationshipId" definition and rules

Definition

This is the numeric value of the SNOMED Relationship ID to which this information applies.

Table 119: TPUU Pharmaceutical Ingredient "RelationshipId" rules

Rule ID	Rule
AMT-TPI-RI-1	This term can only be populated with an integer greater than zero.

6.4.2.4 TPUU Pharmaceutical Ingredient "IngredientStrengthNumeratorValue" definition and rules

Definition

The numeric value of the numerator of the strength of the ingredient, i.e. the quantity of Ingredient Strength Numerator Units.

Table 120: TPUU Pharmaceutical Ingredient "IngredientStrengthNumeratorValue" rules

Rule ID	Rule
AMT-TPI-ISNV-1	This term is only to be populated with decimal numbers (e.g. 0.25, 6.0).
AMT-TPI-ISNV-2	This value is optional.

6.4.2.5 TPUU Pharmaceutical Ingredient "IngredientStrengthDenominatorValue" definition and rules

Definition

The numeric value of the denominator of the strength of the ingredient, i.e. the quantity of Ingredient Strength Denominator Units.

Table 121: TPUU Pharmaceutical Ingredient "IngredientStrengthDenominatorValue" rules

Rule ID	Rule
AMT-TPI-ISDV-1	This term is only to be populated with decimal numbers (e.g. 0.25, 6.0).
AMT-TPI-ISDV-1	This value is optional.

Table 122: Strength Numerator/Denominator examples

Strength Example	Numerator Value	Denominator Value
10 mg	10	None
10 mg/mL	10	1

6.4.2.6 TPUU Pharmaceutical Ingredient "BOSS OtherStrengthRepresentation" definition and rules

Definition

This describes an alternate strength representation to the numerator/denominator strength representation of the BOSS ingredient recorded as the TPUU's pharmaceutical ingredient. This description only exists if an alternate strength representation is required and could be an alternate strength representation of the base ingredient or the salt ingredient, depending on the BOSS.

Table 123: TPUU Pharmaceutical Ingredient "BOSS OtherStrengthRepresentation" rules

Rule ID	Rule
AMT-TPI-BOSR-1	All rules defined in Section 2.2.4.2 (All Description Constraints/Data definitions) apply.
AMT-TPI-BOSR-2	This may be a text string or a numerical value (e.g. a percentage, a ratio, etc).
AMT-TPI-BOSR-3	Population of this term is optional.

7 Data Representation concepts

These concepts are used to assist in the representation of the AMT data in SNOMED-like format and currently include:

- Australian description type concepts (Section 7.1)
- Australian relationship type concepts (Section 7.2)
- Australian status type concepts (Section 7.3)
- Australian characteristic type concepts (Section 7.4)
- Australian refinability type concepts (Section 7.5)

7.1 Australian Description Type concepts

7.1.1 Australian Description Type concepts definition

These concepts are used to identify the type of description that the description record is providing. Examples (expressed as Fully Specified Names) include but are not limited to:

- base form strength denominator value (description type)
- base form strength numerator value (description type)
- fully specified name (description type)
- ingredient strength denominator value (description type)
- ingredient strength numerator value (description type)
- other containered pack information (description type)
- other identifying information (description type)
- other pack description (description type)
- preferred term (description type)
- preferred term order (description type)
- product data availability date (description type)
- relationship id (description type)
- salt form strength denominator value (description type)
- salt form strength numerator value (description type)
- total subpack quantity (description type)
- total unit of use quantity value (description type)
- trade product suffix (description type)
- unit dose form size value (description type)
- unit of use quantity value (description type)

7.1.2 Australian Description Type concepts descriptions

7.1.2.1 Australian Description Type Concepts "Fully Specified Name" definition and rules

Definition

The Fully Specified Name of an Australian Description Type follows the syntax:

```
Australian Description Type FSN := DescriptionType_Name
        " (description type)"
```

where the component parts are described as follows.

Table 124: Australian Description Type Concepts "Fully Specified Name" description

Description Component	Description
DescriptionType_Name	The term used to describe the specific description type concept.
(description type)	The semantic tag used in the FSN of all Description Type concepts.

Table 125: Australian Description Type Concepts "Fully Specified Name" rules

Rule ID	Rule
AMT-ADT-FSN-1	Rules defined in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply.

7.1.2.2 Australian Description Type "Preferred Term" definition and rules

Definition

The Preferred Term of an Australian Description Type follows the syntax:

```
Australian Description Type PT := DescriptionType_Name
```

where the component parts are described as follows.

Table 126: Australian Description Type "Preferred Term" description

Description Component	Description
DescriptionType_Name	The term used to describe the specific description type concept.

Table 127: Australian Description Type "Preferred Term" rules

Rule ID	Rule
AMT-ADT-PT-1	Rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply.

7.2 Australian Relationship Type concepts

7.2.1 Australian Relationship Type concepts definition

These concepts are used to identify the type of relationship being used within the AMT.

Examples of the Australian Relationships Types (expressed as Fully Specified Names) are as follows:

- comes from plant part (relationship type)
- has animal origin (relationship type)
- has MPP (relationship type)
- has MPUU (relationship type)
- has Australian BOSS (relationship type)
- has availability status (relationship type)
- has base form strength denominator units (relationship type)
- has base form strength numerator units (relationship type)
- has base form strength units (relationship type)
- has base ingredient (relationship type)
- has BOSS (relationship type)
- has container type (relationship type)
- has dose form (relationship type)
- has ingredient (relationship type)
- has ingredient activity status (relationship type)
- has ingredient strength denominator units (relationship type)
- has ingredient strength numerator units (relationship type)
- has ingredient strength units (relationship type)
- has international BOSS (relationship type)
- has manufactured dose form (relationship type)
- has MPP (relationship type)
- has MPUU (relationship type)
- has pack (relationship type)
- has pack manufacture indicator (relationship type)
- has pack quantity units (relationship type)
- has pack size indicator (relationship type)
- has pharmaceutical ingredient (relationship type)
- has plant preparation (relationship type)
- has preferred base form strength representation (relationship type)
- has preferred salt form strength representation (relationship type)
- has preferred strength representation (relationship type)
- has proprietary dose form (relationship type)
- has registered route (relationship type)
- has route (relationship type)
- has salt form strength denominator units (relationship type)

- has salt form strength numerator units (relationship type)
- has salt form strength units (relationship type)
- has specific active ingredient (relationship type)
- has sponsor (relationship type)
- has strength units (relationship type)
- has subpack (relationship type)
- has total unit of use quantity units (relationship type)
- has total unit of use size units (relationship type)
- has TPP (relationship type)
- has TPUU (relationship type)
- has trade product group (relationship type)
- has unit dose form indicator (relationship type)
- has unit dose form size units (relationship type)
- has unit dose type units (relationship type)
- has unit of use (relationship type)
- has unit of use quantity units (relationship type)
- has unit of use size units (relationship type)
- has units (relationship type)
- hierarchical relationship type (relationship type)
- historical relationship type (relationship type)
- is modification of (relationship type)

7.2.2 Australian Relationship Type concepts descriptions

7.2.2.1 Australian Relationship Type Concepts "Fully Specified Name" definition and rules

Definition

The Fully Specified Name of an Australian Relationship Type follows the syntax:

```
Australian Relationship Type FSN := RelationshipType_Name
" (relationship type)"
```

where the component parts are described as follows.

Table 128: Australian Relationship Type Concepts "Fully Specified Name" description

Description Component	Description
RelationshipType_Name	The term used to describe the specific relationship type concept.
(relationship type)	The semantic tag used in the FSN of all Relationship Type concepts.

Table 129: Australian Relationship Type Concepts "Fully Specified Name" rules

Rule ID	Rule
AMT-ART-FSN-1	Rules defined in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply.

