



Australian Government

Australian Digital Health Agency

Australian Medicines Terminology Editorial and Naming Rules

15 April 2026 v4.1

Approved for external information

Document ID: DH-4379:2026

Australian Digital Health Agency ABN 84 425 496 912, Level 25, 175 Liverpool Street, Sydney, NSW 2000
Telephone 1300 901 001 or email help@digitalhealth.gov.au
www.digitalhealth.gov.au

Acknowledgements

The Australian Digital Health Agency is jointly funded by the Australian Government and all state and territory governments.

Regenstrief Institute (LOINC)

This material contains content from LOINC (<http://loinc.org>). LOINC is copyright © 1995–2024, Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee and is available at no cost under the license at <http://loinc.org/license>. LOINC® is a registered United States trademark of Regenstrief Institute, Inc.

IHTSDO (SNOMED CT)

This material includes SNOMED Clinical Terms™ (SNOMED CT®) which is used by permission of the International Health Terminology Standards Development Organisation (IHTSDO). All rights reserved. SNOMED CT® was originally created by The College of American Pathologists. “SNOMED” and “SNOMED CT” are registered trademarks of the [IHTSDO](http://www.ihtsd.org).

HL7 International

This document includes excerpts of HL7™ International standards and other HL7 International material. HL7 International is the publisher and holder of copyright in the excerpts. The publication, reproduction and use of such excerpts is governed by the [HL7 IP Policy](#) and the HL7 International License Agreement. HL7 and CDA are trademarks of Health Level Seven International and are registered with the United States Patent and Trademark Office.

Disclaimer

The Australian Digital Health Agency (“the Agency”) makes the information and other material (“Information”) in this document available in good faith but without any representation or warranty as to its accuracy or completeness. The Agency cannot accept any responsibility for the consequences of any use of the Information. As the Information is of a general nature only, it is up to any person using or relying on the Information to ensure that it is accurate, complete and suitable for the circumstances of its use.

Document control

This document is maintained in electronic form and is uncontrolled in printed form. It is the responsibility of the user to verify that this copy is the latest revision.

Copyright © 2024 Australian Digital Health Agency

This document contains information which is protected by copyright. All Rights Reserved. No part of this work may be reproduced or used in any form or by any means – graphic, electronic, or mechanical, including photocopying, recording, taping, or information storage and retrieval systems – without the permission of the Australian Digital Health Agency. All copies of this document must include the copyright and other information contained on this page.

OFFICIAL

Document information

Key information

Owner	Branch Manager, Informatics and Standards
Contact for enquiries	Australian Digital Health Agency Help Centre
	Phone 1300 901 001
	Email help@digitalhealth.gov.au

Product or document version history

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

Product or document version	Date	Release comments
2.3	31 May 2018	This update features updates and additions to: • Section 4.6.2 in relation to the strength representation of Trade Products. • 4.6.3.2 TP Fully Specified Names rules examples • Appendix E, Strength formats and Appendix E2.2 for Acceptable synonyms • Appendix G, Form • Appendix J, Container Types • Appendix K.1, Vaccines – examples
2.4	31 October 2018	This update features updates and additions to: • Substance name changes related to the TGA International Harmonisation of Ingredient Names project work • 4.2.5.2 Combination packs • 6.1 Australian Qualifier definition • Appendix E – General strength formats • Appendix G – Form and Appendix H, Proprietary descriptions and equivalents • Appendix J – Container Types
2.5	30 April 2019	This update features updates and additions to: • 4.6.2 TP details • 4.7.2 TPUU descriptions • 4.8 Trade Product Pack (TPP) • 4.9.2.4 CTPP Preferred Term rules • Appendix B.1 Discernible therapeutic differences to the base (clinically significant modifications) • Appendix G – Form • Appendix E.1 Strength expression rules for specific medication forms • Appendix E.3 Strength expression rules for specific substances • Appendix K.8 Herbal preparations
2.6	31 October 2019	This update features updates and additions to: • 4.2.4 Multi-component • 4.5.2.1 MPP Fully Specified Name definition • 4.5.2.3 MPP Preferred Term definition • 4.7.1.2 Exceptions for products with “inert substance” ingredients • 4.8.2.2.2 TPP Preferred Term brief definition – multi-component TPP • 4.9.2 CTPP descriptions • Appendix E – General strength formats • Appendix G – Form • Appendix J – Container types • Appendix K.8 Herbal preparations

Product or document version	Date	Release comments
2.7	30 April 2020	This update features updates and additions to: • Appendix E – General strength formats • Appendix F – Units of measure • Appendix J – Container types
2.8	31 October 2020	This update features updates and additions to: • 4.5.2.3 MPP Preferred Term definition • 4.6.2 TP details for specific population • Appendix E – Acceptable synonyms • Appendix F – Units of measure
2.9	30 April 2021	This update features updates and additions to: • Appendix F – Units of measure • Appendix F – Proportions
3.0	31 October 2021	This update features updates and additions to: • Appendix G – Form • 4.6.2 TP details for strength representation
4.0	26 September 2024	Update from v3 model to AMT v4.
4.1	14 April 2026	This update features additions to: • Appendix A • A.7.9 Medicinal Cannabis

Table of contents

1	Introduction.....	8
1.1	Purpose.....	8
1.2	Audience.....	9
1.3	Scope	9
2	General Editorial Rules.....	10
2.1	General Naming Conventions	10
2.2	General Modelling Rules.....	11
3	Concept Class Specific Guidance.....	12
3.1	Qualifier Values	12
3.1.1	Substances	12
3.1.2	Units of Measure.....	13
3.1.3	Pharmaceutical Dose Forms.....	14
3.1.4	Container Type.....	16
3.2	Medicinal Product (MP).....	16
3.2.1	Medicinal Product modelling	16
3.2.2	Medicinal Product descriptions	19
3.3	Clinical Drug (CD)	21
3.3.1	Clinical Drug modelling	21
3.3.2	Clinical Drug descriptions	30
3.4	Clinical Drug Package (CDP)	32
3.4.1	Clinical Drug Package modelling.....	32
3.4.2	Clinical Drug Package descriptions	34
3.5	Product Name (Product Name).....	36
3.5.1	Product Name definition.....	36
3.5.2	Product Name descriptions	40
3.6	Branded Clinical Drug (BCD).....	43
3.6.1	Branded Clinical Drug modelling	43
3.6.2	Branded Clinical Drug descriptions.....	48
3.7	Branded Clinical Drug Package (BCDP)	51
3.7.1	Branded Clinical Drug Package modelling.....	51
3.7.2	Branded Clinical Drug Package descriptions	52
3.8	Containerised Branded Clinical Drug Package (CBCDP).....	53
3.8.1	Containerised Branded Clinical Drug Package modelling	53
3.8.2	Containerised Branded Clinical Drug Package descriptions.....	54
3.9	Device Concepts	56
3.9.1	Device Examples	57
3.9.2	Device Naming Rules.....	58

3.9.3	Correlation between Devices, Medicines, and Notable Reference Sets.....	58
Appendix A.		60

1 Introduction

1.1 Purpose

This document provides detailed editorial guidance on the execution of the Australian Medicines Terminology (AMT) V4 concept model, which is described in the AMT v4 Model Specification.¹ The document steps through each of the concept classes relevant to AMT with each section providing complementary guidance on Modelling and Naming rules applicable to the concept class.

Modelling Rules

These are focused on how the AMT v4 modelled is implemented in practice, and describe the specific patterns of attributes and target values used in the formal definition of the concepts within AMT. There are different considerations depending on the type of product being modelled, including current requirements and limitations in the model. Understanding these rules is important for both (internal and external) authors of AMT content and end users of the published terminology to ensure the content is consistent where possible, adhering to the terminology principles of **URU**.²

- **Understandable** - The meaning of a concept can be understood by most healthcare providers, without reference to private or inaccessible information.
- **Reproducible** - Multiple users apply the concept to the same situations.
- **Useful** - The concept has a practical value to users that is self-evident or can be readily explained.

Naming Rules

The Naming Rules are focused exclusively on the human readable terms provided with each concept and are usually a direct consequence of the modelled attributes. Each concept will have at least two terms.³

Fully Specified Name (FSN): A description that represents the meaning of a concept in a way that is unambiguous and independent of the context in which it is used. The FSN should be an accurate reflection of the concepts modelling, however there may be instances where it is not possible to precisely model the concept, and the FSN may provide additional information. The FSN must be unambiguous and as a result may not be desirable in clinical user interfaces.

Synonym: These are alternate descriptions for a concept. Every concept has one Synonym that is marked as **Preferred**, intended for use in clinical user interfaces. It may include consideration for

¹ ADHA, Australian Medicines Terminology: Model Specification, ADHA, Australian Government, 2025, accessed 13 March 2026.

² SNOMED International, [URU](#), SNOMED CT Glossary website, 2025, accessed 05 January 2026.

³ SNOMED International, [term](#), SNOMED CT Glossary website, 2025, accessed 05 January 2026.

clinical safety requirements, user familiarity, and community expectations. Whilst terms should be unambiguous, some tolerance for excluding detail that is regarded as implicit in clinical practice is allowed.

1.2 Audience

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

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

1.3 Scope

This document is intended to assist with:

- The consistent application of the editorial rules (modelling and naming) by terminology authors:
- and
- The interpretation of the published terminology by implementers, both primary software vendors and downstream secondary users (e.g. Analytics).

The document is not intended to provide implementation advice to meet specific use cases or implementation goals.

2 General Editorial Rules

2.1 General Naming Conventions

All terms in AMTv4 will align with the General Naming Conventions as described in the SNOMED CT editorial guide, deviating only when necessary to meet specific Australian requirements.⁴ The specific naming rules vary across SNOMED CT but overarching rules that apply to all content and are relevant to AMT include:

- Descriptions begin with an upper-case letter; the rest of the words in the description lower case except for abbreviations, proper nouns, i.e. names of people, organizations, taxonomic groups (e.g. species, genus, family), etc.⁵
- FSNs should be correct US spelling, unless over-ridden by other specific editorial rules, and include a “semantic tag” suffix.⁶
- The forward slash should not be used in FSNs. When the slash is part of the authoritative name (e.g. representation of heterozygosity in hemoglobinopathies), a hyphen (no space before or after) is used in the FSN. The forward slash, without spaces, may be used in a preferred term or synonym.⁷
- A hyphen is used to join words and to separate syllables. There is no space either before or after a hyphen.
- In general, colons should not be used in fully specified names. Colons are allowed in the descriptions of organisms, substances, or products where the colon is part of the name.
- The single caret (^) is used to represent exponents, i.e. powers of, in alignment with the Unified Code for Units of Measure (UCUM) guidance on the use of powers of ten. E.g. 10^3 for the third power of ten.
- All numeric quantities measured in mass units or volume units in descriptions, will be adjusted by a suitable unit conversion factor so that the numeric value is less than 1000 and greater than or equal to 1. Where mass and volume units are normalised in the modelling to milligrams and millilitre (as per 2.2 below).

For example:

- 0.375 mg → 375 micrograms
- 2000 mL → 2 L

See Appendix A.2 for a list of conversion factors.

- For any value $\geq 10,000$ a space will be included after every third digit starting from the right. For example: 10 000; 500 000; 1 000 000. This will not apply to mass or volume units of measure (as per previous rule).

⁴ SNOMED, [General Naming Conventions](#), SNOMED CT Editorial Guide, 2025, accessed 05 January 2026.

⁵ SNOMED, [Case Significance](#), SNOMED CT Editorial Guide, 2025, accessed 05 January 2026.

⁶ SNOMED, [Fully Specified Name](#), SNOMED CT Editorial Guide, 2025, accessed 05 January 2026.

⁷ SNOMED, [Punctuation and Symbols](#), SNOMED CT Editorial Guide, 2025, accessed 05 January 2026.

2.2 General Modelling Rules

Decimal concrete domain values will only be stated to a precision of 6 decimal places.

All metric mass and volume representations will be normalised to use milligram and millilitre respectively. This ensures consistency within the model, and reliable classification. The units of measure used in descriptions will align with current clinical requirements and expectations. See for Appendix A.2 for more detail.

Other (non-metric) units of measure will be modelled as per their registration details or documentation.

3 Concept Class Specific Guidance

3.1 Qualifier Values

3.1.1 Substances

The concept model and associated rules for Substances are inherited from SNOMED CT core. The editorial rules are summarised here, but the International Editorial rules are the primary reference.⁸

Substances currently have two defining attributes:

- is modification of
- has disposition.

Is modification of – indicates that the concept is a structural modification of another concept.

For example:

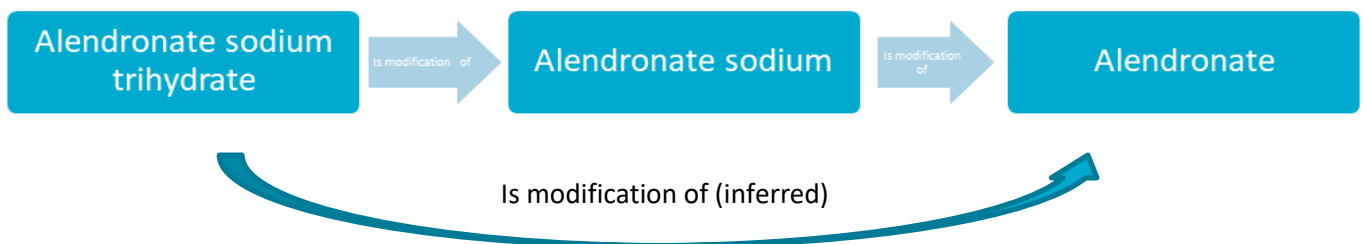
427483001|Amoxicillin sodium| is modification of 372687004|Amoxicillin|

The Is modification of property is transitive meaning that the stated modifications are implicitly inferred through the description logic to subsequent modifications.

For example:

If |Alendronate sodium trihydrate| Is modification of |Alendronate sodium|;
and |Alendronate sodium| Is modification of |Alendronate|
then it can be inferred that:
|Alendronate sodium trihydrate| Is modification of |Alendronate|

Figure 1: Is modification of property example - Alendronate



Within the AMT a “base substance” is defined as the active moiety of within a product name (that is, the segment of the molecule which has an intended therapeutic effect on the body).

A “modified substance” is defined as a base substance with some additive modification which is combined with the base but does not have an additional therapeutic effect on the body. Modified substances may include salts, esters, or waters of hydration. It may be a modification to the base molecule to assist with stability, solubility, bioavailability, or so on. Multiple, cumulative, modifications may apply to a base substance.

⁸ SNOMED, [Substance General Guidelines](#), SNOMED CT Editorial Guide, 2025, accessed 05 January 2026.

Table 1: Modified substances

Base substance	Primary Modification	Secondary Modification
Atenolol	N/A	N/A
Ranitidine	Ranitidine hydrochloride	N/A
Betamethasone sodium phosphate	Betamethasone sodium phosphate	N/A
Suxamethonium chloride dihydrate	Suxamethonium chloride	Suxamethonium chloride dihydrate
Azithromycin monohydrate hemiethanolate	Azithromycin monohydrate	Azithromycin monohydrate hemiethanolate

It is not necessary to model all the intermediate modifications between a modified substance and a base substance. It is acceptable to only add the substances that are required to model a pharmaceutical product. *Is modification of* attributes should target the next closest substance present in the terminology.

Has disposition – enables the creation of an association between a substance concept and a disposition. A disposition is defined as a behaviour that a substance will exhibit or participate in, given the appropriate context. For example:

372897005|Salbutamol| Has disposition 763222000 |Beta-2 adrenergic receptor agonist |

The SNOMED CT supports the inclusion of intermediate grouper concepts based on disposition and chemical structure. By default, these will not be included when new substances are required by AMT products, though they may be inferred (from existing content) or added when specifically required (specified use case).

Additional guidance is available in:

- [Domain specific modelling for substances – Ingredient Substance Attributes - Medicinal Product Model](#)
- [Supporting hierarchy - Disposition - SNOMED CT Editorial Guide](#)

Substance Descriptions

The FSN will follow SNOMED CT editorial rules.⁹ This will typically be the International Nonproprietary Name (INN) for pharmaceutical ingredients. The semantic tag will be “(substance)”

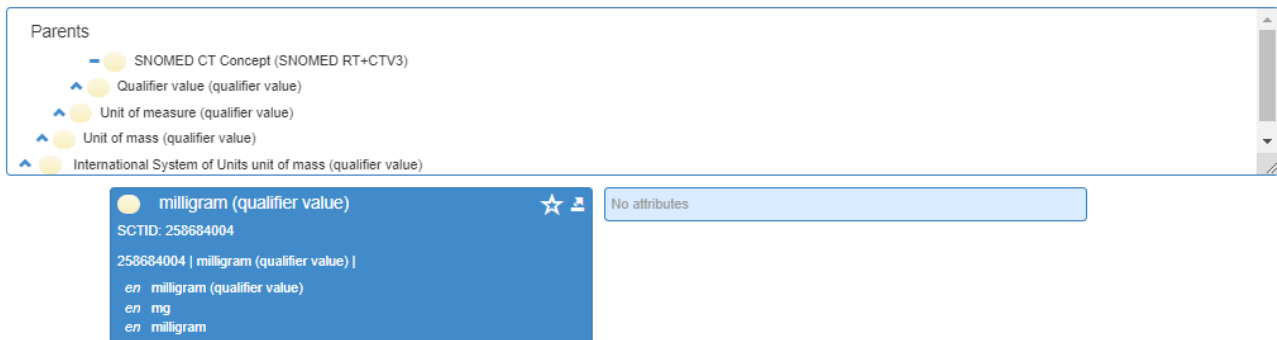
The Preferred Synonym will align with the substance as registered with the TGA.

3.1.2 Units of Measure

The concept model and associated rules for 767524001|Units of measure| are inherited from SNOMED CT core. There is currently no International concept model for this content, and most concepts are organised based on a stated *Is a* hierarchy.

⁹ SNOMED, [Substance General Guidelines](#), SNOMED CT Editorial Guide, 2025, accessed 17 March 2026.