7.2.2.2 Australian Relationship Type "Preferred Term" definition and rules

Definition

The Preferred Term of an Australian Relationship Type follows the syntax:

```
Australian Relationship Type PT := RelationshipType_Name
```

where the component parts are described as follows.

Table 130: Australian Relationship Type "Preferred Term" description

Description Component	Description
RelationshipType_Name	The term used to describe the specific relationship type concept.

Table 131: Australian Relationship Type "Preferred Term" rules

Rule ID	Rule
AMT-ART-PT-1	Rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply.

7.3 Status Type concepts

7.3.1 Status Type Concepts definition

These concepts are used to identify the status of a concept and descriptions within the AMT.

7.3.2 Status Type Concepts descriptions

7.3.2.1 Status Type Concepts "Fully Specified Name" definition and rules

Definition

The Fully Specified Name of a Status Type follows the syntax:

```
Status Type FSN := Status_Name " (AU Status type)"
```

where the component parts are described as follows.

Table 132: Status Type Concepts "Fully Specified Name" description

Description Component	Description
Status_Name	The term used to describe the specific status type concept.
(AU status type)	The semantic tag used in the FSN of all Status Type concepts.

Table 133: Status Type Concepts "Fully Specified Name" rules

Rule ID	Rule
AMT-ST-FSN-1	Rules defined in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply.

7.3.2.2 Status Type "Preferred Term" definition and rules

Definition

The Preferred Term of a Status Type follows the syntax:

```
Status Type PT := Status_Name
```

where the component parts are described as follows.

Table 134: Status Type "Preferred Term" description

Description Component	Description
Status_Name	The term used to describe the specific status type concept.

Table 135: Status Type "Preferred Term" rules

Rule ID	Rule
AMT-STCPT-1	Rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply.

7.4 Characteristic Type concepts

7.4.1 Characteristic Type concepts definition

These concepts (expressed as Fully Specified Names) are used to identify the characteristic type of relationships within the AMT.

- Defining (characteristic type)
- Qualifier (characteristic type)
- Historical (characteristic type)
- Additional (characteristic type)

7.4.2 Characteristic Type concepts descriptions

7.4.2.1 Characteristic Type Concepts "Fully Specified Name" definition and rules

Definition

The Fully Specified Name of a Characteristic Type follows the syntax:

```
Characteristic Type FSN := Characteristic_Name
        " (characteristic type)"
```

where the component parts are described as follows.

Table 136: Characteristic Type Concepts "Fully Specified Name" description

Description Component	Description
Characteristic_Name	The term used to describe the specific Characteristic type concept.
(characteristic type)	The semantic tag used in the FSN of all Characteristic Type concepts.

Table 137: Characteristic Type Concepts "Fully Specified Name" rules

Rule ID	Rule
AMT-CT-FSN-1	Rules defined in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply.

7.4.2.2 Characteristic Type "Preferred Term" definition and rules

Definition

The Preferred Term of a Characteristic Type follows the syntax:

```
Characteristic Type PT := Characteristic_Name
```

where the component parts are described as follows.

Table 138: Characteristic Type "Preferred Term" description

Description Component	Description
Characteristic_Name	The term used to describe the specific Characteristic type concept.

Table 139: Characteristic Type "Preferred Term" rules

Rule ID	Rule
AMT-CT-PT-1	Rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply.

7.5 Refinability Type concepts

7.5.1 Refinability Type concepts definition

These concepts (expressed as Fully Specified Names) are used to identify the refinability type of relationships within the AMT.

- Not refinable (refinability type)
- Optional (refinability type)
- Mandatory (refinability type)

7.5.2 Refinability Type concepts descriptions

7.5.2.1 Refinability Type Concepts "Fully Specified Name" definition and rules

Definition

The Fully Specified Name of a Refinability Type follows the syntax:

```
Refinability Type FSN := Refinability_Name
         " (refinability type)"
```

where the component parts are described as follows.

Table 140: Refinability Type Concepts "Fully Specified Name" description

Description Component	Description
Refinability_Name	The term used to describe the specific Refinability type concept.
(refinability type)	The semantic tag used in the FSN of all Refinability Type concepts.

Table 141: Refinability Type Concepts "Fully Specified Name" rules

Rule ID	Rule
AMT-RT-FSN-1	Rules defined in Section 2.2.4.3.1 (Fully Specified Name Definition and Rules) apply.

7.5.2.2 Refinability Type "Preferred Term" definition and rules

Definition

The Preferred Term of a Refinability Type follows the syntax:

```
Refinability Type PT := Refinability_Name
```

where the component parts are described as follows.

Table 142: Refinability Type "Preferred Term" description

Description Component	Description
Refinability_Name	The term used to describe the specific Refinability type concept.

Table 143: Refinability Type "Preferred Term" rules

Rule ID	Rule
AMT-RT-PT-1	Rules defined in Section 2.2.4.3.2 (Preferred Term Definition and Rules) apply.

8 References

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8.2 IHTSDO

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8.3 Other

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

The Pharmaceutical Press, 2011, *Martindale: The Complete Drug Reference*. Available from: <http://www.medicinescomplete.com/mc/martindale/current/> (Subscription required.)

Appendix A: Capitalisation

A.1 Capitalisation rules

Table 144: 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-9.
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 B: Exception examples for MP and MPUU

As previously described in Section 3.2.1 (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.

Base	Salt
calcium	calcium gluconate
clodronate	clodronate sodium

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

Active Moiety	Compound
perindopril	perindopril arginine
antazoline	antazoline hydrochloride

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.

Salts described in Section B.1 are referred to as clinically significant salts.

B.1 Discernible therapeutic differences to the base

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)).
- 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.

Example:

- doxorubicin, pegylated liposomal

B.1.1 Current exception examples

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

- 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

B.2 Enantiomers

Enantiomers will be represented only if the enantiomers of a racemic mixture have proven significantly different therapeutic potencies, duration of action, onset of action, pharmacological targets or adverse reaction profiles. If, in the opinion of an appropriate expert body, prescribing and administration decisions should be made at the level of the modification to enantiomer, the Medicinal Product will represent the active enantiomer of a racemic mixture.

B.2.1 Current exception examples

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

- dexamphetamine
- dexchlorpheniramine
- dexpanthenol
- dextromethorphan
- dextropropoxyphene
- escitalopram
- esomeprazole
- levobunolol
- levobupivacaine
- levocabastine
- levocetirizine
- levodopa
- levonorgestrel

Appendix C: Ingredient naming conventions

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

C.1 Ingredients ending in "-ate"

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

Only the ingredients listed in the following table will remain unchanged.

Table 145: Exceptions

TGA Ingredient Name	AMT Ingredient Name
folinate	folinic acid

C.2 Clinically significant portion of ingredient name

Ingredients shall have the order of their name changed where necessary, so that the clinically significant part of the salt name is represented first. The table below shows some examples only, and is not considered to be exhaustive.

Table 146: Examples

TGA Ingredient Name	AMT Ingredient Name
calcium folinate	folinate calcium
disodium cocoamphodiacetate	cocoamphodiacetate disodium
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

C.3 Ingredient minus base name

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

Note: This section is under review. The following table contains examples only and is not exhaustive.

Table 147: Examples

Ingredient Name	IngredientMinusBase
ferric pyrophosphate	ferric pyrophosphate
ferrous fumarate	ferrous fumarate
metoclopramide hydrochloride monohydrate	monohydrate
oestrone sulfate sodium	oestrone sulfate sodium
pamidronate disodium	pamidronate disodium
piperazine oestrone sulfate	piperazine sulfate
potassium salt unspecified	salt unspecified
sodium phosphate monobasic	sodium phosphate monobasic

C.4 Waters of hydration

Waters of hydration shall only be expressed for each ingredient in the Fully Specified Name where hydration is present and the salt is deemed to be clinically significant or clinically relevant (according to Appendix B:). 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

C.5 Insulins

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

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

C.6 Medicinal Product Preferred Term sequence of ingredients

The following table provides an incomplete summary of those medicinal products where the sequence of ingredients is not alphabetical. This may be an exception based on one of the following:

- Clinical practice.
- One or more of the ingredients has no inherent action in its own right.
- 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: This exception list is incomplete and should be treated as being indicative only.