Figure 2: Units of measure



AMT extends SNOMED CT with a minor concept model for composite units of measure, with the following two properties:

- has numerator units
- has denominator units

Composite units are used to describe ratios, primarily concentrations but also (time) rates. For example, in AMT, a composite unit of measure could represent the strength of a medication in terms of milligrams per millilitre (mg/mL), where milligrams and millilitres are the numerator and denominator respectively.

Units of Measure Descriptions

The FSN will be fully spelled out, and unambiguous.

The semantic tag will be “(qualifier value)”.fc

The preferred synonym may use abbreviations where these are widely recognised and unambiguous, e.g. “mg” for “milligram (qualifier value)”.

3.1.3 Pharmaceutical Dose Forms

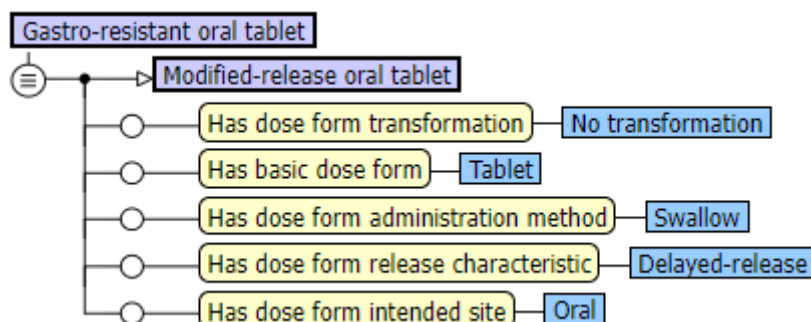
The concept model and associated rules for dose forms in AMT are inherited from SNOMED CT core. The specific editorial guide describing the concept model for Pharmaceutical dose forms is available through SNOMED International.¹⁰

The SNOMED Pharmaceutical dose form concept model aims to be compatible with the following ISO (International Organization for Standardization) IDMP (Identification of Medicinal Products) standards where appropriate:

- ISO 11239 Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
- ISO/TS 20440 Health informatics — Identification of medicinal products — Implementation guide for ISO 11239 data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging.

Figure 3: Dose form example – Gastro-resistant oral tablet

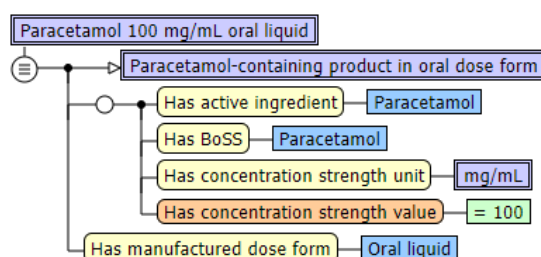
¹⁰ SNOMED, [Pharmaceutical Dose Form](#), SNOMED CT Editorial Guide, 2025, accessed 05 January 2026.



AMT dose form specificity

AMT will not necessarily require all of the attributes, all of the time. Existing SNOMED CT Pharmaceutical dose forms may be more specific than the level of detail known for AMT products or required. Therefore, intermediate dose form concepts may be added by only modelling those attributes that are necessary for AMT.

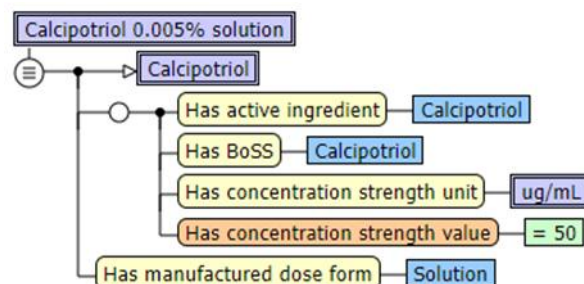
Figure 4: Dose form example – Oral liquid



AMT does not specify if the liquid is a solution, suspension, or elixir etc.

Similarly, AMT does not always specify the intended *route of administration* (“intended site”), as shown below.

Figure 5: Dose form example - Solution



This variable specificity may be revised in the future in response to stakeholder feedback and changes to requirements.

The preferred terms for dose forms in SNOMED CT-AU may differ from International to better align with TGA naming conventions. In particular, implicit or redundant information may be omitted, For example:

Table 2: Dose form differences between International and Australian Preferred Terms

FSN	INT Preferred Term	AU Preferred Term
Conventional release rectal suppository (dose form)	Rectal suppository	Suppository
Conventional release oromucosal lozenge (dose form)	Oromucosal lozenge	Lozenge
Conventional release oromucosal solution for mouthwash (dose form)	Oromucosal solution for mouthwash	Mouthwash

3.1.4 Container Type

This qualifier concept defines the type of containers that a product is packaged in.

Most products are modelled with just the primary packaging, which allows a medicine to be physically handled. Examples include ampoule, bottle, blister pack, syringe and so on. It does not include an article intended for ingestion. For example, an oral capsule (containing granules) is not considered a container.

“Secondary” packaging is only modelled for “Packs of Packs”. These may be packs of existing package concepts, or packs of multiple containered clinical drug products:

- Xiaflex (1 x 900 microgram vial, 1 x 3 mL inert diluent vial), 1 packGardasil injection, 10 x 0.5 mL syringes
- Nexium Hp7 (14 x Nexium tablets, 28 x Amoxil capsules, 14 x Klacid tablets), 1 pack.

Content will be taken from the 260787004|Physical object| top level hierarchy, predominately the 706437002|Container (physical object)| subhierarchy.

There is currently no specific content model associated with this content and it is manually organised as a hierarchy of primitive concepts.

3.2 Medicinal Product (MP)

3.2.1 Medicinal Product modelling

A Medicinal Product (MP) is the abstract representation of the active ingredients or substances (devoid of strength and form), which when formulated as a therapeutic good, are intended for use in treating or preventing disease in humans. This includes medicines authorised by a health care professional as well as medicines for self-treatment. The MP class represents a single moiety (or combination of) intended for use as a therapeutic product. An example MP concept is 90332006|paracetamol|.

All Medicinal Product concepts will have a HAS ACTIVE INGREDIENT relationship to each of their active ingredients.

The Medicinal Product classes have the following knowledge or rules incorporated:

- The active ingredient is generally only specified to the level of modification that produces the intended therapeutic effect. Such that MP concepts aggregate Clinical Drugs (CDs) that may have different formulations but contain the same active moiety.
- Where the ingredient is an enantiomer, (that is, an ingredient that exists as two stereoisomers) the specific enantiomer will only be described if it is defined as part of the Australian Approved Name (AAN) or similar. For example, the AMT uses tryptophan, and not L-tryptophan.

- Where modifications of an active ingredient may imply different release profiles or routes of administration, this level of precision is described at the Clinical Drug (CD) class.
- A limited number of substances with modifications may be deemed to be clinically important and therefore represented in the MP (as the active ingredient) refer to A.4.
- MPs are currently only intended for aggregation of single component products.

As an example, the following products:

- Morphine hydrochloride trihydrate 1 mg/mL oral liquid
- Morphine sulfate pentahydrate 20 mg tablet.

Share a common MP - [Morphine], as the therapeutic moiety - what gives each product its therapeutic intent regardless of specific formulations – is Morphine. These are both “Morphine products”.

Clinically Significant Salt MPs

In AMT v3, judgments about if a salt was “clinically significant” was often subjective and heavily debated. Every salt formulation can influence factors such as chemistry, intended dosage form, pharmacokinetics, and pharmacodynamics of a product.¹¹ Attempts to determine which are “clinically significant” is really making an almost arbitrary decision about the degree the specific salt influences these factors. A goal of AMT v4, is to reduce inconsistencies and make the terminology predictable. As a result, some products that may have had different MPs in AMTv3 may be revised to share a common MP. **Error! Reference source not found.** below shows the two types of haloperidol products are completely disjoint (nothing in common) within AMT v3. In AMT v4, the Haloperidol decanoate MP is a subtype of Haloperidol. Thus, these are all “Haloperidol products” – which is true.

Figure 6: Haloperidol products in V3

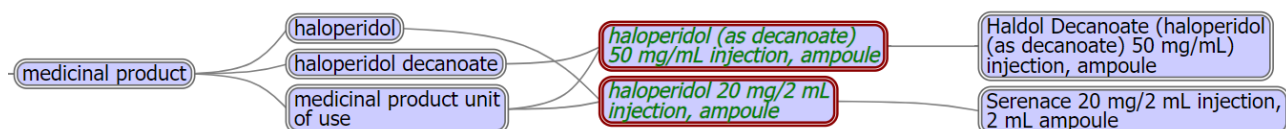
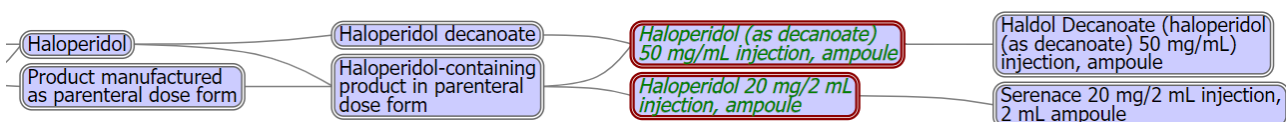


Figure 7: Haloperidol products in V4



Further changes to review and remove intermediate salts has not yet been entirely implemented yet and will be progressively addressed with stakeholder consultation. The MP will focus to the

¹¹ D Gupta, D Bhatia, V Dave, V Sutariya, S Vargheese Gupta, 'Salts of Therapeutic Agents: Chemical, Physicochemical, and Biological Considerations', Molecules, 2018, 23(7): 1719, doi:10.3390/molecules23071719

specific therapeutic moiety, with clinically significant salts, formulations and forms described at the Clinical Drug level.

Table 3: Haloperidol V3 and V4 comparison

V3 MP	V3 MPUU	V4 MP	V4 Clinical Drug
Haloperidol product	Haloperidol 20 mg tablet	Haloperidol product	Haloperidol 20 mg tablet
	Haloperidol 10 mg/mL injection, ampoule		Haloperidol 10 mg/mL injection, ampoule
Haloperidol decanoate	Haloperidol (as decanoate) 50 mg/mL injection, ampoule		Haloperidol (as decanoate) 50 mg/mL injection, ampoule

3.2.2 Medicinal Product descriptions

The Medicinal Product name is derived from the active ingredient according to the modelling rules above.

MP Fully Specified Name definition

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

MP FSN := "Product containing " FSN_Ingredient_Details " (medicinal product)"

The component parts are described as follows:

Table 4: Fully Specified Name Ingredient Details

Description Component	Description
FSN_Ingredient_Details	- A list of the FSNs of each of the substances referenced by the MP's Has active ingredient relationships. - The semantic tag " (substance)" – including leading space, is removed from each. - Ingredient FSNs are ordered alphanumerically, irrespective of casing. - Ingredients are concatenated, separated by either " and " (preferably) or " + " if the product has more than 3 ingredients. - The first character of each ingredient will be made lower case if the term is not marked 900000000000017005[Case sensitive]. With the exception of the lead ingredient, which will be unchanged, such that MP term is Sentence case.

MP Preferred Term definition

The Preferred Term of an MP will follow the syntax:

MP PT := MP_PT_Ingredient_Details

The component parts are described as follows:

Table 5: Medicinal Product Preferred Term Ingredient Details

Description Component	Description
MP_PT_Ingredient_Details	A list of the PTs of each of the substances referenced by the MP's Has active ingredient relationships. Ingredient will be ordered based on the order used by the innovator product. All terms (except first in ordered list) will have first character lowercase if case significance value is not 900000000000017005[Case sensitive] Ingredients are concatenated, separated by a " + "

Note that variation to this syntax may occur to meet the requirements of clinical practice as agreed by the appropriate AMT governance body. Also see Appendix A.5 for exceptions.

Ingredient Order For multi-ingredient products, the order of the ingredients will be based on the order used by the innovator product in the AMT (that is, the AMT product with the lowest ARTG ID). All subsequent products with the same combination of ingredients will follow the order of the innovator product. Where the innovator product stipulates the ingredients as part of the PN, then the ingredients will follow that order.

Example:

MP FSN:	Product containing aspirin and clopidogrel (medicinal product)
MP PT:	Clopidogrel + aspirin
MP FSN:	Product containing clavulanic acid and ticarcillin (medicinal product)
MP PT:	Ticarcillin + clavulanic acid

If an MP already exists for a product being authored, check if it already has AMT CD concepts as immediate subtypes, if not check the ARTG for the innovator product and correct ingredient order.

Products with more than three active ingredients

For Medicinal Products with more than three active ingredients, AMT authors may create a clinically intuitive name based on the review of each individual product. To date, this has primarily been implemented only for vaccines, but will be extended as required through stakeholder feedback.

Large volume parenteral injections products will retain all ingredient names in the MP PT. For example:

- Sodium chloride + potassium chloride + sodium bicarbonate + calcium chloride + magnesium chloride + glucose
- Isoleucine + leucine + valine + phenylalanine + methionine + lysine + threonine + tryptophan + cysteine + histidine + tyrosine + alanine + arginine + aspartic acid + glutamic acid + glycine + proline + serine.

The current exception list is attached as Appendix A.5. The addition of additional exceptions be reviewed on a case-by-case basis.

3.3 Clinical Drug (CD)

3.3.1 Clinical Drug modelling

Clinical Drug (CD) concepts represent a generic (devoid of brand) abstraction of medicinal products. Ideally describing the active ingredients, strength, and form of products. An example CD concept is 23628011000036109 |paracetamol 500 mg tablet|.

The general summary of the properties is listed below:

Table 6: Clinical Drug properties

Has manufactured dose form	The physical form of the product as it is manufactured, e.g. tablet, cream, oral liquid. (The administered dose form of medicines is not currently represented for AMT products, where this is different to the manufactured dose form.)
Has active ingredient	The active moiety ingredient that provides the core therapeutic benefit. The property is inherited from the Medicinal Product class.
Has precise active ingredient	The precise active ingredient in the product, if different salt forms of an active ingredient influence the clinical choice or therapeutic use of a product. For example, haloperidol (as decanoate) for intramuscular injection.
Has basis of strength substance (BoSS)	The substance for which the strength is relative to.
Has concentration strength (Value+Units)	The numerical value and units of measure describing the strength of continuant products. This will (usually) be the concentration of each BoSS within a product but may also be used to describe release rates.
Has total quantity (Value+Units)	The numerical value and units of measure describing the total quantity of a BoSS within a product. For discrete products (e.g. tablets) this is analogous to the strength. For products modelled as a specific quantity (presentation size) of some continuant, this is the total quantity in that presentation.
Has pack size (Value+Units)	The quantity (volume or mass) of a continuant in a specific presentation. Not all clinical drugs have a presentation size.
Has container type	The container a specific presentation is available in. Not all clinical drugs have a container type.
Role Groups	There exists one role group per has Basis of Strength Substance. There exists a single role group per concept for describing the unit of presentation.

CDs can be generalised into one of two categories – Discrete and Continuant products – each with a specific modelling approach and primarily identified by their manufactured dose form.

A “discrete product” typically represents a single “dose” - though can be “halved” and strength is always represented using only *Has total quantity*. The physical size (mass or volume) of the product or concentration is not specified. Continuant forms (e.g. liquids) are modelled as discrete products if the concentration and presentation size is unknown.

Modelling considerations specific to each product type are summarised below.

Table 7: Product type modelling considerations

Attribute	Discrete form products	Continuant form products	Continuant form discrete products
Has manufactured dose form	Necessary	Necessary	Necessary
Has active ingredient	Necessary*	Necessary*	Necessary*
Has precise active ingredient	Optional*	Optional*	Optional*
Has basis of strength substance (BoSS)	Optional	Optional	Optional
Has concentration strength	N/A	Necessary (If Has BoSS present)	Optional (If Has total quantity and Has presentation size present)
Has total quantity	Necessary (If Has BoSS present)	Optional (If Has BoSS present AND If Has presentation size present)	Necessary (If Has BoSS present)
Has pack size	N/A	Optional	Optional
Has container type	N/A	Optional	Optional

*Although the *Has active ingredient* is necessary. It will be superseded by the *Has precise active ingredient* if present. This is due to a combination of:

- *Has precise active ingredient* is a subtype of *Has active ingredient*.
- *Precise ingredients* are either subtypes or modifications of *active ingredients*.
 - *betamethasone valerate* is a modification of *betamethasone*.
- Role Chain *Has precise active ingredient* $\circ$ *Is modification of* $\rightarrow$ *Has active ingredient*
Which means the *modification* of a *precise active ingredient* is inferred to be the *active ingredient*.

Further details of the role chain are described in the SNOMED CT Medicinal Product Model.¹²

Specific examples are included later in this section.

Example Discrete product

Table 8: Examples of discrete products

¹² SNOMED, [Ingredient Substance Attributes](#), SNOMED CT Editorial Guide, 2025, accessed 05 January 2026.

Attribute	Sildenafil 25 mg capsule	Amoxicillin 3 g powder for oral liquid, sachet	Olanzapine (as pamoate) 210 mg modified release injection, vial
Has manufactured dose form	Oral capsule	Powder for oral liquid	Modified release injection
Has active ingredient	Sildenafil	Amoxicillin	Olanzapine
Has precise active ingredient	N/A	N/A	Olanzapine pamoate
Has basis of strength substance (BoSS)	Sildenafil	Amoxicillin	Olanzapine
Has concentration strength	N/A	N/A	N/A
Has total quantity	25 mg	3000 mg	210 mg
Has pack size	N/A	N/A	N/A
Has container type	N/A	Sachet	Vial

Notes:

- *Olanzapine (as pamoate) 210 mg modified release injection, vial* – will be subsumed by the *Olanzapine containing product (medicinal product)*. The *Has active ingredient* is implied through the description logic role chain:

Has precise active ingredient ◦ Is modification of → Has active ingredient

Example Continuous Products

Table 9: Examples of continuous products

Attribute	Insulin glargine 100 units/mL injection, 3 mL pen device	Paracetamol 100 mg/mL oral liquid	Haloperidol (as decanoate) 150 mg/3 mL injection, ampoule
Has manufactured dose form	Injection	Oral liquid	Injection
Has active ingredient	Insulin	Paracetamol	Haloperidol
Has precise active ingredient	Insulin glargine	N/A	Haloperidol decanoate
Has basis of strength substance (BoSS)	Insulin glargine	Paracetamol	Haloperidol
Has concentration strength	100 IU/mL	100 mg/mL	50 mg/mL
Has total quantity	300 IU	N/A	150 mg
Has pack size	3 mL	N/A	3 mL
Has container type	Pen device	N/A	Ampoule

Notes:

- *Insulin glargine 100 units/mL injection, 3 mL cartridge* – Is expected to be subsumed by *Insulin glargine containing product (medicinal product)*. Additionally, *Insulin glargine containing product (medicinal product)* will be subsumed by *Insulin containing product (medicinal product)*, following classification, courtesy of the role chain:

Has active ingredient ○ Is modification of → Has active ingredient

Additional Modelling Considerations

Has concentration strength

This property is only used for continuant dose forms where the information is known (or able to be calculated).

It is not used for continuant dose forms where the information is not known or cannot be calculated.

Has concentration strength (rounding and precision)

The information available (TGA registrations etc.) to model concepts is variable. For continuant products either a normalised concentration (e.g. 3mg/mL) or Total quantity per unit pack size (6mg/2mL) is usually provided. For continuant dose forms, a mathematical relationship exists between the Total quantity, Pack Size and Concentration properties.

Figure 8: Relationship between Total Quantity, Pack Size and Concentration properties

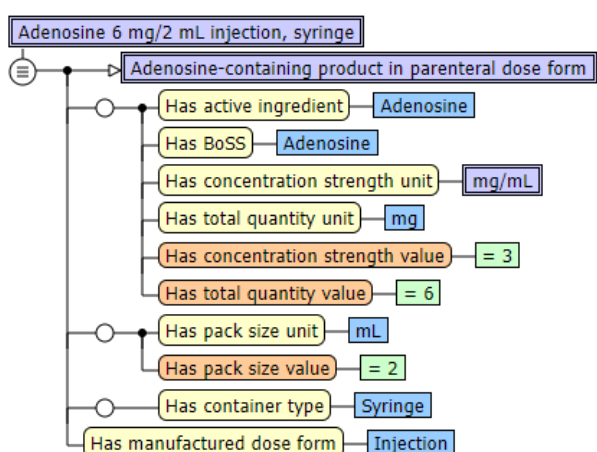


Total Quantity = Concentration x Pack Size

Concentration = Total Quantity / Pack Size

If only the Pack Size and one other property is known, the third can be calculated.

Figure 9: Adenosine normalised concentration example



Pack Size = 2mL
Total Quantity = 6 mg
Concentration Strength = 6mg/2mL = 3mg/mL

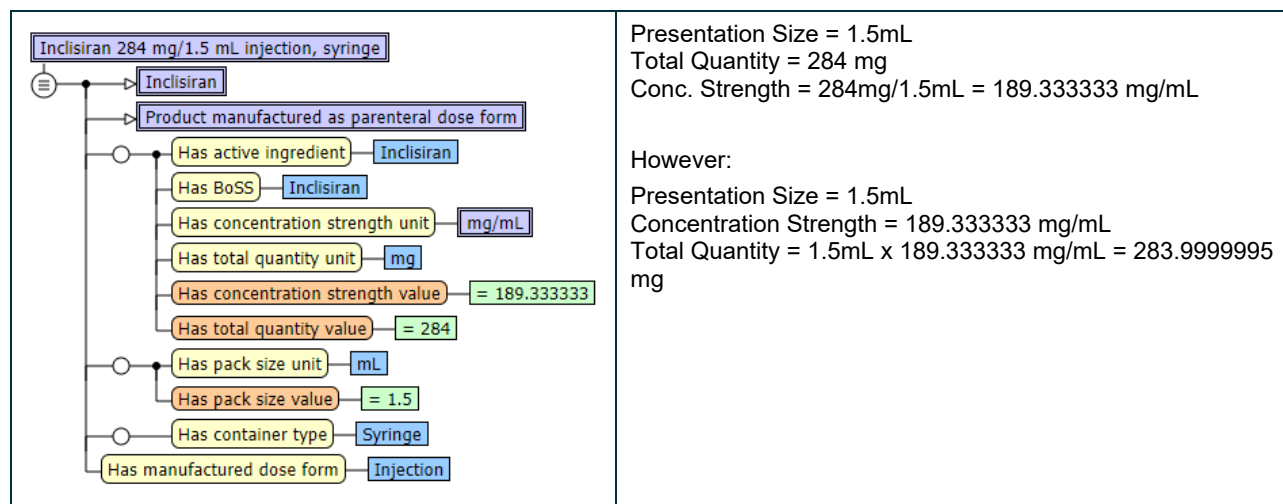
OR

Pack Size = 2mL
Concentration Strength = 3mg/mL
Total Quantity = 2mL x 3mg/mL = 6 mg

If the normalised concentration is calculated, it could produce an integer (as above), or a non-terminating decimal. Within AMT the maximum precision has been set at 6 decimal places. Registration details may describe normalised concentration that is rounded, the nearest integer or just 1 or two decimals.

For some products, the normalised strength calculates to a recurring number. Attempts to calculate total quantity for these will not produce the original value (unless rounding applied) and should be avoided. It should not be necessary to calculate total quantity for comparison of products. However, systems performing dose calculations should implement appropriate use of significant figures and rounding.

Figure 10: Inclisiran normalised strength recurring number example



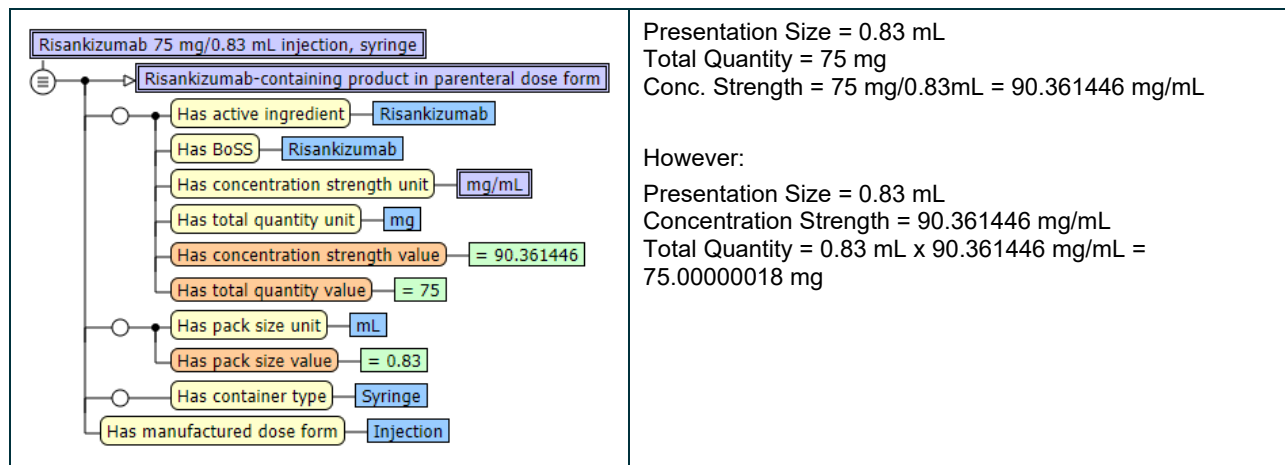
Presentation Size = 1.5mL
Total Quantity = 284 mg
Conc. Strength = 284mg/1.5mL = 189.333333 mg/mL

However:

Presentation Size = 1.5mL
Concentration Strength = 189.333333 mg/mL
Total Quantity = 1.5mL x 189.333333 mg/mL = 283.9999995 mg

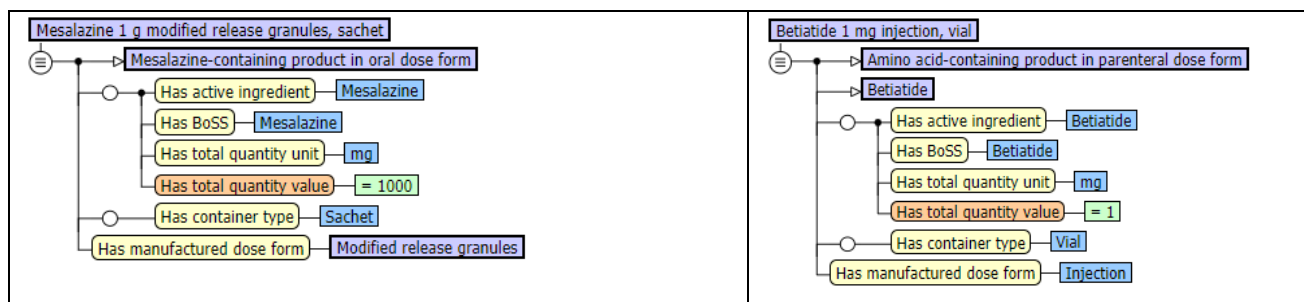
Similarly, some products with a normalised strength may calculate to an irrational number.

Figure 11: Risankizumab normalised strength irrational number example



Total quantity should not be confused with pack size. Some products with continuous dose forms, are available in specific containers (e.g. vials, sachets), but the concentration is not known. The total quantity describes the quantity of *BoSS* in that product, not the quantity of product itself (pack size). Examples of such products are shown below.

Figure 12: Continuous dose form total quantity examples



Has precise active ingredient

It is (currently) not necessary to model the precise ingredient, as this information was not reliably captured in legacy (AMT v3) data. However, as part of AMTv4 it was assumed that the Precise Active Ingredient was the more specific (modified) substance between the Active Ingredient and Basis of Strength Substance; with a small number of known exceptions modelled otherwise.

New content within AMTv4 should specify the Precise Active Ingredient if it is known. If the Precise Active Ingredient is a “clinically significant salt” it must be modelled. If it is *clinically significant* it is expected the Precise Active Ingredient will be described in the registration details.

Has total quantity

Discrete Dose forms

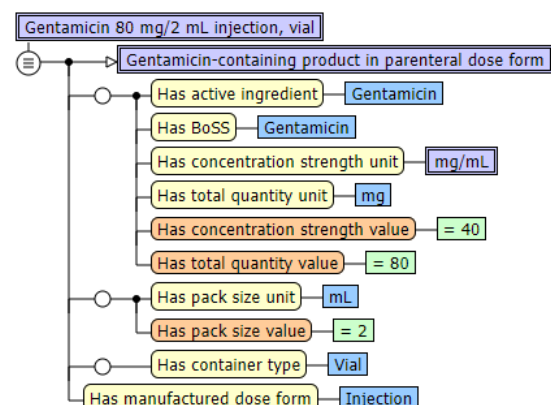
Has Total Quantity is included for each BoSS - if the strength (quantity per form) is known.

Continuant Dose Forms

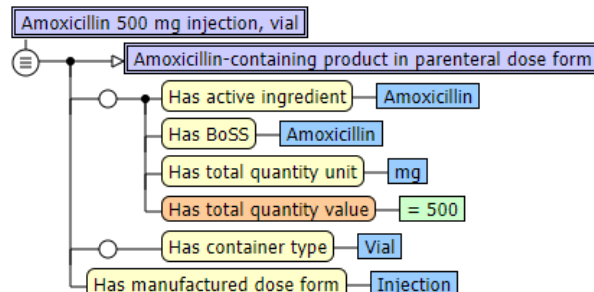
Has Total Quantity is included for each BoSS under two scenarios:

Table 10: Continuous dose forms Has total quantity examples

Both the concentration and pack size are known.
Or if presentation size and total quantity known,
concentration can be calculated.



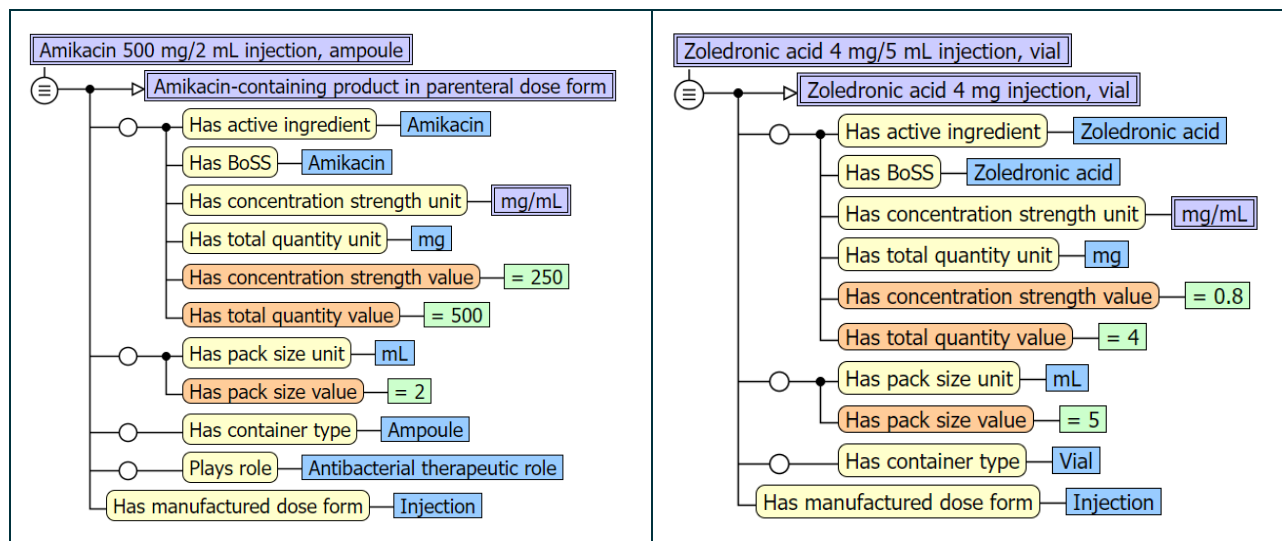
Only total quantity (unit strength) is known.
The specific size of the product or concentration is not
registered.



Has pack size

Some products are modelled as packs at the clinical drug concept class. Typically, these are solutions for injection, or other continuant forms, where a containered product is intended as a single dose. *Has Pack Size* describes the quantity of product within the container.

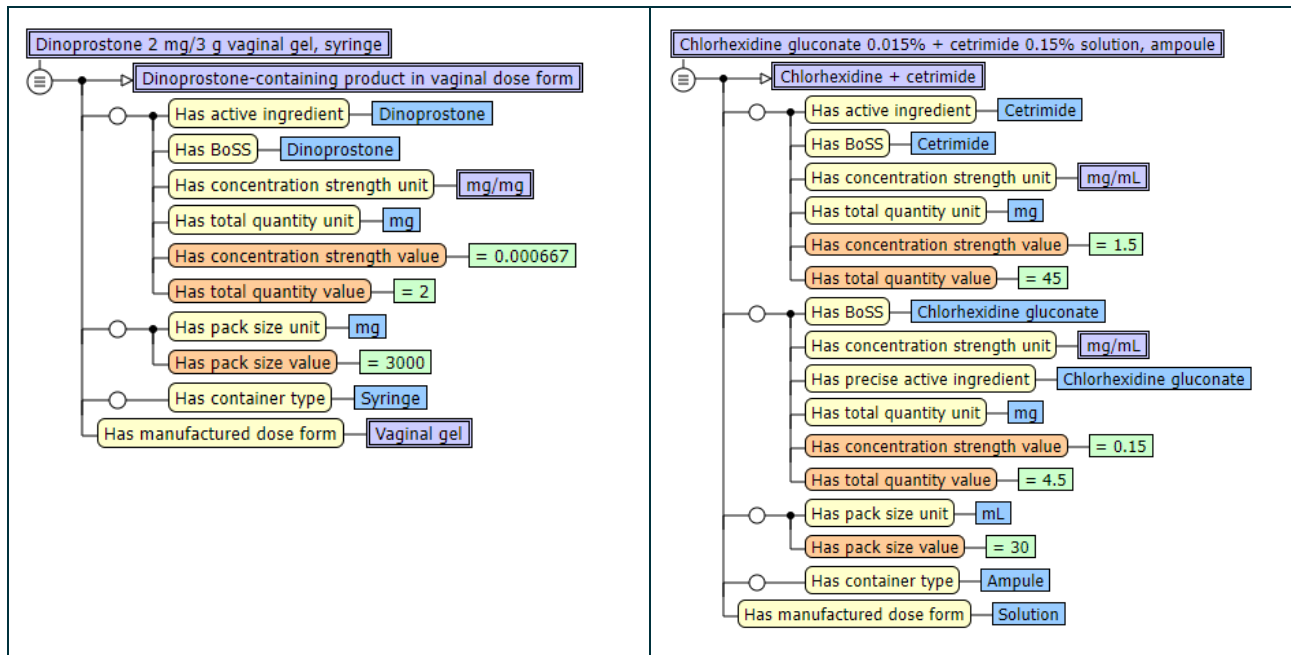
Figure 13: Single dose products Has pack size examples



Has container type

Some products are modelled as packs at the clinical drug concept class. Typically, these are solutions for injection, or other continuant forms, where a containered product is intended as a single dose. *Has Container Type* describes the container this single dose comes in. The Pack Size may or may not be known.

Figure 14: Single dose products Has container type examples



Alternative Axioms

Alternate strengths

AMT v4 leverages the SNOMED CT description logic to represent alternate strength representation as alternate axioms. These axioms on their own are not sufficient but provide machine readable access and assist with strength representation. These strengths can be used for term generation and are also machine readable. Alternate strengths are not currently implemented in AMT v4 but are proposed here for consideration.

Table 11: Alternate strength aciclovir example

aciclovir 5% cream		
Attribute	Primary axiom	Alternate axiom
Has concentration strength value	0.05	5
Has strength units	mg/mg	%w/w

Table 12: Alternate strength prilocaine hydrochloride example

prilocaine hydrochloride 0.5% (250 mg/50 mL) injection		
Attribute	Primary axiom	Alternate axiom
Has concentration strength value	50	0.5
Has strength units	mg/mL	%w/v

The consequence of this is all strength representations would be present in the published (necessary normal) form. Alternate axioms will only be implemented following further stakeholder consultation and impact analysis.