Table 148: Exceptions

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

Alphabetical order MP	Exception order MP	Trade Product or Trade Product Group example
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)
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

Alphabetical order MP	Exception order MP	Trade Product or Trade Product Group example
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
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

Alphabetical order MP	Exception order MP	Trade Product or Trade Product Group example
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)
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
dydrogesterone + oestradiol	oestradiol + dydrogesterone	Femoston
emtricitabine + tenofovir	tenofovir + emtricitabine	Truvada
enalapril + lercanidipine	lercanidipine + enalapril	Zan-Extra

Alphabetical order MP	Exception order MP	Trade Product or Trade Product Group example
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
gramicidin + neomycin sulfate + nystatin + triamcinolone	triamcinolone + neomycin sulfate + gramicidin + nystatin	Kenacomb
hydrochlorothiazide + irbesartan	irbesartan + hydrochlorothiazide	Karvezide
hydrochlorothiazide + olmesartan	olmesartan + hydrochlorothiazide	Olmetec Plus

Alphabetical order MP	Exception order MP	Trade Product or Trade Product Group example
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
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 D: Examples of products with more than three ingredients

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

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 149: Examples

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 E: General strength formats

E.1 General rules

Table 150: 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. (Therapeutic Goods Order No. 69 – General requirements for labels for medicines).
AMT-APP-STR-2	The strength units will be consistent with the Unit of Measure (AU qualifier) reference set.
AMT-APP-STR-3	Note that any overage contained in the product to allow the formulated amount to be administered is not specified.

Rule ID	Description
AMT-APP-STR-4	In general, the strength of an active ingredient should be expressed by a number between one and 999 metric units. If the number of units is less than one, 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 Pharmaceutical Ingredient and/or BOSS and/or base according to the above rule, all strength units for the ingredient will 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. Strengths of ingredients less than one microgram will be reviewed on a case-by-case basis to ensure the represented strength conforms to current clinical practice (e.g. calcitriol is expressed as 0.25 micrograms 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"). Where the value for volume is less than one millilitre it will not be converted (i.e. to conform to current clinical practice these volumes will not be expressed as microlitres). Where the molar value is less than one micromole it will not be converted (i.e. to conform to current clinical practice these values will not be expressed as nanomoles). 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 (i.e. it will continue to exist as 0.5 IR).
AMT-APP-STR-5	A space will be inserted between the strength value and strength unit of measure. This space must be a non-breaking space to ensure that the strength value and strength unit expressions are always kept together.
AMT-APP-STR-6	Strength units of measure will be expressed as singular if the value is less than or equal to unity, and will be expressed as plural if the value is greater than unity. (Note that the use of plurals is not yet fully implemented.)

Rule ID	Description
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

E.1.1 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 151: Examples of exceptions and associated rules

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

Medication Form	Rules
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 for
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 for
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, for example: • chlorhexidine gluconate 1.2 mg/mL sachet
Continuous solid unit doses – granules, powder.	Granules, powder Strength is to be expressed as the weight of the active ingredient per container, for example: • sodium bicarbonate 1.76 g/4 g sachet
Continuous semi-solid preparations – creams, gels, ointments	Strength is to be expressed as a percentage, for example: • 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), for example: • 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, for example: • erythromycin 200 mg/5 mL oral liquid • cyclosporin 100 mg/mL oral liquid Note: where a powder for oral suspension is labelled in terms of the reconstituted form, the strength will be represented as the amount of active ingredient in the reconstituted dose volume, for example: • amoxycillin 250 mg/5 mL oral liquid: powder for
Continuous solid preparations – granules, powders	Strength will usually be expressed as weight per weight or weight per volume, for example: • psyllium husk powder 535 mg/g powder: oral
Patches	Strength will be expressed as the amount of active drug released over a stated time, for example: • oestradiol 25 microgram/24 hours patch
Inhalers and sprays – inhalers and sprays, pressurised inhalers, dry powder inhalers, nasal spray, sublingual spray	Metered dose inhalers: The strength is expressed as the amount (weight) per actuation, for example: • beclomethasone 50 microgram/actuation inhalation: powder for Other inhalers: The strength is expressed as per mL or per mg, whichever is appropriate to the form of the inhaler.
Implants	The strength is expressed either as the amount per implant or device, for example: • oestradiol 20 mg implant
Dry powder injections	The strength is expressed as the amount per vial (usually as a weight) , for example: • amoxycillin 500 mg injection: powder for

E.2 Dual representation

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

- adrenaline for parenteral use, 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); and
- 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 F: Units of Measure

F.1 Rules

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

Table 152: 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)

F.2 Preferred Terms

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

Note: This is yet to be implemented.

Table 153: Examples

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

F.3 Units of Measure

The Units of Measure list below is derived from TGA Units.

Table 154: Area

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

Table 155: 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 156: Mass

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

Table 157: 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 158: Molecular equivalents

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

Table 159: Time

Description	Abbreviation
hour unit	hour

Table 160: Type Of International Units

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

Table 161: Type Of Pharmacopoeial Units

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

Table 162: Volume

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

F.4 Proportions

The Units of Measure list below is derived from TGA Expressions of Proportion.

Table 163: Proportions

Description	Unit/Proportion
kilogram/litre	kg/L
gram/gram	g/g
gram/millilitre	g/mL
gram/litre	g/L
milligram/actuation	mg/actuation
milligram/gram	mg/g
milligram/milligram	mg/mg
milligram/millilitre	mg/mL
milligram/litre	mg/L
milligram/24 hour	mg/24 h
microgram/actuation	microgram/actuation
microgram/gram	microgram/g
microgram/millilitre	microgram/mL
microgram/litre	microgram/L
microgram/24 hour	microgram/24 h
nanogram/gram	nanogram/g
nanogram/millilitre	nanogram/mL

Description	Unit/Proportion
litre/litre	L/L
millilitre/millilitre	mL/mL
millilitre/litre	mL/L
millilitre/gram	mL/g
microlitre/gram	microlitre/g
microlitre/millilitre	microlitre/mL
microlitre/litre	microlitre/L
nanolitre/millilitre	nanolitre/mL
mole/litre	mol/L
millimole/millilitre	mmol/mL
millimole/litre	mmol/L
micromole/millilitre	micromole/mL
micromole/litre	micromole/L
unit/millilitre	unit/mL
unit/gram	unit/g
unit/milligram	unit/mg
unit/microgram	unit/microgram

F.5 Descriptive Units of Measure

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

For example:

1 ampoule
5 ampoules

1 metered dose
120 metered doses

F.5.1 Valid descriptive units of measure

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

- %
- % 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
- 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
- strip
- suppository
- syringe
- system
- tablet
- tube
- unit dose
- vial
- wafer

Appendix G: Form

The form will be derived from the TGA Approved Dosage Forms, 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. Note also that the TGA term "capsule: modified release" will be used when it is not possible to specifically apply this term. This also applies to "tablet: sustained release".