3.3.2 Clinical Drug descriptions

CD Fully Specified Name definition

The Fully Specified Name of an CD follows the syntax:

CD FSN := {Ingredient_With_Strength} “ ” Form [“, ”
Pack_Size_Details] “ (Clinical Drug)”

where the component parts are described as follows:

Table 13: Clinical Drug Fully Specified Name description

Description Component	Description
Ingredient_With_Strength	Repeatable component, with an Ingredient_With_Strength for each BoSS role group. Ingredient_With_Strength:= Ingredient “ ” Strength Ingredient:= Basis of Strength Substance preferred term. Strength:= Dependent on available attributes. ▪ If Has total quantity and Has Pack Size exist: Strength:= Has_Total_Quantity “/” Has_Pack_Size Has_Total_Quantity:= Has_Total_Quantity.Value “ “ Has_Total_Quantity.Units.PT If Has_Pack_Size.Value == 1 Has_Pack_Size:= Has_Pack_Size.Units.PT ELSE Has_Pack_Size:= Has_Pack_Size.Value “ “Has_Pack_Size.Units.PT ▪ If ONLY Has concentration strength is available: Strength:=Has_Concentration_Strength.Value Has_Concentration_Strength.Units ▪ If ONLY Has Total Quantity is available: Strength:=Has_Total_Quantity.Value Has_Total_Quantity.Units Each Ingredient_With_Strength will be separated by a “ + ”. If the Has_Active_Ingredient OR Has_Precise_Active_Ingredient values are modifications of the BoSS. Ingredient will be suffixed with [(“as” Modification)], where modification is the differing salt component. If no BoSS ingredient exists, then Ingredient_With_Strength will be just the Has_Precise_Active_Ingredient.PreferredTerm or (Has_Active_Ingredient.PreferredTerm if not precise ingredient) The order of Ingredient_With_Strength components will be alphanumeric.
Form	The Preferred term of the manufactured dose form.
Pack_Size_Details	Pack_Size_Details:= Has Pack Size value “ ” Has_Pack_Size.Units.PT “ ” HasContainerType.PT Do not show any null values.
(Clinical Drug)	The semantic tag used in the Fully Specified Name of all CD concepts.

CD Preferred Term definition

The Preferred Term of an CD follows the syntax:

CD PT := {Ingredient_With_Strength} “ ” Form [“ , ”
Pack_Size_Details]

where the component parts are described as follows:

Table 14: Clinical Drug Preferred Term description

Description Component	Description
Ingredient_With_Strength	Repeatable component, with an Ingredient_With_Strength for each BoSS role group. Ingredient_With_Strength:= Ingredient “ ” Strength Ingredient:= Basis of Strength Substance preferred term. Strength:= Dependent on available attributes. ▪ If Has total quantity and Has Pack Size exist: Strength:= Has_Total_Quantity “/” Has_Pack_Size Has_Total_Quantity:= Has_Total_Quantity.Value “ “ Has_Total_Quantity.Units.PT If Has_Pack_Size.Value == 1 Has_Pack_Size:= Has_Pack_Size.Units.PT ELSE Has_Pack_Size:= Has_Pack_Size.Value “ “Has_Pack_Size.Units.PT ▪ If ONLY Has concentration strength is available: Strength:=Has_Concentration_Strength.Value Has_Concentration_Strength.Units ▪ If ONLY Has Total Quantity is available: Strength:=Has_Total_Quantity.Value Has_Total_Quantity.Units Each Ingredient_With_Strength will be separated by a “ + ”. If the Has_Active_Ingredient OR Has_Precise_Active_Ingredient values are modifications of the BoSS. Ingredient will be suffixed with [(“as” Modification”)], where modification is the differing salt component. If no BoSS ingredient exists, then Ingredient_With_Strength will be just the Has_Precise_Active_Ingredient.PreferredTerm or (Has_Active_Ingredient.PreferredTerm if not precise ingredient) If no BoSS strength exists, then the strength representation shown will be the text string from the Other Strength Representation if it exists, otherwise no strength will be shown. ○ The order of Ingredient_With_Strength components will be alphanumeric.
Form	The Preferred term of the manufactured dose form.

Description Component	Description
Pack_Size_Details	If no Strength details exist Pack_Size_Details:= Has Pack Size value “ ” Has_Pack_Size.Units.PT “ ” HasContainerType.PT If Strength details exist Pack_Size_Details:= HasContainerType.PT Do not show any null values.

3.4 Clinical Drug Package (CDP)

3.4.1 Clinical Drug Package modelling

A Clinical Drug Package (CDP) is an abstract concept representing some quantity of CD concepts.

Two patterns exist depending on the type of Clinical Drug concept(s) being packaged:

- **Discrete** Clinical Drug concepts - those modelled a *Has Total Quantity* attributes.
- **Continuant** Clinical Drug concepts - those modelled without any *Has Total Quantity* attributes.

Table 15: Clinical Drug Package modelling

Contains clinical drug	This attribute references the Clinical Drug(s) that are contained within the package. A pack may contain: one or more different Discrete CDs; or a single Continuant CD.
Has pack size	The quantity of CD(s) within a given pack. A single <i>Has Pack Size</i> attribute is grouped with each <i>Contains clinical drug</i> attribute. More details below.
Count of contained component ingredient	Always grouped with a Contains clinical drug. The number of active ingredients within the referenced Clinical Drug. This attribute is present to support the description logic.
Count of clinical drug type	A single self-grouped instance per concept. The number of unique Clinical Drug concepts within the package. This attribute is present to support the description logic.

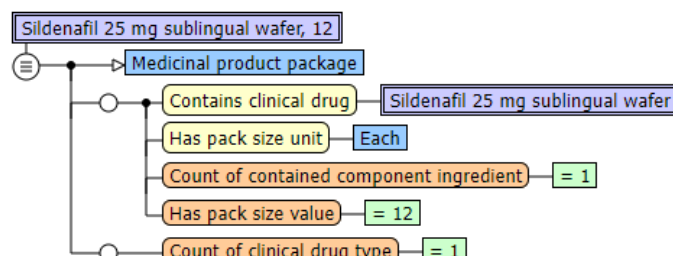
Specific Modelling Considerations

Has pack size

For discrete CDs, the CDP will describe a pack containing some **count** of these CD units. For example: 1220651000168102 | Sildenafil 25 mg sublingual wafer, 12 | - describes a quantity of 12

“units” of Sildenafil 25 mg sublingual wafer. When pack size is a count the Has pack size unit value is simply “Each”, regardless of the specific form.

Figure 15: Clinical Drug Package Discrete Clinical Drug example



For continuous CDs (those modelled without any Has Total Quantity attributes) the CDP will describe a volume or mass **quantity** of the relevant CD. Because pack size is a quantity, the unit of measure will always be a mass or volume quantity.

Figure 16: Clinical Drug Package Continuous Clinical Drug example

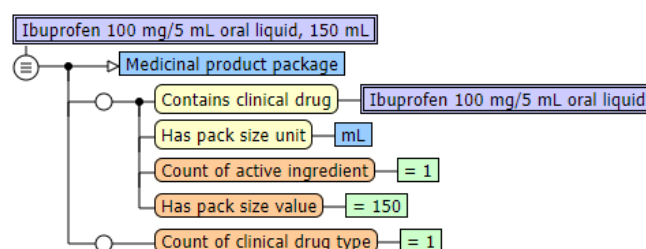


Table 16: Comparative examples of packs of discrete and continuant Clinical Drugs

	CDP	CD	Has pack size	Has pack size unit
Packs of Discrete Clinical Drugs	Paracetamol 500 mg tablet, 24	Paracetamol 500 mg tablet	24	N/A
	Dexamethasone phosphate 8 mg/2 mL injection, 10 x 2 mL vials	Dexamethasone phosphate 8 mg/2 mL injection, vial	10	N/A
Packs of Continuant Clinical Drugs	paracetamol 24 mg/mL oral liquid, 100 mL	Paracetamol 24 mg/mL oral liquid	100	mL
	Cetomacrogol aqueous cream, 475 g	Cetomacrogol aqueous cream	475	g

Note that every CDP will have one or more corresponding Branded Clinical Drug Packages (BCDP) associated with it.

3.4.2 Clinical Drug Package descriptions

CDP Fully Specified Name definition

The Fully Specified Name of a CDP follows the syntax:

CDP FSN := CD_Details {“ (&) ” CD_Details} {“, “Total_Quantity_Size_Details} “ (clinical drug package)”

where the component parts are described as follows:

Table 17: Clinical Drug Package Fully Specified Name description

Description Component	Description
CD_Details	The detail about an individual contains clinical drug role groups within the CDP: Each CD_Details has the syntax: If Count of clinical drug type == 1 CD_Details := Contains_Clinical_Drug.PT “, ” Has_Pack_Size.Value “ ” Pack_Units Else If Count of clinical drug type > 1 CD_Details := Contains_Clinical_Drug.PT “ [” Has_Pack_Size.Value “ ” Pack_Units “]” The list of CD_Details will be ordered alphanumerically Each instance of CD_Details will be separated by a “ (&) ”. If CDP.HasPackSize.Units exists Pack_Units:= CDP.HasPackSize.Units.PT Else If Contains_Clinical_Drug.HasContainerType exists Pack_Units:= Contains_Clinical_Drug. HasContainerType.PT Else Pack_Units:= Contains_Clinical_Drug.HasManufacturedDoseForm.PT If the HasContainerType or HasManufacturedDoseForm properties are used as Pack_Units (discrete CDs) and Has_Pack_Size.Value greater than 1; The associated Pack_Units.PT will be pluralised.
Total_Quantity_Size_Details	If Count of clinical drug type == 1 Total_Quantity_Size_Details:= null Else If Count of clinical drug type > 1 AND all Pack_Units the same Total_Quantity_Size_Details:= Sum of HasPackSize.Values “ ” Pack_Units.pluralised. Else Total_Quantity_Size_Details:= “1 Pack”
(clinical drug package)	The semantic tag used in the Fully Specified Name of all CDP concepts.

CDP Preferred Term definition

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

CDP PT := CD_Details {“ (&) ” CD_Details} {“, “Total_Quantity_Size_Details”}

where the component parts are described as follows:

Table 18: Clinical Drug Package Preferred Term description

Description Component	Description
CD_Details	The detail about an individual contains clinical drug role groups within the CDP: Each CD_Details has the syntax: If Count of clinical drug type == 1 CD_Details := Contains_Clinical_Drug.PT “, ” Has_Pack_Size.Value “ ” Pack_Units Else If Count of clinical drug type > 1 CD_Details := Contains_Clinical_Drug.PT “ [” Has_Pack_Size.Value “ ” Pack_Units “]” The list of CD_Details will be ordered alphanumerically Each instance of CD_Details will be separated by a “ (&) ”. If CDP.HasPackSize.Units exists Pack_Units:= CDP.HasPackSize.Units.PT Else If Contains_Clinical_Drug.HasContainerType exists Pack_Units:= Contains_Clinical_Drug.HasContainerType.PT Else Pack_Units:= Contains_Clinical_Drug.HasManufacturedDoseForm.PT If the HasContainerType or HasManufacturedDoseForm properties are used as Pack_Units (discrete CDs) and Has_Pack_Size.Value greater than 1; The associated Pack_Units.PT will be pluralised.
Total_Quantity_Size_Details	If Count of clinical drug type == 1 Total_Quantity_Size_Details:= null Else If Count of clinical drug type > 1 AND all Pack_Units the same Total_Quantity_Size_Details:= Sum of HasPackSize.Values “ ” Pack_Units.pluralised. Else Total_Quantity_Size_Details:= “1 Pack”

3.5 Product Name (Product Name)

3.5.1 Product Name definition

During the AMTv4 consultation phase, although all stakeholders recognised there were issues with the Trade Product class from AMT v3, a consensus on the purpose of this class and acceptable solution was unable to be reached. Combined with minimising impacts to existing implementers of the AMT flat file, no substantial changes have been made.

The Product Name concept class is a direct reflection of the Trade Product class, recreated as subtypes of 774167006| Product name (product name)|. The Editorial Rules from AMT v3, have been reproduced here, but are expected to be revised as part of the future AMTv4 roadmap.

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

Table 19: Examples of Product Name Fully Specified Names and Preferred Terms

Fully Specified Name	Preferred Term
Amoxil (product name)	Amoxil
Morphine Sulfate (Hospira) (product name)	Morphine Sulfate (Hospira)
Canesten Clotrimazole (product name)	Canesten Clotrimazole
Canesten Bifonazole (product name)	Canesten Bifonazole
Panadeine Forte (product name)	Panadeine Forte
Cold and Flu (Chemmart) (product name)	Cold and Flu (Chemmart)
Triphasil (product name)	Triphasil
- Nexium Hp7 (product name) - Nexium (product name) - Klacid (product name) - Amoxil (product name)	- Nexium Hp7 - Nexium - Klacid - Amoxil

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

The Product Name concept is not currently associated with any modelling, and each concept is essentially a string to be referenced by other concepts by the *Has product name* attribute.

Guidance on how to determine the product name is currently inherited from AMTv3 and described below.

Table 20: Product Name Guidance

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

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

Additional Information	Include in Product Name	Preferred Term Example
Indication	Yes	Aciclovir Cold Sore (Your Pharmacy) Clofeme Thrush Treatment Comfeel Plus Pressure Relieving
	Where there is an abbreviated medical diagnosis for a nutritional supplement, the abbreviation will form the first part of the PN.	MSUD Lophlex HCU Anamix Junior PKU Lophlex LQ
	Where a product includes a specific population group as part of their product name, this will not form the first part of the PN.	Panadol Children's Claratyne Children's Ibuprofen Children's (Chemmart) Nurofen for Children Baby 3+ Months
Information that denotes a manufacturer's product code that is relevant at the Unit of Use or pack levels.	Yes (for bandages and dressings only)	Aquacel (177902) Hydrocoll (900939/1) Tielle (MTL101E)
Sponsor details	No, except where a product has a generic name (that is, the name of the product is a substance name or an indication for treatment) the sponsor, manufacturer, house brand or combination pack details will also be included as part of the PN. Any extra detail such as country affiliation, PTY LTD status will be omitted from the PN.	Amlodipine (Terry White Chemists) Ibuprofen (Herron) Krill Oil (Nature's Own) Acid and Heartburn Relief (GenRx) Cold Sore Fighter (Bioglan) Magmin (no sponsor is included as this is not a generic name) Evicel Thrombin
Substance modification or hydration details (for generic products)	No, except: The PN for a generic product will only include modifications (including hydration status) where it forms part of the product name in the sponsor information such as the PI or CMI. (no current example available)	Morphine (Juno) (While the actual substance used to formulate this product and the BoSS are both morphine hydrochloride trihydrate, the hydrochloride trihydrate is not included in the Product Name as it does not form part of the product name in the PI or CMI.)
Information that denotes a particular monograph (for example, APF, BP) on which the product formulation is based. The standard will only be included in marketed products if it is necessary to include it to differentiate between two products. The year of the monograph will not be included. Note that for non-commercially marketed products, the sponsor name will be "extemporaneous".	No, except where the product is a non-commercially marketed product	Emulsifying Ointment (David Craig) Aqueous Cream (David Craig) Podophyllin Compound BP (extemporaneous) Thymol Compound APF (extemporaneous)

Additional Information	Include in Product Name	Preferred Term Example
Information that denotes a release or pharmacokinetic characteristic of the product.	Yes	Ritalin LA Asasantin SR Seroquel XR
Textual description that is logically part of the brand name, or which is necessary to distinguish between items in a product range.	Yes	Abbocillin VK Accu-Chek Advantage II Pegatron Combination Therapy
	Commas and full stops will be used where appropriate, as represented on the product label and in the supporting documentation.	Sinutab Sinus, Allergy and Pain Relief Zinc, Starch and Talc Dusting Powder APF (extemporaneous) B.I.P. Paste O.R.S. (Aspen)
	Where the conjunction "&" or "+" appear in the product name, the ampersand character "&" shall be converted to "and", and "+" shall be converted to "plus".	Lemsip Max Cold and Flu Dimetapp PE Day plus Night Cough Cold plus Flu
	Where the symbol cannot be substituted with the word, the symbol will be retained in the PN. (For example: *, ~)	Centrum Advance 50+ Sunsense Ultra SPF 30+ BGstar

3.5.2 Product Name descriptions

PN Fully Specified Name definition

The Fully Specified Name of a PN follows the syntax:

PN_FSN := Product_Name_String " (product name)"

where the component parts are described as follows:

Table 21: Product Name Fully Specified Name description

Description Component	Description
Product_Name_String	The product brand name, for either single component products, or components of multicomponent products, and including any necessary additional information as defined throughout section 3.5.1 Examples include: a textual description that is necessary to distinguish between items in a product range; a strength representation for multi-ingredient products (where required for differentiation); or a proprietary form, delivery device or container.
(product name)	The semantic tag used in the Fully Specified Name of all PN concepts.

PN Preferred Term definition

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

PN PT := Product_Name_String

Table 22: Product Name Preferred Term description

Description Component	Description
Product_Name_String	The product brand name, for either single component products, or components of multicomponent products, and including any necessary additional information as defined throughout section 3.5.1 Examples include: a textual description that is necessary to distinguish between items in a product range; a strength representation for multi-ingredient products (where required for differentiation); or a proprietary form, delivery device or container.

Product Name Rules

Table 23: Product Naming Rules

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

Rule ID	Description
AMT-PN-FSN-3	A generic product is one in which the name of the product is a substance name or an indication for treatment. For generic products, the Product Name will be populated with the generic name, followed by a " " and the sponsor/manufacturer/house brand name surrounded by "(" and ")". For example: • Simvastatin (GenRx) • Methotrexate (Ebewe). Where a generic product name includes an abbreviation for a sponsor/manufacturer/house brand name as a hyphenated suffix, the Product Name will be populated with generic name followed by a " " and the abbreviation for the sponsor/manufacturer/house brand name surrounded by "(" and ")". For example: Meloxicam (GA). Where a modified base is included as part of the Product Name, the first letter of the modification will be uppercased. Note: This rule also applies to products that consist of a standard formulation, for example, Calamine Lotion.
AMT-PN-FSN-4	For products where the name consists of a house brand name and a brand name, the Product Name will consist of the brand name only. The sponsor will not be included. For example: Magmin, not Magmin (Blackmores).

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

Where disambiguation is required for two or more products, each of the ingredients will be included in the Product Name. The ingredients shall appear in the same order in which they are referred to in the Product Name, and shall be enclosed within a single bracket, with each of the ingredients separated by a "/" with no spacing around it. Each ingredient shall be represented as the BoSS without hydration.

For example, "Coveram 5 mg/10 mg tablet, 30" is ambiguous as it is not possible to distinguish it from Coveram 10 mg/5 mg tablet, 30. Disambiguation as described above results in the creation of the following unambiguous descriptions:

Term according to rules: Coveram 5 mg/10 mg

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

Term according to rules: Coveram 10 mg/5 mg

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

3.6 Branded Clinical Drug (BCD)

3.6.1 Branded Clinical Drug modelling

During the AMTv4 consultation phase, although all stakeholders recognised there were issues with the Trade Product class from AMT v3, a consensus on the purpose of this class and acceptable solution was unable to be reached. Combined with minimising impacts to existing implementers of the AMT flat file, no substantial changes have been made.

Additional properties may be introduced as part changes to the Product Name class to be scheduled on the AMTv4 roadmap.

A Branded Clinical Drug (BCD) is branded variant of a Clinical Drug (CD). Every BCD is a subtype of a CD. It has the same properties as those described for parent CD, with the addition of the following attributes:

Table 24: Branded Clinical Drug attributes

Attribute	Cardinality	Details
Has product name	1..1	The associated Product Name. Analogous to “Brand Name” (or “Trade Product” from AMTv3). A single, self-grouped attribute per BCD.
Has other identifying information	1..1	Additional details (not otherwise able to be captured within the concept model) that are required to avoid ambiguity or duplication within the terminology. This information should be descriptive information that is specific to the Trade concept (for example, “Sugar Free”, “Refill”, “Strawberry”). A string concrete domain. A single, self-grouped attribute per BCD. If there are no specific “additional details” the value is “None”. Allows all BCD concepts to be sufficiently defined, whilst supporting the expected description logic classification.
Count of active ingredient	1..1	An integer concrete domain, describing the number of active ingredients within the product. A single, self-grouped attribute per BCD. Allows all BCD concepts to be sufficiently defined, whilst supporting the expected description logic classification. Specifically such that overlapping combinations of products with the same Product Name do not subsume each other.

Example Discrete products

Table 25: Branded Clinical Drug discrete product examples

Attribute	Nicabate Minis Orange 1.5 mg lozenge	Amoxil 3 g powder for oral liquid, sachet	Zyprexa Relprevv (olanzapine (as pamoate) 210 mg) modified release injection, vial
IS A	Nicotine 1.5 mg lozenge	Amoxicillin 3 g powder for oral liquid, sachet	Olanzapine (as pamoate) 210 mg modified release injection, vial
Has product name	Nicabate Minis	Amoxil	Zyprexa Relprevv
Has manufactured dose form	Lozenge	Powder for oral liquid	Modified release injection
Has active ingredient	Nicotine	Amoxicillin	
Has precise active ingredient	N/A	N/A	Olanzapine pamoate
Has basis of strength substance (BoSS)	Nicotine	Amoxicillin	Olanzapine
Has concentration strength	N/A	N/A	N/A
Has total quantity	1.5 mg	3000 mg	210 mg
Has other identifying information	"Orange"	"None"	"None"
Count of active ingredient	1	1	1
Has pack size	N/A	N/A	N/A
Has container type	N/A	Sachet	Vial

Example Continuous Products

Table 26: Branded Clinical Drug continuous product examples

Attribute	Nurofen for Children Baby 3+ Months Strawberry 40 mg/mL oral liquid	H-B-Vax II Preservative Free 10 microgram/mL injection, syringe	Hylo-Fresh 0.1% eye drops
IS A	Ibuprofen 40 mg/mL oral liquid	Hepatitis B adult vaccine 10 microgram/mL injection, syringe	Hyaluronate sodium 0.1% eye drops
Has product name	Nurofen for Children Baby 3+ Months	H-B-Vax II	Hylo-Fresh
Has manufactured dose form	Oral liquid	Injection	Eye drops
Has active ingredient	Ibuprofen	Hepatitis B surface antigen	Hyaluronate sodium
Has precise active ingredient	N/A	N/A	N/A
Has basis of strength substance (BoSS)	Ibuprofen	Hepatitis B surface antigen	Hyaluronate sodium
Has concentration strength	40 mg/mL	0.01 mg/mL	1 mg/mL
Has total quantity	N/A	0.01 mg	N/A
Has pack size	N/A	1 mL	N/A
Has other identifying information	"Strawberry"	"Preservative Free"	"None"
Count of active ingredient	1	1	1
Has container type	N/A	Syringe	N/A

Examples of Multi-ingredient BCDs

Figure 16: Multi-ingredient Branded Clinical Drug

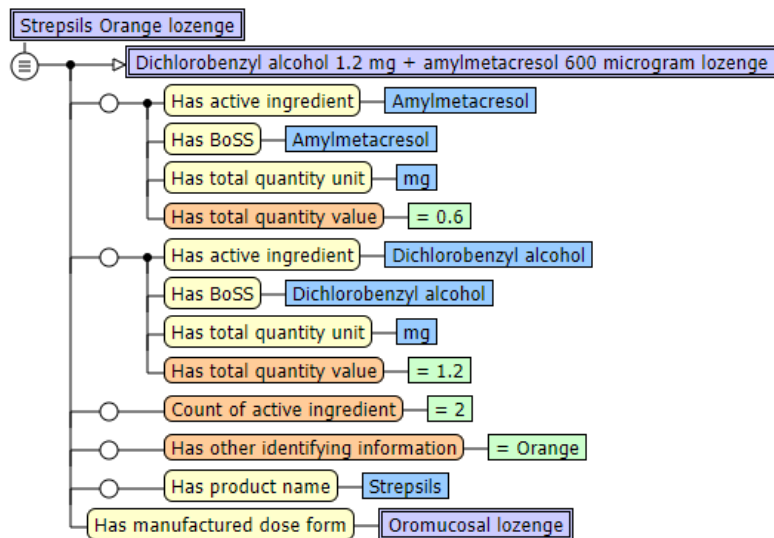
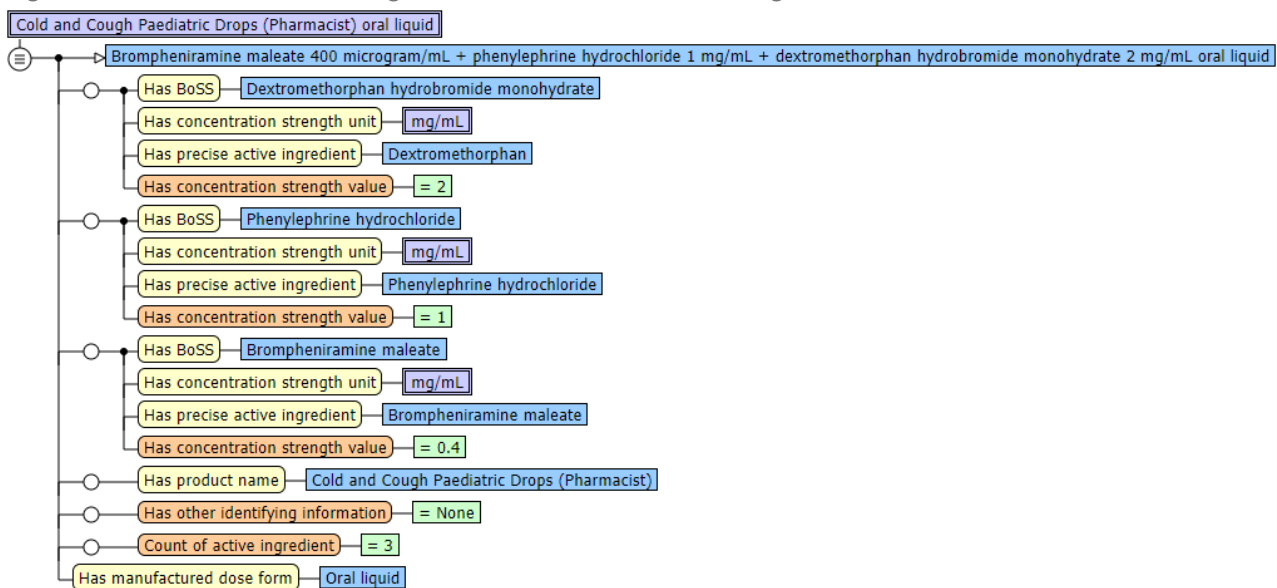


Figure 17: Continuant Multi-ingredient Branded Clinical Drug



"Other identifying information" - definition and rules

"Other identifying information" (OI) is string property allows optional descriptive information about the BCD to be displayed (for example, Sugar Free, Refill, a given flavour). This information is required to avoid ambiguity or duplication in the constructed descriptions for BCD. This will be sourced from TGA data, Sponsor's Product Information or Consumer Medicine Information. There are currently no specific rules, and the information should not be parsed by machine. The values may be used to filter similar products.

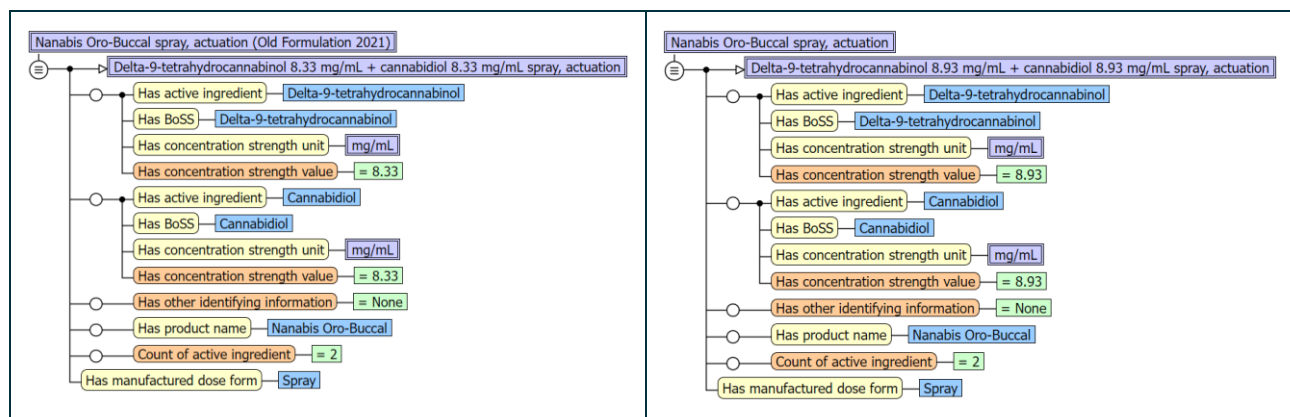
New Formulations

Occasionally, new formulations of existing products come to market. This introduces to opportunities for duplicate concepts and ambiguity into AMT:

1. The new formulation is due to excipients, so each product has identically modelled properties (as excipients are currently out of scope of AMT). This will produce logically equivalent concepts, and duplicate preferred terms.
2. The new formulation of may have a minor change in active ingredients, but the resultant AMT product has the same preferred term as the existing formulation due to the editorial rules for multi-ingredient products.

Both formulations are valid as active concepts in the terminology, but to mitigate having two duplicate Preferred Terms of the existing (older) product will be differentiated with the term 'Old Formulation', in title casing, followed by the year that the old formulation was superseded. The information pertaining to the date that the old formulation was superseded will be confirmed by sponsor information. The term and date will be applied to the end of the Preferred Term of the Branded Clinical Drug, Branded Clinical Drug Package and Containered Branded Clinical Drug Package, contained within brackets.

Figure 18: Old and New Formulations



The method to apply this change is to create a new Preferred Term that contains the differentiating information, then retire the old Preferred Term to avoid ambiguity. The new formulation will not have any additional text applied.

3.6.2 Branded Clinical Drug descriptions

BCD Fully Specified Name definition

The Fully Specified Name of a BCD follows the syntax:

BCD FSN := Product_Name [" " Other_Identifying_Information] [" (" Ingredient_Strength
{" + "

Ingredient_Strength} ")"] " " Form [" , " Pack_Size_Details] " (branded clinical drug)"

where the component parts are described as follows:

Table 27: Branded Clinical Drug Fully Specified Name description

Description Component	Description
Product_Name	The preferred term of the Has product name attributes target.
Other_Identifying_Information	The string value from the "Has other identifying information" property.
Ingredient_Strength	Repeatable component, with an Ingredient_With_Strength for each BoSS role group. Same rules as per CD FSN. Repeatable component, with an Ingredient_With_Strength for each BoSS role group. Ingredient_With_Strength:= Ingredient " " Strength Ingredient:= Basis of Strength Substance preferred term. Strength:= Dependent on available attributes. ▪ If Has total quantity and Has Pack Size exist: Strength:= Has_Total_Quantity "/" Has_Pack_Size Has_Total_Quantity:= Has_Total_Quantity.Value " " Has_Total_Quantity.Units.PT If Has_Pack_Size.Value == 1 Has_Pack_Size:= Has_Pack_Size.Units.PT ELSE Has_Pack_Size:= Has_Pack_Size.Value " Has_Pack_Size.Units.PT ▪ If ONLY Has concentration strength is available: Strength:=Has_Concentration_Strength.Value Has_Concentration_Strength.Units ▪ If ONLY Has Total Quantity is available: Strength:=Has_Total_Quantity.Value Has_Total_Quantity.Units Each Ingredient_With_Strength will be separated by a " + ". If the Has_Active_Ingredient OR Has_Precise_Active_Ingredient values are modifications of the BoSS. Ingredient will be suffixed with ["(as" Modification)"], where modification is the differing salt component. If no BoSS ingredient exists, then Ingredient_With_Strength will be just the Has_Precise_Active_Ingredient.PreferredTerm or (Has_Active_Ingredient.PreferredTerm if not precise ingredient) The order of Ingredient_With_Strength components will be alphanumeric.

Description Component	Description
Form	The Preferred term of the manufactured dose form.
Pack_Size_Details	Pack_Size_Details:= Has Pack Size value “ ” Has_Pack_Size.Units.PT “ ” HasContainerType.PT Do not show any null values.
(branded clinical drug)	The semantic tag used in the Fully Specified Name of all Branded Clinical Drug concepts.

BCD Preferred Term definition

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

BCD PT := Product_Name [" " Other_Identifying_Information] [" (" Ingredient_Strength ")"] [" "
Form]
[" " Pack_Size_Details]

where the component parts are described as follows:

Table 28: Branded Clinical Drug Preferred Term description

Description Component	Description
Product_Name	The preferred term of the <i>Has product name</i> attribute's target.
Other_Identifying_Information	The string value from the <i>Has other identifying information</i> property.
Strength	For single ingredient products Just the Strength values as described for BCD FSN Ingredient_Strength component, but without the ingredient. For multi-ingredient products, neither ingredient strength nor ingredient name are displayed. EXCEPTIONS: There are a small number of exceptions to inclusion of ingredient name and strength. Refer to exceptions notes below.
Form	The Preferred term of the manufactured dose form. Not included if already part of the Product Name. For example, "QV Cream".
Pack_Size_Details	Pack_Size_Details:= Has Pack Size value “ ” Has_Pack_Size.Units.PT “ ” HasContainerType.PT Do not show any null values.

Exceptions to BCD Preferred Term descriptions

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

- duplicate or identical Preferred Terms (which may have different concept IDs); or
- misleading terms which would be created for those units of use containing “inert substance” as the ingredient.
- For multi-component products where one or more of the components is multi-ingredient, the ingredients should be included in every component.

For example: For the BCDP Preferred Term “Brevinor 28 Day (21 x 500 microgram/35 microgram tablets, 7 x inert tablets), 4 x 28”

Table 29: Branded Clinical Drug examples

BCD FSN	Brevinor 28 Day (ethinylestradiol 35 microgram + norethisterone 500 microgram) tablet (branded clinical drug)
BCD PT	Brevinor 28 Day (norethisterone 500 microgram + ethinylestradiol 35 microgram) tablet
BCD FSN	Brevinor 28 Day (inert substance) tablet (branded clinical drug)
BCD PT	Brevinor 28 Day (inert substance) tablet

Without the ingredient detail, the BCDs would have the same Preferred Term of “Brevinor 28 day tablet.

Additional BCD Preferred Term Guidance

Table 30: Additional Branded Clinical Drug Preferred Term guidance

Rule ID	Description
AMT-BCD-PT-2	Strength expression. The BCD Preferred Term will include strength expression (if available) for single ingredient products only. The strength expression general rules and application to specific medication forms is outlined in Appendix E. EXCEPTIONS See AMT-APP-STR-9 in Appendix E. Strength expression may include an alternative strength representation different to the typical numerator/denominator strength expression. Refer to Appendix A.6 for additional rules and exceptions associated with strength representation.

3.7 Branded Clinical Drug Package (BCDP)

3.7.1 Branded Clinical Drug Package modelling

A Branded Clinical Drug Package (BCDP) is the set quantity of BCD products that are supplied for direct patient use. A BCDP may contain multiple BCD components, each of which may or may not be available for supply as an independent prescribable product.

Note that the BCDP does not contain details of Container Type, unless already specified by the referenced BCD. The specific container type is included in the Containered Branded Clinical Drug Package (CBCDP).

The BCDP shares the same properties as CDP, with the addition of the *Has product name*.

The Contains clinical drug property on BCDPs shall reference a BCD. That BCD shall be a subtype of the parent CDPs referenced CD.