Table 164: Examples

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

Fully Specified Name	Description	Preferred Term
bandage: short stretch	A bandage which has a short degree of stretch.	bandage: short stretch
bandage: small B/C size	A bandage available in a small B/C size.	bandage: small B/C size
bandage: small limb size	A bandage available in a small limb size.	bandage: small limb size
bandage: small size	A bandage available in a small size.	bandage: small size
bandage: straight	A bandage available in a straight length.	bandage: straight
bandage: triangular	A square of cloth folded or cut in the shape of a triangle. It may be used as a sling, a cover, or a thick pad to control bleeding.	bandage: triangular
bandage: two layer	A bandage made up of two layers.	bandage: two layer
bandage: XX/large size	A bandage available in an XX/large size.	bandage: XX/large size
bar	A solid preparation containing one or more active ingredients in bar form.	bar
bar: soap	A solid preparation derived from the action of a solution of alkali on fats or oils of animal or vegetable origin and containing one or more active ingredients in bar form.	bar: soap
block	A solid (food) substance usually chocolate, serving as a vehicle for one or more active ingredients.	block
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

Fully Specified Name	Description	Preferred Term
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
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

Fully Specified Name	Description	Preferred Term
DRESSING	A clean or sterile covering applied directly to a wound or diseased tissue.	
dressing	A clean or sterile covering applied directly to a wound or diseased tissue.	dressing
dressing: hydroactive	A dressing for wounds with medium to high exudate, generally multi-layered highly absorbent polymer, with a surface adhesive and a waterproof outer layer. Exudate fluid is trapped within the dressing to maintain a moist environment.	dressing: hydroactive
dressing: island	A dressing with a non-adherent wound pad, which absorbs wound exudates without sticking to the wound, surrounded by an adhesive area extending on all sides of the pad.	dressing: island
dressing: medicated	A dressing containing one or more active ingredients.	dressing: medicated
dressing: sacral	A dressing intended to be applied directly to the sacral area.	dressing: sacral
dressing: tulle	A dressing composed of a soft fine weave or net which is generally non-adherent.	dressing: tulle
DRUG DELIVERY SYSTEM	A system containing active ingredients for releasing or targeting these ingredients to the body at a constant rate over a period of time.	
drug delivery system	A system containing active ingredients for releasing or targeting these ingredients to the body at a constant rate over a period of time.	drug delivery system
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.	

Fully Specified Name	Description	Preferred Term
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
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

Fully Specified Name	Description	Preferred Term
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
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

Fully Specified Name	Description	Preferred Term
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

Fully Specified Name	Description	Preferred Term
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.	
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-coated	Granules which resist the action of gastric fluid but are attacked by intestinal fluid to release the active ingredients.	granules: enteric-coated
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

Fully Specified Name	Description	Preferred Term
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
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

Fully Specified Name	Description	Preferred Term
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.	
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

Fully Specified Name	Description	Preferred Term
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. E.g. aroma therapy oils can be used for inhalation, topically or orally.	liquid: multi-purpose
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

Fully Specified Name	Description	Preferred Term
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
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

Fully Specified Name	Description	Preferred Term
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

Fully Specified Name	Description	Preferred Term
oral gel	A semi-solid preparation usually consisting of a solution or dispersion in a suitable base, prepared with the aid of a suitable gelling agent, intended for oral administration or use within the oral cavity.	oral gel
ORAL LIQUID	A preparation usually consisting of a solution, a suspension or an emulsion of one or more active ingredients in a suitable vehicle. They are intended to be swallowed either undiluted or after dilution.	
oral liquid	A preparation usually consisting of a solution, a suspension or an emulsion of one or more active ingredients in a suitable vehicle. They are intended to be swallowed either undiluted or after dilution.	oral liquid
oral liquid: emulsion	A dispersion of an oily liquid in an aqueous liquid either of which may contain dissolved solids, in which the aqueous liquid forms the continuous phase. Solids may be suspended in the emulsion.	oral liquid: emulsion
oral liquid: for freezing	A preparation usually consisting of a solution of one or more active ingredients in a suitable vehicle, intended to be frozen and then sucked as an iceblock until consumed.	oral liquid: for freezing
oral liquid: powder for	One or more active ingredients in a dry form to be reconstituted for use as an oral liquid.	oral liquid: powder for
oral liquid: solution	A liquid preparation composed of or containing one or more active ingredients dissolved in a suitable vehicle.	oral liquid: solution
oral liquid: suspension	A liquid preparation containing one or more active ingredients dispersed as solid particles throughout a liquid phase. In addition it may contain other active ingredients which are dissolved.	oral liquid: suspension
oral 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.	

Fully Specified Name	Description	Preferred Term
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
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 is intended to produce a local effect by diffusion of the active ingredients to the skin.	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.	

Fully Specified Name	Description	Preferred Term
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 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 vaginal capsule.	pessary: shell
POWDER	A mixture of solid, finely divided substances containing one or more active ingredients intended for internal or external use.	
powder	A mixture of solid, finely divided substances containing one or more active ingredients intended for internal or external use.	powder
powder: dusting	A finely divided powder composed of or containing one or more active ingredients intended for application to the skin, mucous membranes or wounds.	powder: dusting
powder: dusting-sterile	A sterile finely divided powder composed of or containing one or more active ingredients intended for application to the skin, mucous membranes or wounds.	powder: dusting sterile
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

Fully Specified Name	Description	Preferred Term
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
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

Fully Specified Name	Description	Preferred Term
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
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

Fully Specified Name	Description	Preferred Term
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-coated	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-coated
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

Fully Specified Name	Description	Preferred Term
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
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 H: Dose Form and Associated Proprietary Form

Some manufacturers have dosage forms with a name that is specific to their product(s). This appendix lists these Proprietary Forms and links them to AMT dosage forms.

Note: These lists are not exhaustive and may be added to as new proprietary forms become available.

Table 165: Examples of Dose Forms in AMT

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 166: Examples of Proprietary Forms in AMT

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 I: 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.

Table 167: Pack Quantity Unit of Measure examples

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
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

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
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
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

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
eye and ear	g or mL (dependent on form)	g or mL (dependent on form)
eye and ear drops	mL	mL
eye 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
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[5]	g or sachet	g or sachets
granules: effervescent[6]	g or sachet	g or sachets
granules: enteric-coated[7]	g or sachet	g or sachets

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

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

[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'.

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
granules: modified release[8]	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)
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)

[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'.

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
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
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

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
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
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

Fully Specified Name	Pack Quantity Unit of Measure (Singular)	Pack Quantity Unit of Measure (Plural)
solution: irrigation	mL	mL
solution: perfusion	mL	mL
solution: peritoneal dialysis	mL	mL
solution: powder for	mL	mL
solution: powder for dialysis	mL	mL
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-coated	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 J: Trade Product Unit of Use flavours

The list of flavours used to populate the terminology will be derived from product descriptions provided by the sponsor. Flavours will only be included in the TPUU, TPP and CTPP where they are necessary to differentiate between two or more flavours of exactly the same concept.

Note: This list is not exhaustive and additional flavours will be added as required.

- almond
- aniseed
- apple
- apple and blackcurrant
- apple and pear
- apricot
- asparagus
- banana
- berry
- blackcurrant
- butterscotch
- cappuccino
- caramel
- cherry
- cherry and vanilla
- chicken
- chicken and mushroom
- chocolate
- chocolate mint
- citrus
- citrus burst
- citrus cola
- classic flavour
- coffee
- cola
- cranberry
- double mint
- egg nog
- eucalyptus and menthol
- forest fruits
- fresh mint
- fruit
- fruit(s) of the forest
- grapefruit
- honey
- honey and lemon
- leek and potato
- lemon
- lemon and menthol
- lemon lime
- liquorice
- melon
- menthol
- menthol and eucalyptus
- mint
- mint fresh
- mixed fruit
- mocha
- mushroom
- natural flavour
- neutral flavour
- nut
- orange
- orange and lemon
- orange and pineapple
- orange citrus
- original flavour
- peach
- peach and orange
- pear and cherry
- peppermint
- pineapple
- plain
- plum

- raspberry
- raspberry and blackcurrant
- regular flavour
- savoury tomato
- spearmint
- strawberry
- strawberry and raspberry
- summer fruits
- toffee
- tropical
- tropical fruits
- tropical surprise
- tutti frutti
- unflavoured
- vanilla
- vegetable cream
- wild berry
- wild berry and hot orange

Appendix K: Container Types

Container Types will be derived from TGA Approved Container Types as listed below.