For example:

Panadol Extra tablet, 10 (BCDP) **Contains clinical drug** Panadol Extra tablet

Panadol Extra tablet, 10 **IS A** Paracetamol 500 mg + caffeine 65 mg tablet, 10

Paracetamol 500 mg + caffeine 65 mg tablet, 10 **Contains clinical drug** Paracetamol 500 mg + caffeine 65 mg tablet

Panadol Extra tablet **IS A** Paracetamol 500 mg + caffeine 65 mg tablet

3.7.2 Branded Clinical Drug Package descriptions

BCDP Fully Specified Name definition

The Fully Specified Name of a CDP follows the syntax:

CDP FSN := {Product_Name} “ ” BCD_Details {“ (&) ” BCD_Details } “ (branded clinical drug package)”

where the component parts are described as follows:

Table 31: Branded Clinical Drug Package Fully Specified Name description

Description Component	Description
Product_Name	The preferred term of the <i>Has product name</i> attribute's target. The Product_Name is only required when it is different to the component BCDs. For Example. "Nexium Hp7"
BCD_Details	The detail about an individual Contains clinical drug role group that is contained within the CDP: Each BCD_Details has the syntax: BCD_Details:= BCD_PT “ , ” Has_Pack_Size “ ” Has_Pack_Size_Unit BCD_PT – Is the preferred term of the current BCD Has_Pack_Size := the numeric value of the Has Pack Size attribute Has_Pack_Size_Unit := • For continuant products, the preferred term of the Has Pack Size Unit attributes target concept. • For discrete products; The preferred term of the BCD.hasContainerType or If no BCD.hasContainerType, the BCD.HasManufacturedDoseform. Whichever term used is plural if > 1 The list of BCD_Details will be ordered alphanumerically Each instance of BCD_Details will be separated by a “ (&) ” – as per EBNF syntax.
(branded clinical drug package)	The semantic tag used in the Fully Specified Name of all CDP concepts.

BCDP Preferred Term definition

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

BCDP PT := {Product_Name} “ ” BCD_Details {“ (&)” BCD_Details}

where the component parts are described as follows:

Table 32: Branded Clinical Drug Package Preferred Term description

Description Component	Description
Product_Name	The preferred term of the <i>Has product name</i> attribute's target. The Product_Name is only required when it is different to the component BCDs. For Example. “Nexium Hp7”
BCD_Details	The detail about an individual Contains clinical drug role group that is contained within the CDP: Each BCD_Details has the syntax: BCD_Details:= BCD_PT “,” Has_Pack_Size “ ” Has_Pack_Size_Unit BCD_PT – Is the preferred term of the current BCD Has_Pack_Size := the numeric value of the Has Pack Size attribute Has_Pack_Size_Unit := • For continuant products, the preferred term of the Has Pack Size Unit attributes target concept. For discrete products; The preferred term of the BCD.hasContainerType or If no BCD.hasContainerType, just show the quantity value. Each instance of BCD_Details will be separated by a “ (&) ” – as per EBNF syntax.

3.8 Containered Branded Clinical Drug Package (CBCDP)

3.8.1 Containered Branded Clinical Drug Package modelling

The Containered Branded Clinical Drug Package (CBCDP) is the packaged product that is supplied for direct patient use and includes details of the container type. The Container Type defines the type of container that immediately covers the medicine. This is the packaging which directly contains the referenced Clinical Drug concepts such as a blister pack for a tablet, or a sachet for a patch (which might then be placed inside a box, the secondary package). It does not include an article intended for ingestion. Examples of Container Type include ampoule, bottle, blister pack, and vial.

The CBCDP share the same properties as its parent BCDP, with the addition of a *Has container type* property.

The referenced BCD's already have a container type. The *Has container type* value will simply be “Pack”.

3.8.2 Containered Branded Clinical Drug Package descriptions

CBCDP Fully Specified Name definition

The Fully Specified Name of a CBCDP follows the syntax:

$\text{CBCDP FSN} := \text{BCDP_FSN_Details} \text{ “ , “ } \{ \text{Container} \} \text{ “ (containered branded clinical drug package) ”}$

where the component parts are described as follows:

Table 33: Containered Branded Clinical Drug Package Fully Specified Name description

Description Component	Description
BCDP_FSN_Details	The details included in the Fully Specified Name of the associated BCDP, but without the semantic tag (that is, without “(branded clinical drug package)”).
Container	The Preferred Term of the Has container type target.
(containered branded clinical drug package)	The semantic tag used in the Fully Specified Name of all CBCDP concepts.

Multipacks and Subpacks

Where the CBCDP has a subpack, then the container type (where shown) will be pluralised.

CBCDP Preferred Term definition

Preferred Term of a CBCDP, by default, follows the syntax:

$\text{CBCDP PT} := \text{BCDP_PT_Details} [\text{“ , “ Container}]$

where the component parts are described as follows:

Table 34: Containered Branded Clinical Drug Package Preferred Term description

Description Component	Description
BCDP_PT_Details	The details included in the Preferred Term of the associated BCDP.
Container	The Preferred Term of the <i>Has container type</i> target. If the container type is “Pack”, it will not be rendered when the product uses the “Contains clinical drug”. Instead the container portion of the BCDP_PT_Details component will be pluralised (if pack size is > 1 each)

Figure 19: Containered Branded Clinical Drug Package Preferred Term inclusion of 'Pack' example

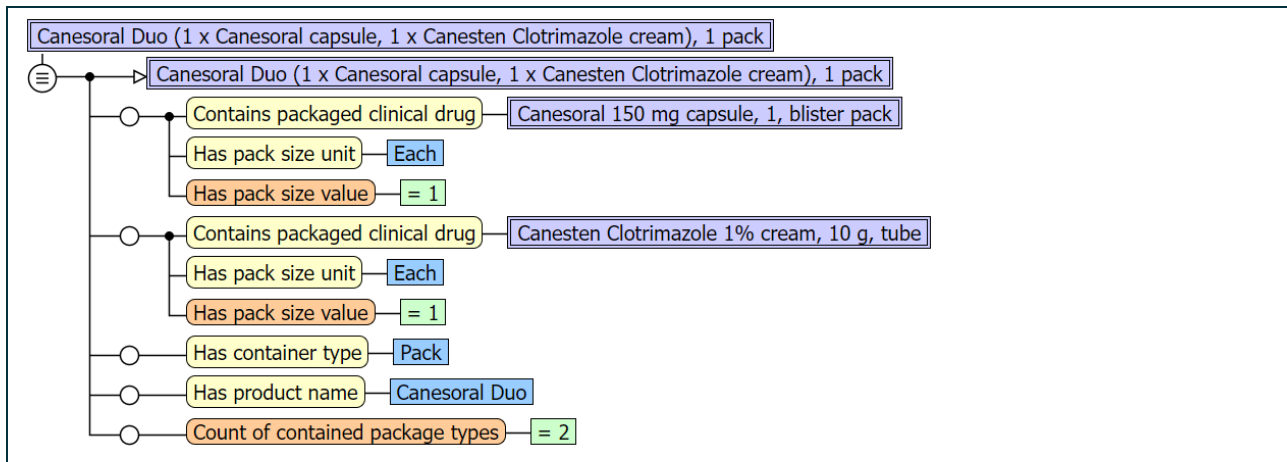
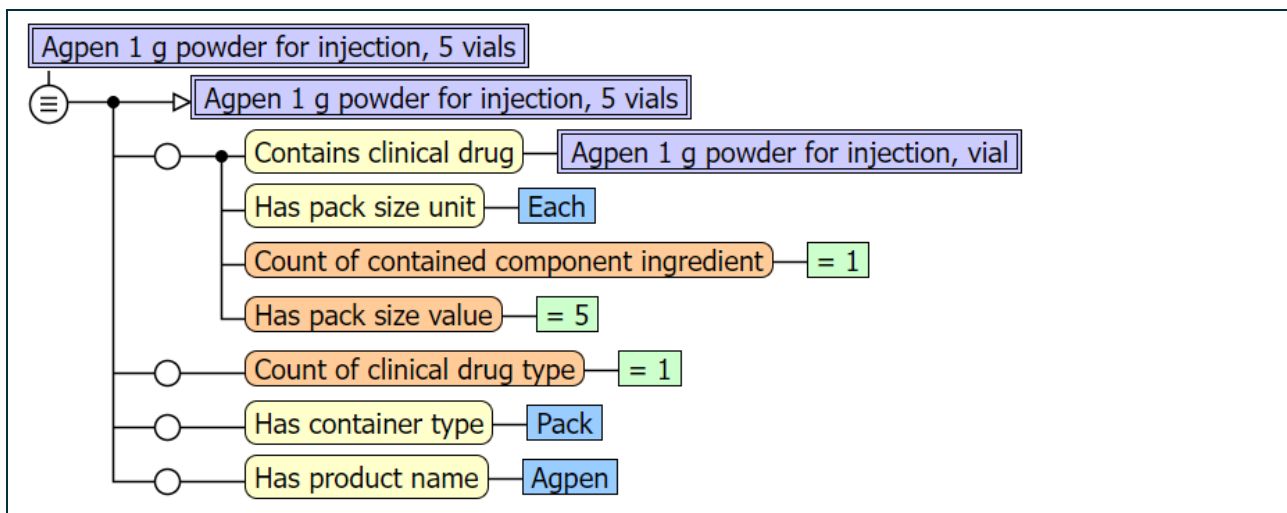


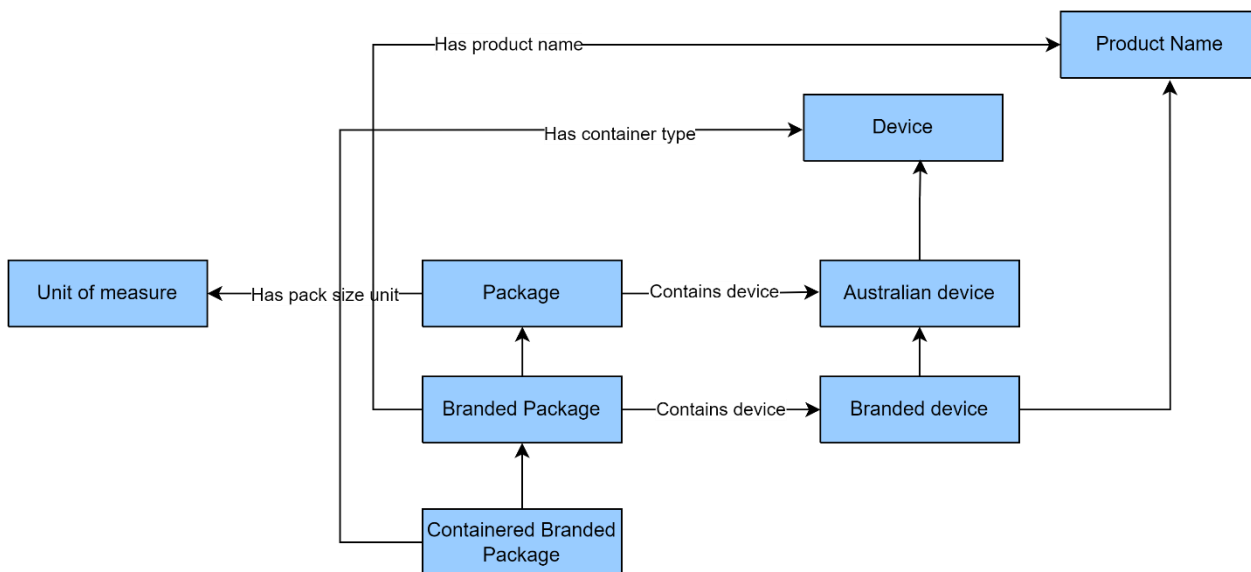
Figure 20: Containered Branded Clinical Drug Package Preferred Term exclusion of 'Pack' example



3.9 Device Concepts

AMTv4 introduces a dedicated hierarchy for modelling device products, whereas in AMTv3 devices were included using the same concept model as medicinal products. The current hierarchy retains analogous concepts to the familiar “7 box” model, and whilst the content is mostly undefined it provides an opportunity to develop a more appropriate model to describe this content and support the associated use cases.

Figure 21: AMT v4 Device model



As noted above, the current device model is minimal, with only the following attributes used

Table 35: AMT v4 Device model attributes

Has product name	The associated Product Name. Analogous to “Brand Name” (or “Trade Product” from AMTv3). A single, self-grouped attribute.
Has container type	The container a specific presentation is available in. Not all clinical drugs have a container type.
Contains device	This attribute references the devices that are contained within the package.
Has pack size	The quantity of CD(s) within a given pack. A single <i>Has Pack Size</i> attribute pair (value + unit) is grouped with each <i>Contains device</i> attribute. All devices are “discrete” and come in packs of countable quantities.

3.9.1 Device Examples

Figure 22: Device example

Device

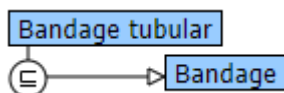


Figure 23: Australian Device and Branded Device examples

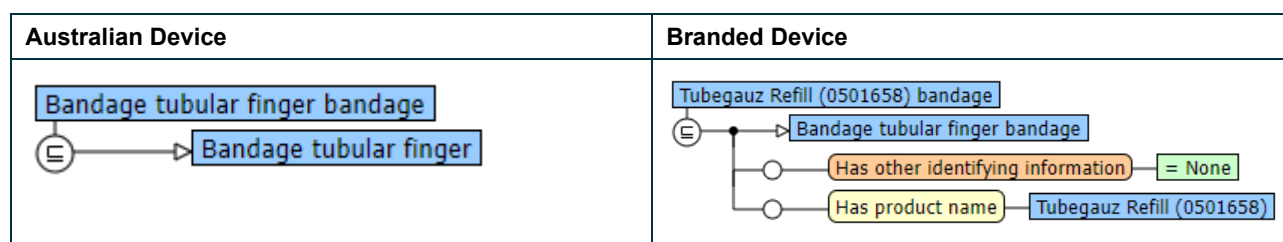


Figure 24: Package and Branded Package examples

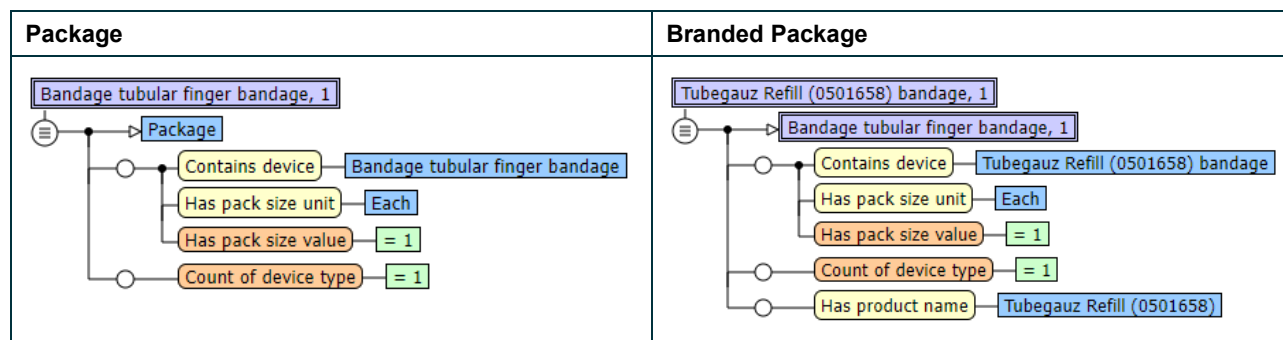
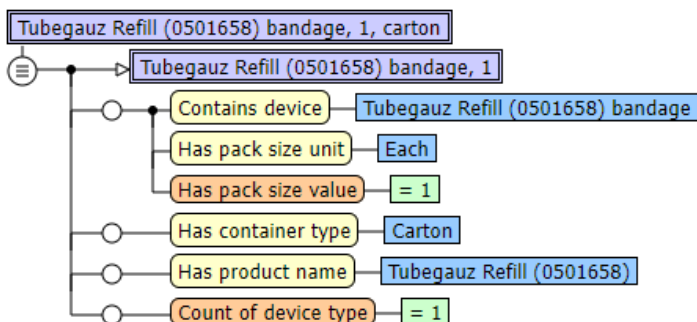


Figure 25: Containered Branded Package example

Containered Branded Package



It is anticipated that a more comprehensive model will be developed, specifically at the **Australian device** level, which may define the material composition and size of devices. This model will be developed in consultation with stakeholders.

Minimal changes are anticipated for the *package* concepts.

3.9.2 Device Naming Rules

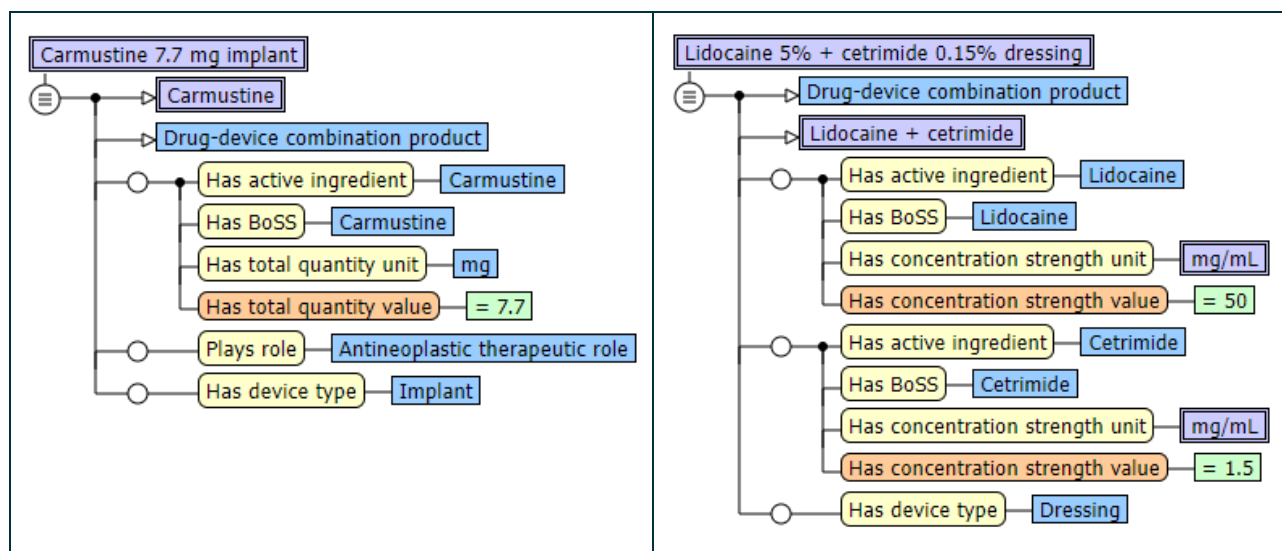
Until a comprehensive concept model for Australian devices is developed, the terms used to label these concepts will be created manually with the primary goal to unambiguously describe the products.

The naming rules for packs of devices will align with those for medicinal products, where the referenced devices are described along with the Pack Size properties, and optional container type.

3.9.3 Medicinal Devices

Some devices do contain medicinal substances for example implants. Such concepts will be modelled using the medicines model, with the exception of using the **Has device type** instead of the **Has manufactured dose form**. These concepts will exist as subtypes of 411115002|Drug-device combination product| as well as their applicable Medicinal Product concept. Some examples are shown below.

Figure 26: Drug-device combination product examples



3.9.4 Correlation between Devices, Medicines, and Notable Reference Sets

The correlation between the device concepts, medicinal concepts and notable reference sets is described in Table 36.

Table 36: Device, Medicine, and Reference Set Correlation

Devices	Medicines	Notable Reference Set
Device	Medicinal Product	MP refset
Australian Device	Clinical Drug	MPUU refset

Devices	Medicines	Notable Reference Set
Package	Clinical Drug Package	MPP refset
Product Name	Product Name	TP refset
Branded Device	Branded Clinical Drug	TPUU refset
Branded Package	Branded Clinical Drug Package	TPP refset
Containerised Branded Packaged	Containerised Branded Clinical Drug Package	CTPP refset

Appendix A

A.1 Extended Backus-Naur Form

The rules for generating the descriptions for AMT products and supporting concepts, are specified 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 and uses the following characters.¹³

Table 37: EBNF characters

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

¹³ International Organization for Standardization. [ISO/IEC 14977:1996 Information technology – Syntactic metalanguage – Extended BNF, 1996](#), Edition 1, accessed 32 March 2026

A.2 Unit Conversion Factors

AMT v4 normalises all mass and volume quantities to use milligram and millilitre units to model concepts, regardless of the actual units used in descriptions. This ensures predictable classification results and provides a consistent target for any calculations that implementers may wish to use.

Table 38 provides a list of conversion factors for moving between the general units and normalised units. The left side of the table lists the mass and volume units of measure used in AMT, and right-side alternative units. The conversion factor is used to move between the two.

To get alternative units from the modelled AMT units (left to right)
divide the value by the conversion factor.

e.g. 1200 mg / 1000 → 1.2g

To normalise alternative units to AMT modelled units (right to left)

Multiply the value by the conversion factor.

e.g. 823 ug/g * 0.000001 → 0.000823 mg/mg

Table 38: Unit Conversion Factors

Modelled AMT Unit of Measure		Conversion Factor	Alternative Unit of Measure	
Concept ID	Preferred Term		Concept ID	Preferred Term
258684004	mg	1000	258682000	g
56601000168105	mg/application	1000	331000168106	g/application
408169001	mg/mg	0.001	396167009	g/kg
258798001	mg/mL	1	258794004	g/L
258798001	mg/mL	1000	396169007	g/mL
408164006	IU/mg	0.001	408163000	IU/g
258684004	mg	1000000	258683005	kg
258773002	mL	1000	258770004	L
258684004	mg	0.001	258685003	mcg
408105009	mg/actuation	0.001	408104008	mcg/actuation
408169001	mg/mg	0.001	408168009	mg/g
258798001	mg/mL	1000	258796002	mg/L
999000121000168104	mL/mg	0.001	419805009	mL/g
419346007	mL/mL	0.001	1381201000168109	mL/L
258836006	mg/24h	1000	258840002	ug/24h
408169001	mg/mg	0.000001	258802000	ug/g
258834009	mg/h	1000	258838007	ug/h
258798001	mg/mL	0.001	258801007	ug/mL

A.3 Capitalisation Rules

Table 39: Capitalisation rules

Rule ID	Description
V4-CAP-1	Descriptions will align with the SNOMED CT editorial approach.¹⁴ <i>“descriptions begin with an upper-case letter; the rest of the words in the description lower case except for abbreviations, proper nouns, i.e. names of people, organizations, taxonomic groups (e.g. species, genus, family), etc.”</i>
AMT-APP-CAP-2	Product Names and Other Identifying Information will have each word in the name expressed as title case, including the form, where it appears as part of the Product_Name_String (for example, Dimetapp Chesty Cough Elixir). Individual words which appear as all upper or all lower cased will be title cased (for example, Ganfort not GANFORT, Elevit not elevit). Each word in a hyphenated name will be expressed as title case (for example, Duro-Tuss, Anti-Inflammatory). EXCEPTIONS Unique brand specific casing will be maintained only if it assists with readability. This also applies to concatenated terms (for example, DaktaGold not DaktaGOLD, GlucoOz). Articles such as “the” will be in lower case. Conjunctions such as “and” and prepositions such as “with” will be in lower case. Certain words, such as “plus” may be either in title case or lower case, depending on their use. Where “plus” is used as a conjunction it will be “plus” (for example, Day plus Night) and when it is used as a noun it will be “Plus” (for example, Coversyl Plus). Where an abbreviation which is included in the PN is an abbreviation for a substance name, then this abbreviation will be upper cased. For example: where the letters “hct” or “hctz” are used to indicate “hydrochlorothiazide” then they will be shown as “HCT” or “HCTZ”; where the letters “rbv” are used to represent “ribavirin”, then they will be shown as “RBV”. Where an acronym is included in the PN then this acronym will be upper cased. For example: “SR” as an acronym for sustained release; “LD” as an acronym for low dose; ZSC; Restore O.R.S. Where a PN contains a series of letters which do not form a word, these letters will be upper cased. For example, Aridon APN.
AMT-APP-CAP-3	Proper nouns will always be expressed in title case (for example, Bacillus Calmette and Guerin, Brisbane).
AMT-APP-CAP-4	Roman numerals will always be expressed in upper case (for example, factor XIII, antithrombin III).

Error! Bookmark not defined. SNOMED, [Case Significance](#).

Rule ID	Description
AMT-APP-CAP-5	Chemical element symbols will be expressed in upper case (for a single letter) or in a mixture of upper and lower case (for more than one letter) according to International Union of Pure and Applied Chemistry (IUPAC) convention (for example, carbon (C), chromium (51Cr) edetate, cyanocobalamin (57Co)). ¹⁵

¹⁵ G P Moss, 'Basic Terminology of Stereochemistry (IUPAC Recommendations 1996)', Pure and Applied Chemistry, 1996, 68(12): 2193–2222, doi:10.1351/pac199668122193

A.4 Clinically Significant Salts

This topic is subject to ongoing discussion and will be revised following further analysis, review, and discussion in consultation with clinical stakeholders. The guidance below is retained from AMT v3. Changes are expected due to the introduction of Has precise ingredient, and more powerful description logic capabilities in AMT v4.

As previously described in **Error! Reference source not found. [Section 3.2.1](#)**, the Medicinal Product will be represented free of chemical modifications to a base unless one or more of the following exceptions apply, in which case the name will be represented by the full name including the modification.

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

The base of a modified base, for example:

modified base	base
calcium gluconate	calcium
clodronate sodium	clodronate

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

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

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

A.4.1 Discernible therapeutic differences to the base (clinically significant modifications)

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

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

Modifications to a base will also include the following:

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

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

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

Modifications which may be made to a base include:

- albumin bound formulations
- lipid formulations
- liposomal formulations.

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

- doxorubicin hydrochloride (as pegylated liposomal).

A.5 Examples of products with more than three ingredients

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

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

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

Table 40: Exception examples – More than 3 ingredients specified in Medicinal Product Preferred Term

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

A.6 Strength representation in descriptions guidelines

The rules described in this section pertain to strength details as represented in the description text of AMT concepts only, and should not be confused with strength details as represented within the modelled attributes.

Table 41: General Strength Format Rules

Rule ID	Description
V4-STR-1	Strength is to be expressed in accordance with the requirements stipulated by the <i>General requirements for labels for medicines</i> . ¹⁶
V4-STR-2	The strength units will be consistent with the <i>Unit of Measure</i> .
V4-STR-3	Note that any overage contained in the product to allow the formulated amount to be administered is not specified.

¹⁶[Therapeutic Goods \(Standard for Medicinal Cannabis\) \(TGO 93\) Order 2017](#) subsection 10(1)

Rule ID	Description
V4-STR-4	In general, the strength of an active ingredient should be expressed by a number between 1 and 999 metric units, and where required, to a maximum of 3 decimal places. If the number of units is less than 1, the next lower unit level should be used (for example, 500 micrograms should be used in preference to 0.5 mg). If the number of units is equal to or greater than 1000, the next higher unit level should be used (for example, 2 g should be used in preference to 2000 mg). This means that the units of strength may vary across a range of products. For example ceftriaxone may have powder for injection strengths of 500 mg, 1 g and 2 g. Where the Product Name of a product implies a strength unit, this will be disregarded in the strength expression of the product, and the above rules will apply (for example, Naprosyn SR 1000 (naproxen 1 g) modified release tablet, 1 tablet (branded clinical drug)). EXCEPTIONS Safety considerations will be taken into account when converting units. If dose titration is likely to occur across a range of products, then strength units for the product group will be reviewed on an individual basis, especially if titration involves use of more than one strength unit. Current exceptions (listed at the base level) are: fentanyl will always be expressed as micrograms, for example, fentanyl 1600 microgram lozenge. dexmedetomidine will always be expressed as micrograms, for example, dexmedetomidine 1000 microgram/10 mL injection. vitamin A and vitamin A derivatives will always be expressed as microgram RE, for example, retinol palmitate 1050 microgram RE. Strengths of ingredients less than 1 microgram will be reviewed on a case-by-case basis to ensure that the represented strength conforms to current clinical practice, for example, calcitriol 0.25 microgram capsule (not 250 nanograms). Where the value for volume is less than 1 millilitre it will not be converted (that is, to conform to current clinical practice these volumes will not be expressed as microlitres), for example, dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, syringe. Where the molar value is less than 1 micromole it will not be converted (that is, to conform to current clinical practice these values will not be expressed as nanomoles), for example, no examples currently exist in the AMT. Where the Unit of Measure is an index of reactivity (IR) with a value of less than 1, it will not be converted, as there is no appropriate unit to convert it to (for example, it will continue to exist as 0.5 IR). For example: for example, house dust mite American + European 0.1 IR/mL injection, vial.
V4-STR-5	A space will be inserted between the strength value and strength Unit of Measure. This space must be a non-breaking space to ensure that the strength value and strength unit expressions are always kept together. For any value $\geq 10,000$ a space will be included after every third digit starting from the right. For example: 10 000; 500 000; 1 000 000. For any value $\geq$ one million, the value will be expressed as a digit to state the number of millions (or part thereof) followed by the text "million". For example, the numerical value of 1 000 000 would be represented as "1 million", the numerical value of 1 500 000 would be represented as "1.5 million".
V4-STR-6	Strength units of measure will be expressed as singular if the value is less than or equal to "1", and will be expressed as plural if the value is greater than "1". This rule applies to full descriptions only – it does not apply to abbreviations. EXCEPTION: The strength units of measure of "microgram" will always be singular.
V4-STR-7	The full term "units" will be used rather than the abbreviated "U".
V4-STR-8	The percentage strength will not be qualified with the appropriate w/w or w/v unless required to avoid duplication of descriptions which only show an Other Strength Representation. For example, "coal tar prepared 1% w/w lotion" and "coal tar prepared 1% w/v lotion".

Rule ID	Description
V4-STR-9	A strength expression is mandatory unless defined as an exception as follows: Where a product is an allergen extract, the strength expression general rules will apply, except that no ingredient strength denominator will be expressed. The denominator value will be assumed from the pack size details. Where a product is a vaccine. Refer to A.7.1 Where a product is an antivenom. Refer to A.7.2 Where an ingredient is inert in its own right and a strength expression would not be appropriate, then no strength is expressed. This includes Water, water purified, water for injections, water for irrigation, inert substance diluent etc. Where a group of ingredients forms a compound where the inclusion of strength is meaningless at either the ingredient level or the product level. Examples include aqueous cream, calamine lotion, vitamin B compound.
V4-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.
V4-STR-11	Where the strength or volume of a product is expressed with a lower limit or an approximate (that is, contains not less than, contains equal to or greater than, more than, or approximately) the strength or volume will be expressed as a specific value without any other descriptors. This rule is mostly encountered with medicines containing biological components where an exact strength cannot be stated. For example: factor II factor X von Willebrand factor
V4-STR-12	The percentage strength of a product, where included as defined in Appendix A.6.1 will not be shown when this value is equal to 100%.

A.6.1 Strength expression rules for specific medication forms

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

Table 42: Examples of exceptions and associated rules for strength expressions

Medication Form	Rules	Example
Solid unit dose forms e.g. tablets, capsules, pessaries, suppositories, lozenge, pastille, chewing gum	Strength is to be expressed as the amount per unit dose form.	amoxicillin 500 mg capsule fentanyl 400 microgram lozenge
Liquid unit dose forms e.g. single dose injections	The strength of liquid single dose injections is to be expressed as the amount of drug present in the unit dose volume.	gentamicin 80 mg/2 mL injection
	EXCEPTION Water for injection will not have a specified strength. This will also apply to other products that do not have an associated specific strength.	water for injection 10 mL injection

Medication Form	Rules	Example
Liquid unit dose forms e.g. multidose injections	Strength is to be expressed as the amount of active ingredient per mL. This method will be used for insulins and other identified multidose injections where the intention is that only a proportion of the total quantity will be administered at any one time.	insulin aspart 100 units/mL injection
Liquid unit dose forms – others e.g. sachets of liquid	Strength is to be expressed as the amount of drug per mL.	chlorhexidine gluconate 1.2 mg/mL sachet
Continuous solid unit doses e.g. granules, powder	Strength is to be expressed as the weight of the active ingredient.	sodium bicarbonate 1.76 g sachet
Continuous semi-solid preparations e.g. creams, gels, ointments	If a product is applied locally and is intended to have a local effect, then a single strength as % should be displayed.	hydrocortisone 1% cream
	If a product is applied locally and is intended to have a systemic effect, then a single strength as mg (or similar) should be displayed. If the product documentation also represents the strength in a different form (such as %), then dual strength as % followed by mg (or similar) in brackets should be displayed.	testosterone 1% (12.5 mg/actuation) gel, actuation
Continuous liquid preparations, other than for ingestion e.g. mouthwash, paints, eye drops, ear drops, nasal drops, etc.	Strength is to be expressed as weight or volume per gram or mL (or other weight or volume of the product as appropriate).	
	If a product is applied locally and is intended to have a local effect, then a single strength as % should be displayed.	chlorhexidine gluconate 0.2% mouthwash
	If a product is applied locally and is intended to have a systemic effect, then a single strength as mg (or similar) should be displayed. If the product documentation also represents the strength in a different form (such as %), then dual strength as % followed by mg (or similar) in brackets should be displayed.	(no current example available)
Continuous liquid preparations for ingestion e.g. oral solutions, oral suspensions, oral emulsions, oral liquids	Strength will be expressed as the amount of active ingredient in a stated volume, as is represented on the package label.	erythromycin 200 mg/5 mL oral liquid ciclosporin 100 mg/mL oral liquid
	Note: where a powder for oral suspension is labelled in terms of the reconstituted form, the strength will be represented as the amount of active ingredient in the reconstituted dose volume.	amoxicillin 250 mg/5 mL powder for oral liquid

Medication Form	Rules	Example
Continuous solid preparations e.g. granules, powders	Strength will usually be expressed as weight per weight or weight per volume.	psyllium husk powder 535 mg/g powder for oral liquid
Patches	Strength will be expressed as the amount of active drug released over a stated time.	estradiol 25 microgram/24 hours patch
Inhalers and sprays e.g. inhalers and sprays, pressurised inhalers, dry powder inhalers, nasal spray, sublingual spray	Metered dose inhalers: The strength is expressed as the amount (weight) per actuation. Other inhalers: The strength is expressed as per mL or per mg, whichever is appropriate to the form of the inhaler.	beclomethasone 50 microgram/actuation powder for inhalation
Implants	The strength is expressed either as the amount per implant or device.	estradiol 20 mg implant
Dry powder injections	The strength is expressed as the amount per vial (usually as a weight).	amoxicillin 500 mg powder for injection

A.6.2 Dual strength representation

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

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

Examples of items where this may be used include:

- Adrenaline and noradrenaline for parenteral use. For example, adrenaline 1 in 1000 (1 mg/mL) injection, ampoules.
- Calcium supplement for osteoporosis. For example, calcium carbonate 1.5 g (calcium 600 mg) tablet.
- Hormone replacement products. For example, testosterone 1% (25 mg/2.5 g) gel, sachet.

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

A.6.3 Strength representation for products containing potassium

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

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

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

Note:

- If this information is not readily available in the product documentation, the mmol strength will need to be calculated (and rounded up to 1 decimal place) to ensure it is within range.
- If no maximum daily dose is available in the product information, then the mmol strength will only be included if it contains at least 7.5 mmol/unit dose.
- The % strength will be dropped off for the potassium component in parenteral products as no more than two strengths should be displayed. For example, potassium chloride 2.98 g (potassium 40 mmol)/L + sodium chloride 0.584% (5.84 g/L) injection, bag.
- The mmol strength will follow the numerator/denominator strength of the substance. For example:
 - single source of potassium - monobasic potassium phosphate 1.361 g (potassium 10 mmol)/10 mL injection, ampoule
 - multiple sources of potassium - potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) effervescent tablet.

A.6.4 Acceptable synonyms

When a product is expressed with both a single strength and a strength range, an acceptable synonym displaying the alternate strength may be added to the CD, CDP, BCD, CBDP and CBCDP concepts. For example:

- Oncotice BCG
- Product label states a strength of 5×10^8 CFU
- Prescribed, and PI states a strength of $2\text{--}8 \times 10^8$ CFU.