Note: Additional container types will be added if required.

Table 168: Container Type examples

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 a disease being "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*) 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*.

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 169: Strength examples

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 AMT and those listed on the PBS, and as such, the pack size is representative of the PBS quantity.

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 Braun, Lesley and Cohen, Marc (2007), *Herbs & Natural Supplements: An Evidence-based Guide* (2nd ed.). 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.

Example:

- "Vaccinium myrtillus" is described by its common name of "bilberry".

Appendix M: Fully Specified Name (FSN) examples

Table 170: Fully Specified Name examples

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

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
• ganciclovir (medicinal product)	• ganciclovir 4.5 mg implant (medicinal product unit of use)	• ganciclovir 4.5 mg implant, 1 implant (medicinal product pack)	• Vitrasert (trade product)	• Vitrasert (ganciclovir 4.5 mg) implant (trade product unit of use)	• Vitrasert (ganciclovir 4.5 mg) implant, 1 implant (trade product pack)	• Vitrasert (ganciclovir 4.5 mg) implant, 1 implant, sachet (containered trade product pack)
• carboplatin (medicinal product)	• carboplatin 150 mg / 15 mL injection, 15 mL vial (medicinal product unit of use)	• carboplatin 150 mg / 15 mL injection, 1 x 15 mL vial (medicinal product pack)	• Carboplatin Ebewe (trade product)	• Carboplatin Ebewe (carboplatin 150 mg / 15 mL) injection, 15 mL vial (trade product unit of use)	• Carboplatin Ebewe (carboplatin 150 mg / 15 mL) injection, 1 x 15 mL vial (trade product pack)	• Carboplatin Ebewe (carboplatin 150 mg / 15 mL) injection, 1 x 15 mL vial, vial (containered trade product pack)
• frusemide (medicinal product)	• frusemide 10 mg / 1 mL oral liquid, 1 mL measure (medicinal product unit of use)	• frusemide 10 mg / 1 mL oral liquid, 30 mL (medicinal product pack)	• Lasix (trade product)	• Lasix (frusemide 10 mg / 1 mL) oral liquid: solution, 1 mL measure (trade product unit of use)	• Lasix (frusemide 10 mg / 1 mL) oral liquid: solution, 30 mL (trade product pack)	• Lasix (frusemide 10 mg / 1 mL) oral liquid: solution, 30 mL, bottle (containered 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 (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 (trade product pack)	• Nilstat cream pessaries (nystatin 100000 international units) pessary: shell, 15 pessaries, bottle (containered trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
• ondasetron (medicinal product)	• ondansetron 4 mg wafer (medicinal product unit of use)	• ondansetron 4 mg wafer, 10 wafers (medicinal product pack)	• Zofran (trade product)	• Zofran Zydis (ondansetron 4 mg) wafer (trade product unit of use)	• Zofran Zydis (ondansetron 4 mg) wafer, 10 wafers (trade product pack)	• Zofran Zydis (ondansetron 4 mg) wafer, 10 wafers, blister pack (containered 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 (trade product pack)	• Amoxil (amoxycillin (as trihydrate) 500 mg) capsule: hard, 20 capsules, blister pack (containered trade product pack)
• salbutamol (medicinal product)	• salbutamol 100 microgram / 1 actuation inhalation (medicinal product unit of use)	• salbutamol 100 microgram / 1 actuation inhalation, 200 actuations (medicinal product pack)	• Airomir (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 (trade product pack)	• Airomir inhaler (salbutamol (as sulfate) 100 microgram / 1 actuation) inhalation: pressurised, 200 actuations, aerosol can: metered dose (containered trade product pack)
• 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 (trade product pack)	• Austrapen (ampicillin (as sodium) 500 mg) injection: powder for, 5 x 500 mg vials, vial (containered trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
• hydrocortisone (medicinal product) • hydrocortisone sodium succinate (medicinal product) • inert substance (medicinal product)	• hydrocortisone 100 mg | hydrocortisone sodium succinate 134 mg injection, vial (medicinal product unit of use) • inert substance diluent, vial (medicinal product unit of use)	• hydrocortisone 100 mg | hydrocortisone sodium succinate 134 mg injection [1 x 100 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack (medicinal product pack)	• Solu-Cortef (trade product)	• Solu-Cortef ACT-O-VIAL (hydrocortisone (as sodium succinate) 100 mg) injection: powder for, vial (trade product unit of use) • Solu-Cortef ACT-O-VIAL (inert substance) diluent, vial (trade product unit of use)	• Solu-Cortef ACT-O-VIAL (hydrocortisone (as sodium succinate) 100 mg) injection: powder for [1 x 100 mg vial] (&) (inert substance) diluent [1 x 2 mL vial], 1 pack (trade product pack)	• Solu-Cortef ACT-O-VIAL (hydrocortisone (as sodium succinate) 100 mg) injection: powder for [1 x 100 mg vial] (&) (inert substance) diluent [1 x 2 mL vial], 1 pack, dual chamber composite pack (containered 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 (trade product pack)	• Ceclor (cefaclor (as monohydrate) 125 mg / 5 mL) oral liquid: powder for, 100 mL, bottle (containered trade product pack)
• diclofenac (medicinal product)	• diclofenac 46.54 mg tablet (medicinal product unit of use) • diclofenac 46.54 mg | diclofenac sodium 50 mg tablet (medicinal product unit of use)	• diclofenac 46.54 mg | diclofenac sodium 50 mg tablet, 50 tablets (medicinal product pack)	• Voltaren (trade product)	• Voltaren 50 (diclofenac sodium 50 mg) tablet: enteric-coated, 1 tablet (trade product unit of use)	• Voltaren 50 (diclofenac sodium 50 mg) tablet: enteric-coated, 50 tablets (trade product pack)	• Voltaren 50 (diclofenac sodium 50 mg) tablet: enteric-coated, 50 tablets, bottle (containered trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
• terbinafine (medicinal product)	• terbinafine 8.89 mg / 1 g cream (medicinal product unit of use) • 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 (trade product pack)	• Lamisil (terbinafine hydrochloride 10 mg / 1 g) cream, 15 g, tube (containered trade product pack)
• budesonide + eformoterol (medicinal product)	• budesonide 100 microgram / 1 actuation + eformoterol 4.92 microgram / 1 actuation inhalation (medicinal product unit of use) • budesonide 100 microgram / 1 actuation + eformoterol 4.92 microgram / 1 actuation | eformoterol fumarate dihydrate 6 microgram / 1 actuation inhalation (medicinal product unit of use)	• budesonide 100 microgram / 1 actuation + eformoterol 4.92 microgram / 1 actuation | eformoterol fumarate dihydrate 6 microgram / 1 actuation inhalation, 120 actuations (medicinal product pack)	• Symbicort (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 (trade product pack)	• Symbicort Turbuhaler 100/6 (budesonide 100 microgram / 1 actuation + eformoterol fumarate dihydrate 6 microgram / 1 actuation) inhalation: powder for, 120 actuations, inhaler: dry powder (containered trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
• fluphenazine (medicinal product) • 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 for, 0.5 mL ampoule (trade product unit of use)	• Modecate (fluphenazine decanoate 12.5 mg / 0.5 mL) injection: solution for, 5 x 0.5 mL ampoules (trade product pack)	• Modecate (fluphenazine decanoate 12.5 mg / 0.5 mL) injection: solution for, 5 x 0.5 mL ampoules, ampoule (containered trade product pack)
• sodium (medicinal product) • 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 (trade product pack)	• Sodium Chloride 0.9% (Baxter) (sodium chloride 9 g / 1000 mL) injection: intravenous infusion, 1 x 1000 mL bag, bag (containered trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
• ipratropium (medicinal product)	• ipratropium 403.1 microgram / 1 mL, inhalation, 1 mL ampoule (medicinal product unit of use) • ipratropium 403.1 microgram / 1 mL | ipratropium bromide anhydrous 500 microgram / 1 mL inhalation, 1 mL ampoule (medicinal product unit of use)	• ipratropium 403.1 microgram / 1 mL | ipratropium bromide anhydrous 500 microgram / 1 mL inhalation, 30 x 1 mL ampoules (medicinal product pack)	• Atrovent (trade product)	• Atrovent adult unit dose vial (ipratropium bromide anhydrous (as bromide monohydrate) 500 microgram / 1 mL) inhalation: solution for, 1 mL ampoule (trade product unit of use)	• Atrovent adult unit dose vial (ipratropium bromide anhydrous (as bromide monohydrate) 500 microgram / 1 mL) inhalation: solution for, 30 x 1 mL ampoules (trade product pack)	• Atrovent adult unit dose vial (ipratropium bromide anhydrous (as bromide monohydrate) 500 microgram / 1 mL) inhalation: solution for, 30 x 1 mL ampoules, ampoule (containered 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 (trade product pack)	• Combivir (lamivudine 150 mg + zidovudine 300 mg) tablet: film-coated, 60 tablets, bottle (containered trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP 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 (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 (trade product pack)	• Caduet 10/20 (amlodipine (as besylate) 10 mg + atorvastatin (as calcium) 20 mg) tablet: film-coated, 30 tablets, blister pack (containered trade product pack)
• antazoline + naphazoline (medicinal product)	• antazoline 4.1 mg / 1 mL + naphazoline 426 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 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 mL | naphazoline hydrochloride 500 microgram / 1 mL eye drops, 15 mL (medicinal product pack)	• Albalon-A (trade product)	• Albalon-A Liquifilm 0.5% / 0.05% (antazoline phosphate 5 mg / 1 mL + naphazoline hydrochloride 500 microgram / 1 mL) eye drops: solution (trade product unit of use)	• Albalon-A Liquifilm 0.5% / 0.05% (antazoline phosphate 5 mg / 1 mL + naphazoline hydrochloride 500 microgram / 1 mL) eye drops: solution, 15 mL (trade product pack)	• Albalon-A Liquifilm 0.5% 0.05% (antazoline phosphate 5 mg / 1 mL + naphazoline hydrochloride 500 microgram / 1 mL) eye drops: solution, 15 mL, bottle (containered trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
• codeine + paracetamol (medicinal product)	• codeine 23.43 mg + paracetamol 500 mg tablet (medicinal product unit of use) • 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 (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 (trade product pack)	• Panadeine Forte (codeine phosphate 30 mg + paracetamol 500 mg) tablet: uncoated, 20 tablets, blister pack (containered trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
• 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 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 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)	• Triphasil (trade product)	• 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 (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 (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)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP 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)	• Brevinor (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] (trade product pack)	• Brevinor 21 day (ethinyloestradiol 35 microgram + norethisterone 500 microgram) tablet: uncoated, 84 tablets [4 x 21 tablets], blister pack (containered trade product pack)
• norethisterone + oestradiol (&) oestradiol (medicinal product) • norethisterone acetate + oestradiol (&) oestradiol (medicinal product) • norethisterone + oestradiol (medicinal product) • 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 (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, dial dispenser pack (containered trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
• calcium (&) etidronic acid (medicinal product) • calcium carbonate (&) etidronate disodium (medicinal product) • calcium (medicinal product) • calcium carbonate (medicinal product) • etidronic acid (medicinal product) • etidronate disodium (medicinal product)	• etidronic acid 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] (&) etidronic acid 164.8 mg | etidronate disodium 200 mg tablet [28 tablets], 104 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 (trade product pack)	• 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)
• 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)	• Risperdal (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 (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, composite pack (containered trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP 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)	• Somatuline (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 (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, composite pack (containered trade product pack
• 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)	• 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 (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, composite pack (containered trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
• calcium + chloride + polygeline + potassium + sodium (medicinal product)	• calcium 125 mg / 500 mL + chloride 2.574 g / 500 mL + polygeline 17.5 g / 500 mL + potassium 99.71 mg / 500 mL + sodium 1.67 g / 500 mL injection, 500 mL bottle (medicinal product unit of use)	• calcium 125 mg / 500 mL + chloride 2.574 g / 500 mL + polygeline 17.5 g / 500 mL + potassium 99.71 mg / 500 mL + sodium 1.67 g / 500 mL injection, 1 x 500 mL bottle (medicinal product pack)	• 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 (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, bottle (containered trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
• peginterferon alfa-2b (medicinal product) • ribavirin (medicinal product) • inert substance (medicinal product) • peginterferon alfa-2b (&) ribavirin (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)	• Rebetrol (trade product) • PEG-Intron (trade product) • Pegatron (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 (trade product pack)	• 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)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
• calcium + potassium + sodium (medicinal product) • calcium chloride + potassium chloride + sodium chloride (medicinal product)	• calcium 87.04 mg / 1000 mL | calcium chloride 320 mg / 1000 mL + potassium 157.3 mg / 1000 mL | potassium chloride 300 mg / 1000 mL + sodium 3.83g / 1000 mL | sodium chloride 8.6 g / 1000 mL injection, 1000 mL bag (medicinal product unit of use)	• calcium 87.04 mg / 1000 mL | calcium chloride 320 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)	• Compound Sodium Chloride (Pharmatel Fresenius Kabi) (trade product)	• Compound Sodium Chloride (Ringer's) (Pharmatel Fresenius Kabi) (calcium chloride 320 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)	• Compound Sodium Chloride (Ringer's) (Pharmatel Fresenius Kabi) (calcium chloride 320 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)	• Compound Sodium Chloride (Ringer's) (Pharmatel Fresenius Kabi) (calcium chloride 320 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)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
• esomeprazole (medicinal product) • clarithromycin (medicinal product) • amoxycillin (medicinal product) • amoxycillin (&) clarithromycin (&) esomeprazole (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 (trade product) • Klacid (trade product) • Amoxil (trade product) • Nexium Hp 7 (trade product)	• Nexium (esomeprazole (as magnesium trihydrate) 20 mg) tablet: enteric-coated, 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 (trade product unit of use)	• Nexium Hp 7 (amoxycillin (as trihydrate) 500 mg) capsule [28 capsules] (&) (clarithromycin 500 mg) tablet: film-coated [14 tablets] (&) (esomeprazole (as magnesium trihydrate) 20 mg) tablet: enteric-coated [14 tablets], 1 pack (trade product pack)	• Nexium Hp 7 (amoxycillin (as trihydrate) 500 mg) capsule [28 capsules] (&) (clarithromycin 500 mg) tablet: film-coated [14 tablets] (&) (esomeprazole (as magnesium trihydrate) 20 mg) tablet: enteric-coated [14 tablets], 1 pack, composite pack (containered trade product pack)
• mirtazapine (medicinal product)	• mirtazapine 15 mg tablet (medicinal product unit of use)	• mirtazapine 15 mg tablet, 30 tablets (medicinal product pack)	• Avanza (trade product)	• Avanza (mirtazapine 15 mg) SolTab, 1 tablet (trade product unit of use)	• Avanza (mirtazapine 15 mg) SolTab, 30 tablets (trade product pack)	• Avanza (mirtazapine 15 mg) SolTab, 30 tablets, blister pack (containered trade product pack)

MP FSN	MPUU FSN	MPP FSN	TP FSN	TPUU FSN	TPP FSN	CTPP FSN
• vinblastine (medicinal product)	• vinblastine 8.92 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, 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 (trade product pack)	• Vinblastine Sulfate (DBL) (vinblastine sulfate 10 mg / 10 mL) injection: solution, 5 x 10 mL vials, vial (containered trade product pack)

Appendix N: Preferred Term (PT) examples

Table 171: Preferred Term examples

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
• amorolfine	• amorolfine 5% (50 mg/mL) application	• amorolfine 5% (50 mg/mL) application, 5 mL	• Loceryl	• Loceryl Nail Lacquer (amorolfine (as hydrochloride) 5% (50 mg/mL)) application	• Loceryl Nail Lacquer 5% (50 mg/mL) application, 5 mL	• Loceryl Nail Lacquer 5% (50 mg/mL) application, 5 mL, bottle
• oestradiol	• oestradiol 100 microgram/ 24 hours patch	• oestradiol 100 microgram/ 24 hours patch, 8	• Estraderm	• Estraderm (oestradiol 100 microgram/ 24 hours) patch	• Estraderm 100 microgram/ 24 hours patch, 8	• Estraderm 100 microgram/ 24 hours patch, 8, sachet
• mesalazine	• mesalazine 500 mg granules: modified release, sachet	• mesalazine 500 mg granules: modified release, 100 x 500 mg sachets	• Salofalk	• Salofalk (mesalazine 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 (ganciclovir 4.5 mg) implant	• Vitrasert 4.5 mg implant, 1	• Vitrasert 4.5 mg implant, 1, sachet
• carboplatin	• carboplatin 150 mg/15 mL injection, vial	• carboplatin 150 mg/15 mL injection, 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 (frusemide 10 mg/mL) oral liquid solution	• Lasix 10 mg/mL oral liquid solution, 30 mL	• Lasix 10 mg/mL oral liquid solution, 30 mL, bottle

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
• nystatin	• nystatin 100 000 units pessary	• nystatin 100 000 units pessary, 15	• Nilstat	• Nilstat cream pessaries (nystatin 100 000 units), 1 pessary	• Nilstat cream pessaries 100 000 units, 15 pessaries	• Nilstat cream pessaries 100 000 units, 15 pessaries, bottle
• ondasetron	• ondansetron 4 mg wafer	• ondansetron 4 mg wafer, 10	• Zofran	• Zofran Zydis (ondansetron 4 mg) wafer	• Zofran Zydis 4 mg wafer, 10	• Zofran Zydis 4 mg wafer, 10, blister pack
• amoxycillin	• amoxycillin 500 mg capsule	• amoxycillin 500 mg capsule, 20	• Amoxil	• Amoxil (amoxycillin (as trihydrate) 500 mg) capsule: hard, 1 capsule	• Amoxil 500 mg capsule: hard, 20 capsules	• Amoxil 500 mg capsule: hard, 20 capsules, blister pack
• salbutamol	• salbutamol 100 microgram/ actuation inhalation	• salbutamol 100 microgram/ actuation inhalation, 200 actuations	• Airomir	• Airomir inhaler (salbutamol (as sulfate) 100 microgram/ actuation) inhalation: pressurised	• Airomir inhaler 100 microgram/ actuation inhalation: pressurised, 200 actuations	• Airomir inhaler 100 microgram/ actuation inhalation: pressurised, 200 actuations, metered dose aerosol can
• ampicillin	• ampicillin 500 mg injection, vial	• ampicillin 500 mg injection, 5 x 500 mg vials	• Austrapen	• Austrapen (ampicillin (as sodium) 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, vial
• hydrocortisone • hydrocortisone sodium succinate • inert substance	• hydrocortisone (as sodium succinate) 100 mg injection, vial • inert substance diluent, vial	• hydrocortisone (as sodium succinate) 100 mg injection [1 x 100 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack	• Solu-Cortef	• Solu-Cortef ACT-O-VIAL (hydrocortisone (as sodium succinate) 100 mg) injection: powder for, vial • Solu-Cortef ACT-O-VIAL diluent, vial	• Solu-Cortef ACT-O-VIAL (1 x 100 mg vial), 1 pack	• Solu-Cortef ACT-O-VIAL (1 x 100 mg vial), 1 pack, dual chamber composite pack

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
• cefaclor	• cefaclor 125 mg/5 mL oral liquid: powder for	• cefaclor 125 mg/5 mL oral liquid: powder for, 100 mL	• Ceclor	• Ceclor (cefaclor (as monohydrate) 125 mg/5 mL) oral liquid: powder for	• Ceclor 125 mg/5 mL oral liquid: powder for, 100 mL	• Ceclor 125 mg/5 mL oral liquid: powder for, 100 mL, bottle
• diclofenac	• diclofenac 46.54 mg tablet • diclofenac sodium 50 mg tablet	• diclofenac sodium 50 mg tablet, 50	• Voltaren	• Voltaren (diclofenac sodium 50 mg) tablet: enteric-coated, 1 tablet	• Voltaren 50 mg tablet: enteric-coated, 50 tablets	• Voltaren 50 mg tablet: enteric-coated, 50 tablets, bottle
• terbinafine	• terbinafine 8.89 mg/g cream • terbinafine hydrochloride 1% (10 mg/g) cream	• terbinafine hydrochloride 1% (10 mg/g) cream, 15 g	• Lamisil	• Lamisil (terbinafine hydrochloride 1% (10 mg/g)) cream	• Lamisil 1% (10 mg/g) cream, 15 g	• Lamisil 1% (10 mg/g) cream, 15 g, tube
• budesonide + eformoterol	• budesonide 100 microgram/ actuation + eformoterol 4.92 microgram/ actuation inhalation • budesonide 100 microgram + eformoterol fumarate dihydrate 6 microgram/ actuation inhalation	• budesonide 100 microgram/ actuation + eformoterol fumarate dihydrate 6 microgram/ actuation inhalation, 120 actuations	• Symbicort	• Symbicort Turbuhaler 100/6 (budesonide 100 microgram/ actuation + eformoterol fumarate dihydrate 6 microgram/ actuation) inhalation: powder for	• Symbicort Turbuhaler 100/6 inhalation: powder for, 120 actuations	• Symbicort Turbuhaler 100/6 inhalation: powder for, 120 actuations, dry powder inhaler
• fluphenazine • 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 (fluphenazine decanoate 12.5 mg/0.5 mL) injection: solution for, ampoule	• Modecate 12.5 mg/0.5 mL injection: solution for, 5 x 0.5 mL ampoules	• Modecate 12.5 mg/0.5 mL injection: solution for, 5 x 0.5 mL ampoules

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
• sodium • 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) (sodium chloride 0.9% (9 g/1000 mL)) intravenous infusion, bag	• Sodium Chloride (Baxter) 0.9% (9 g/1000 mL) intravenous infusion, 1 x 1000 mL bag	• Sodium Chloride (Baxter) 0.9% (9 g/1000 mL) intravenous infusion, 1 x 1000 mL bag AHB 1324
• ipratropium	• ipratropium 403.1 microgram / mL inhalation, ampoule • ipratropium bromide anhydrous 500 microgram/ mL inhalation, ampoule	• ipratropium bromide anhydrous 500 microgram/ mL inhalation, 30 x 1 mL ampoules	• Atrovent	• Atrovent adult unit dose vial (ipratropium bromide anhydrous (as bromide monohydrate) 500 microgram/ mL inhalation: solution for, ampoule	• Atrovent adult unit dose vial 500 microgram/mL inhalation: solution for, 30 x 1 mL ampoules	• Atrovent adult unit dose vial 500 microgram/ mL inhalation: solution for, 30 x 1 mL ampoules
• lamivudine + zidovudine	• lamivudine 150 mg + zidovudine 300 mg tablet	• lamivudine 150 mg + zidovudine 300 mg tablet, 60	• Combivir	• Combivir (lamivudine 150 mg + zidovudine 300 mg) tablet; film-coated, 1 tablet	• Combivir tablet: film-coated, 60 tablets	• Combivir tablet: film-coated, 60 tablets, bottle
• amlodipine + atorvastatin	• amlodipine 10 mg + atorvastatin 20 mg tablet	• amlodipine 10 mg + atorvastatin 20 mg tablet, 30	• Caduet	• Caduet 10/20 (amlodipine (as besylate) 10 mg + atorvastatin (as calcium) 20 mg) tablet: film-coated, 1 tablet	• Caduet 10/20 tablet: film-coated, 30 tablets	• Caduet 10/20 tablet: film-coated, 30 tablets, blister pack

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
• antazoline + naphazoline	• antazoline 4.1 mg/mL + naphazoline 426 microgram/ mL eye drops • 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	• Albalon-A Liquifilm 0.5% / 0.05% (antazoline phosphate 0.5% (5 mg/mL) + naphazoline hydrochloride 0.05% (500 microgram/mL)) eye drop solution	• Albalon-A Liquifilm 0.5% / 0.05% eye drop solution, 15 mL	• Albalon-A Liquifilm 0.5% / 0.05% eye drop solution, 15 mL, bottle
• paracetamol + codeine	• paracetamol 500 mg + codeine 23.43 mg tablet • paracetamol 500 mg + codeine phosphate 30 mg tablet	• paracetamol 500 mg + codeine phosphate 30 mg tablet, 20	• Panadeine	• Panadeine Forte (paracetamol 500 mg + codeine phosphate 30 mg) tablet: uncoated, 1 tablet	• Panadeine Forte tablet: uncoated, 20 tablets	• Panadeine Forte tablet: uncoated, 20 tablets, blister pack

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP 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]	• 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]	• Triphasil, 112 tablets [4 x 28 tablets], blister pack
• norethisterone + ethinyloestradiol	• norethisterone 500 microgram + ethinyloestradiol 35 microgram tablet	• norethisterone 500 microgram + ethinyloestradiol 35 microgram tablet, 84 [4 x 21 tablets]	• Brevinor	• Brevinor 21 day (norethisterone 500 microgram + ethinyloestradiol 35 microgram) tablet: uncoated, 1 tablet	• Brevinor 21 day tablet: uncoated, 84 tablets [4 x 21 tablets]	• Brevinor 21 day tablet: uncoated, 84 tablets [4 x 21 tablets], blister pack

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
• norethisterone + oestradiol (&) oestradiol • norethisterone acetate + oestradiol (&) oestradiol • oestradiol + norethisterone • 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 (osetradiol (as hemihydrate) 2 mg) tablet: film-coated, 1 tablet • Trisequens (norethisterone acetate 1 mg + oestradiol (as hemihydrate) 2 mg) tablet: film-coated, 1 tablet • Trisequens (oestradiol (as hemihydrate) 1 mg) tablet: film-coated, 1 tablet	• Trisequens, 28 tablets	• Trisequens, 28 tablets, dial dispenser pack
• etidronic acid (&) calcium • etidronate disodium (&) calcium carbonate • calcium • calcium carbonate • etidronic acid • 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	• Didronel • Calcium carbonate (Sanofi-Aventis) • Didrocal	• Didronel (etidronate disodium 200mg) tablet: uncoated, 1 tablet • Calcium carbonate (Sanofi-Aventis) (calcium (as carbonate) 500 mg) tablet: film-coated, 1 tablet	• Didrocal, 104 tablets	• Didrocal, 104 tablets, blister pack

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP 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	• Risperdal	• Risperdal Consta (risperidone 25 mg) injection: modified release, vial • Risperdal Consta diluent, syringe	• Risperdal Consta (1 x 25 mg vial), 1 pack	• Risperdal Consta (1 x 25 mg vial), 1 pack, composite 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	• Somatuline	• Somatuline LA (lanreotide (as acetate) 30 mg) injection: modified release, vial • Somatuline LA diluent, ampoule	• Somatuline LA (1 x 30 mg vial), 1 pack	• Somatuline LA (1 x 30 mg vial), 1 pack, composite pack
• 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	• Flolan	• Flolan (epoprostenol (as sodium) 500 microgram) injection: powder for, vial • Flolan diluent, vial	• Flolan (1 x 500 microgram vial), 1 pack	• Flolan (1 x 500 microgram vial), 1 pack, composite pack

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
• polygeline + potassium + sodium + calcium + chloride	• polygeline 17.5 g/500 mL + potassium 99.71 mg/500 mL + sodium 1.67 g/500 mL + calcium 125 mg/500 mL + chloride 2.574 g/500 mL injection, bottle	• polygeline 17.5 g/500 mL + potassium 99.71 mg/500 mL + sodium 1.67 g/500 mL + calcium 125 mg/500 mL + chloride 2.574 g/500 mL injection, 1 x 500 mL bottle	• Haemaccel	• Haemaccel (polygeline 17.5 g/500 mL + potassium (as salt unspecified) 99.71 mg/500 mL + sodium (as salt unspecified) 1.67 g/500 mL + calcium (as salt unspecified) 125 mg/500 mL + chloride (as base unspecified) 2.574 g/500 mL) intravenous infusion, bottle	• Haemaccel intravenous infusion, 1 x 500 mL bottle	• Haemaccel intravenous infusion, 1 x 500 mL bottle
• peginterferon alfa-2b • ribavirin • inert substance • peginterferon alfa-2b (&) ribavirin	• 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	• Rebetol • PEG-Intron • Pegatron	• PEG-Intron Redipen Injector (peginterferon alfa-2b 100 microgram) injection: powder for, cartridge • Rebetol (ribavirin 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	• Pegatron Combination Therapy (4 x 100 microgram cartridges, 112 x 200 mg capsules), 1 pack, composite pack

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
• sodium + potassium + calcium • sodium chloride + potassium chloride + calcium chloride	• sodium chloride 8.6 g/1000 mL + potassium chloride 300 mg/1000 mL + calcium chloride 320 mg/1000 mL injection, bag	• sodium chloride 8.6 g/1000 mL + potassium chloride 300 mg/1000 mL + calcium chloride 320 mg/1000 mL injection, 1 x 1000 mL bag	• Compound Sodium Chloride (Pharmatel Fresenius Kabi)	• Compound Sodium Chloride (Ringer's) (Pharmatel Fresenius Kabi) (sodium chloride 8.6 g/1000 mL + potassium chloride 300 mg/1000 mL + calcium chloride 320 mg/1000 mL) intravenous infusion, bag	• Compound Sodium Chloride (Ringer's) (Pharmatel Fresenius Kabi) intravenous infusion, 1 x 1000 mL bag	• Compound Sodium Chloride (Ringer's) (Pharmatel Fresenius Kabi) intravenous infusion, 1 x 1000 mL bag
• esomeprazole • clarithromycin • amoxycillin • 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	• Nexium • Klacid • Amoxil • Nexium Hp 7	• Nexium (esomeprazole (as magnesium trihydrate) 20 mg) tablet: enteric-coated, 1 tablet • Klacid (clarithromycin 500 mg) tablet: film-coated, 1 tablet • Amoxil (amoxycillin (as trihydrate) 500 mg) capsule	• Nexium Hp 7, 1 pack	• Nexium Hp 7, 1 pack, composite pack
• mirtazapine	• mirtazapine 15 mg tablet	• mirtazapine 15 mg tablet, 30	• Avanza	• Avanza (mirtazapine 15 mg) SolTab, 1 tablet	• Avanza 15 mg SolTab, 30 tablets	• Avanza 15 mg SolTab, 30 tablets, blister pack

MP PT	MPUU PT	MPP PT	TP PT	TPUU PT	TPP PT	CTPP PT
• vinblastine	• vinblastine 8.92 mg/10 mL injection, vial • 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) (vinblastine sulfate 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