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

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

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

A.6.5 Strength expression rules for specific substances

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

Table 43: Substances with specific strength representation requirements

Substance	Strength Representation
alpha tocopherol	mg with units in (...)
dl-alpha-tocopheryl acetate	mg with units in (...)
anti-D rho immunoglobulin, human	units only
antithrombin III	units only
bacitracin zinc	units only
bleomycin sulfate	units only
colecalfiferol	mg with units in (...)
d-alpha-tocopherol	mg with units in (...)
d-alpha-tocopheryl acetate	mg with units in (...)
d-alpha-tocopheryl acid succinate	mg with units in (...)
epoetin alfa	units only
epoetin beta	units only
epoetin lambda	units only
factor II	units only
factor IX	units only
factor VIII	units only
factor XIII	units only
felypressin	units only
follitropin alfa	units with mg in (...)
follitropin beta	units with mg in (...)
gonadotrophin - chorionic human	units only
gonadotrophin-menopausal human	units only
heparin sodium	units only
hyaluronidase	units only
interferon alfa-2a	units with mg in (...)
interferon alfa-2b	units with mg in (...)
interferon beta-1a	units with mg in (...)
interferon beta-1b	units with mg in (...)
interferon gamma-1b	units with mg in (...)
lenograstim	units with mg in (...)
lutropin alfa	units only
moroctocog alfa	units only
nonacog alfa	units only
nystatin	units only
octocog alfa	units only
ornipressin	units only
oxytocin	units only
pancreatic extract	units only
protein C	units only
calcitonin salmon (salcatonin)	units only
somatropin	mg only
streptokinase	units only
tenecteplase	mg only
vitamin A and vitamin A derivatives	microgram RE

A.7 Considerations for 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.

A.7.1 Vaccines

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

Substances

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

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

For example:

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

Fully Specified Names of Notable Concepts

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

For example:

- Hepatitis A virus antigen (medicinal product)
- Measles virus live antigen + mumps virus live antigen + rubella virus live antigen (medicinal product).

Preferred Terms of Medicinal Concepts

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

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

For example:

- Hepatitis A vaccine
- Measles + mumps + rubella live vaccine

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

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

For example:

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

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

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

As such, the tuberculosis vaccine will be named:

- MP FSN: “Mycobacterium bovis (*Bacillus Calmette and Guerin*) live antigen (medicinal product)”
- MP PT: “Mycobacterium bovis (BCG) live vaccine”.

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

Valency

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

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

- bivalent
- trivalent
- quadrivalent
- pentavalent

- hexavalent.

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

- 13 valent
- 23 valent.

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

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

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

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

- A/California/7/2009 (H1N1) pdm09-like virus
- A/Hong Kong/4801/2014 (H3N2)-like virus
- B/Brisbane/60/2008-like virus.

Classification of technology

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

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

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

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

The *Haemophilus influenzae* type b vaccine exists in two forms, one with polyribosylribitol phosphate to tetanus toxoid conjugation, and the other with polyribosylribitol phosphate to outer membrane protein conjugation. Given that the variations have significantly different clinical

implications, the terms “conjugate (PRP-T)” and “conjugate (PRP-OMP)” will always be included in the Fully Specified Name and Preferred Term.

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

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

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

- Bexsero Clinical Drug: meningococcal B 4 component vaccine injection, 0.5 mL syringe.

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

Strength

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

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

For example:

- Engerix-B Adult Clinical Drug: hepatitis B adult vaccine *20 microgram/1 mL* injection, syringe.
- H-B-Vax II Clinical Drug: hepatitis B adult vaccine *10 microgram/1 mL* injection, syringe.

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

For example, differentiated Clinical Drug Preferred Terms:

- Menactra: meningococcal A 4 microgram/0.5 mL + meningococcal C 4 microgram/0.5 mL + meningococcal W135 4 microgram/0.5 mL + meningococcal Y 4 microgram/0.5 mL conjugate vaccine injection, vial.

- Nimenrix: meningococcal A 5 microgram + meningococcal C 5 microgram + meningococcal W135 5 microgram + meningococcal Y 5 microgram conjugate vaccine injection, vial.

Instances will occur where two products exist with different amounts of antigen intended for different clinical indications or populations. These differences may have implications affecting dosing schedules. In this circumstance, a generic term describing the population for which the formulation is intended will be included. If a population descriptor is included, it will precede the technology (if required) and term “vaccine”. The following terms have no set definition or age ranges assigned to them and are intended only for differentiation. For example:

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

Year and season-specific formulations

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

- influenza trivalent vaccine 2015
- influenza quadrivalent vaccine 2015.

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

For example, the following Medicinal Product Preferred Terms:

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

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

For example, the following Medicinal Product Preferred Terms:

- influenza vaccine pandemic 2009.

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

For example, the following Medicinal Product Preferred Terms:

- influenza trivalent vaccine 2011-2012.

Multi-ingredient vaccines

Multi-ingredient vaccines refer to pre-formulated combination vaccines that are designed to be delivered in a single administration, for the prevention of more than one disease (in distinction to a multivalent vaccine for the prevention of one particular disease only, caused by multiple variants of

the same organism). Preferred Terms for multi-ingredient vaccines will follow the multi-ingredient editorial rules. Ingredients will always appear in the order stipulated by the *Australian Immunisation Handbook*. For example, the following Medicinal Product Preferred Terms:

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

Note: In the context of AMT, “multi-ingredient vaccines” refers to what clinicians and *The Australian Immunisation Handbook* consider to be “combination vaccines”.¹⁷

Vaccine preparations for other uses

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

The specific indication, such as “skin test”, of the preparation will be included from the Medicinal Product level where required. For example:

- Medicinal Product Preferred Term: Q fever skin test
- Clinical Drug Preferred Term: Q fever skin test injection, 0.5 mL vial.

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

For example Immucyst will be described as:

- Clinical Drug Preferred Term: Mycobacterium bovis (BCG) live non-vaccine injection, vial.

Synonyms

Acceptable Synonyms

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

For example:

- Fully Specified Name: rotavirus serotype G1P1A(8) live antigen 1 million CCID50 units / 1.5 mL oral liquid, 1.5 mL syringe (clinical drug).
- Acceptable synonym: rotavirus type G1P1A(8) live antigen 1 million CCID50 units/1.5 mL oral liquid, syringe.

Acronyms

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

¹⁷ Australian Technical Advisory Group on Immunisation (ATAGI), Australian Immunisation Handbook, immunisationhandbook.health.gov.au, 2025, accessed 5 January 2026.

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

For example:

- Medicinal Product Acceptable Synonym: MMR (measles + mumps + rubella) live vaccine.
- Clinical Drug Acceptable Synonym: MMR (measles + mumps + rubella) live vaccine injection, vial.
- Clinical Drug Package Acceptable Synonym: MMR (measles + mumps + rubella) live vaccine injection, 10 vials.

Additional information – preservatives, adjuvants, production media, microbial strains

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

A.7.2 Antivenoms

Fully Specified Name

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

Preferred Term

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

Strength

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

A.7.3 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.

A.7.4 Diagnostic Agent

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

A.7.5 Dressings and Bandages

Dressings and bandages included in the AMT currently comprise of such products as listed in the PBS and RPBS. Most products in this class do not have an active ingredient and hence do not have strength. The MP refset member (least specific concept type) "Device" usually describes the type of bandage or dressing. The Australian Device concepts (MPUU refset type) may include additional information related to 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

As noted in 3.9, the modelling (and subsequent naming) of devices concepts is on the AMT roadmap for review and is subject to future changes.

A.7.6 Enteral Feeds

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

A.7.7 Extemporaneous preparations

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

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

A.7.8 Herbal preparations

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

Substance

Herbal substances will follow the existing Editorial Rules outlined in 5.2 Substance Descriptions. The substance name will be derived from the monograph name used in *Herbs & Natural Supplements: An Evidence-based Guide*.¹⁸ Where this reference does not describe the ingredient, alternative sources such as the sponsor's Product Information or Consumer Medicine Information, or sponsor's website are used to assign a common ingredient name.

Fully Specified Name

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

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

Preferred Term

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

For example, Preferred Term: bilberry extract

A.7.9 Medicinal Cannabis

The rules governing the medicinal cannabis class of products have been created in consultation with the Medicinal Cannabis Terminology User Group that was created by the NCTS, and involved stakeholders across government agencies, departments, as well as clinical software vendors, with expertise across healthcare settings, policy, and clinical software and implementation.

Substance

Medicinal cannabis is a herbal medicine and is available in various forms of refinement, including extracts, isolates and plant material. The cannabinoid substance only will be stated, and the level of refinement (extract, isolate, flower) will not be captured.

Cannabinoid substances include, but are not limited to:

- Cannabidiol
- Cannabigerol
- delta-9-tetrahydrocannabinol.

For a cannabinoid substance to be considered an active ingredient, it must meet at least one of the two requirements:

1. the strength related to the BoSS is a concrete value. The strength cannot be an inequality.
2. meets the Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017 definition of an active cannabinoid:¹⁹
 - Any tetrahydrocannabinol (THC), including corresponding acids, ≥ 1.0 % w/w or w/v of the product.
 - Any other cannabinoids, including corresponding acids, ≥ 2.0 % w/w or w/v of the product.

¹⁸ L Braun, M Cohen, *Herbs & Natural Supplements: An Evidence-based Guide* 4th Edition: Elsevier, Chatswood, 2015.

¹⁹ [Therapeutic Goods \(Standard for Medicinal Cannabis\) \(TGO 93\) Order 2017](#) (subsection 10(1))

NB: Where a cannabis product states a concrete strength value but does not meet the TGO93 definition of an active cannabinoid, it will still be considered an active ingredient. This is because the cannabis product is making a statement that ‘x’ amount of ‘y’ cannabinoid is in this product.

The omission of a cannabinoid does not mean that a product is absent of that cannabinoid; as cannabis is a natural product, it may contain trace amounts of other cannabinoids. The AMT, however, will only include cannabinoids meeting the above definition.

Strength Representation

Strength will not be represented as an inequality and it must be a concrete domain. Any cannabinoid that is represented as an inequality and does not meet the active ingredient threshold defined by TGO93 will not be defined as an active ingredient or BoSS in the terminology.

If the cannabinoid is represented as a concrete value and is less than the TGO93 definition of an active cannabinoid, the AMT will regard this as an active ingredient, as the product is making a statement that this product will always contain that amount of cannabinoid.

If the cannabinoid is represented by an inequality that exceeds the TGO93 active cannabinoid thresholds, then the product will be ineligible for inclusion into AMT.

Product Name

Source and derivation

The PN shall be derived from the name appearing in the CMI (Consumer Medicines Information) but must agree with the other supplied documentations.

The PN shall reflect the most stable core identity and exclude transient ordering or formatting differences. Preference shall be given to noun-based elements (e.g. “Varaski”, “Topaz”) rather than descriptors referring to strength or form.

For example:

- 2024 CMI Title: *T18 Jasmin Flower*.
- 2025 CMI Title: *Cannatrek Jasmin THC 18 %*.

Editorial outcome: *Cannatrek Jasmin*

Structure and order

The Preferred Term of a medicinal cannabis PN, by default, follows the syntax:

PN PT := Product_Name_String

Table 44: Medicinal Cannabis Product Name Preferred Term description

Description Component	Description
Product_Name_String	The product name for medicinal cannabis products will be expressed in the following order: 1. Sponsor or brand 2. Noun or name 3. Numeric element (if applicable).

Only elements required for unique identification within a range shall be included.

Sponsor / Brand element

The PN must include a sponsor or brand family name to prevent confusion between similarly named products.

Abbreviation or truncation is permitted where consistent with label or CMI usage and where the resulting term remains unambiguous.

Editorial preference is for the shortest unambiguous form used in the market.

Table 45: Medicinal Cannabis Product Name sponsor short form

Full sponsor name	Accepted short form	Rationale
Little Green Pharma	LGP	Widely recognised abbreviation.
Kind Medical	Kind	Consistent with label and CMI usage.

Decisions on abbreviation must balance user search behaviour and long-term stability and be recorded in the editorial justification.

Numeric elements

A numeric element shall be included in the PN only when it forms part of the product's branding and is required to differentiate products within a range in a way not otherwise represented elsewhere in the model.

Examples: C200, 1:100, C115, C9T7

Inclusion of numeric elements supports searchability and alignment with market presentation.

Numeric elements in the PN do not represent cannabinoid strength or concentration and must not be interpreted as indicating clinical equivalence between products.

Exclusion rule:

Numeric elements that merely repeat a formal strength value shall not be included in the PN.

Such values are already represented at the Branded Clinical Drug (BCD) level and their inclusion in the PN would reduce naming stability over time.

For example:

- *T24 in Cannatrek Narooma T24.*

Here “T24” only reflects a THC concentration of 24%, which is already expressed as the strength at the BCD level.

If the product were later released at 25%, the PN would need to change to “Cannatrek Narooma T25”, creating unnecessary maintenance.

By omitting the numeric value from the PN “Cannatrek Narooma” future strength variations (e.g. 24%, 25%) can be represented under the same PN, preserving continuity.

Exception: If the numeric element denotes a distinct branded variant that conveys more than a single-strength iteration (for example, 1:30 representing a defined ratio such as THC 3.3 mg/mL / CBD 100 mg/mL), it shall be retained as part of the PN:

- MP 1:30.

In this case, “1:30” is intrinsic to the brand identity and not fully represented by downstream strength attributes. It is also the only other CMI element available to distinguish it from others of the same range.

Exclusion of generic or redundant terms

Generic terms shall be removed from the PN unless required for disambiguation within a product family.

These include:

- plant-part terms (“flower”, “flos”, “bud”, “inflorescence”)
- strain/type terms (“sativa”, “indica”, “hybrid”)
- marketing descriptors (“Day”, “Night”, “Calm”, “Balance”).

Exception: A marketing term may be retained only when its removal would prevent accurate identification or retrieval of the intended product. Such cases require editorial justification.

Acceptable Synonyms

Acceptable synonyms will be included to represent cannabinoid substances as their common abbreviation to aid searchability:

- Delta-9-tetrahydrocannabinol = THC
- Cannabidiol = CBD
- Cannabigerol = CBG.

Please note that this is not a complete list.

An acceptable synonym will be included for the substance concept, as well as the MP, CD, CDP where the acceptable synonym will be based on the preferred term syntax.

An acceptable synonym will be included for the BCD, BCDP, and CBCDP where the acceptable synonym will be based on the FSN syntax, minus the semantic tag.

The expanded substance name will not be included in the acceptable synonym.

Limitation of Cannabis Modelling and Implications for Scheduling

AMT models only those attributes that are ontologically stable, specifically the active ingredient(s) and their strength, as these are the only characteristics that hold in perpetuity for a clinical drug concept. In medicinal cannabis, however, regulatory scheduling is dependant on the full cannabinoid profile, including constituents present at trace or non-active levels, which AMT does not and cannot model without embedding fluctuating regulatory rules into the ontology.

As a consequence, a Branded Clinical Drug may be Schedule 8, but its corresponding Clinical Drug will not be, as the determinative information lies entirely in non-active cannabinoids that fall outside AMT's modelling scope. This is an expected and intentional limitation: AMT can only represent what is universally true of the medicinal product, not what depends on external regulatory thresholds or batch-specific cannabinoid composition.

For example: While the Branded Clinical Drug Tasmanian Botanics CBD 100 mg/mL oral liquid is classified (via sponsor provided information) as schedule 8 due to the presence of trace THC, its corresponding Clinical Drug, cannabidiol 100 mg/mL oral liquid, is not.

A.8 Discrete vs Continuous Clinical Drug Example

A.8.1 Discrete Clinical Drug Examples

Figure 27: Discrete Clinical Drug capsule example

49611000036105| Ibuprofen 400 mg capsule (clinical drug) |

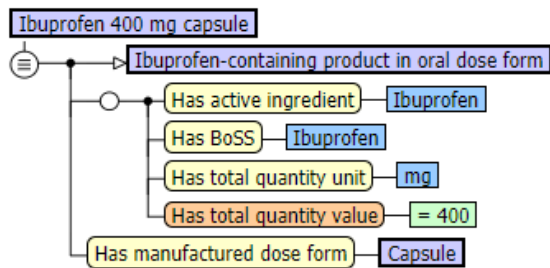


Figure 28: Discrete Clinical Drug chewing gum example

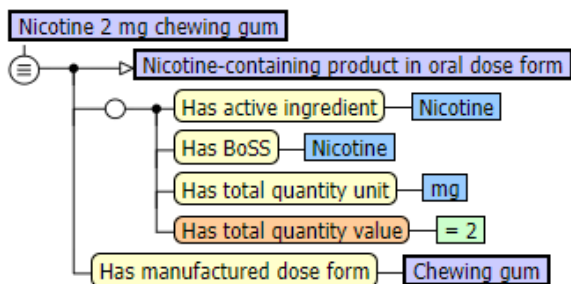
62070011000036102| Nicotine 2 mg chewing gum (clinical drug) |

Figure 29: Discrete Clinical Drug implant example

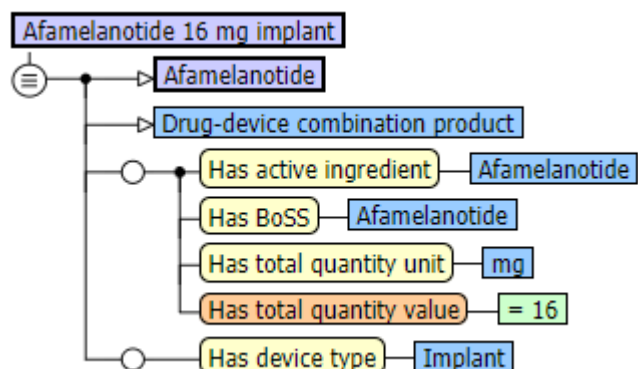
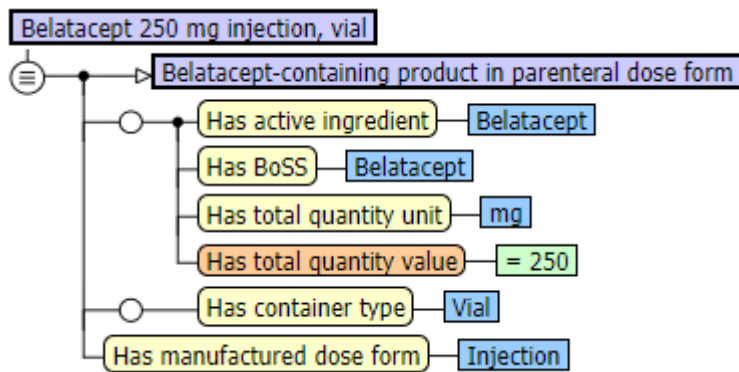
1514851000168106|Afamelanotide 16 mg implant (product)|

Figure 30: Discrete Clinical Drug injection example

699891000168108|Belatacept 250 mg injection, vial (clinical drug) |



A.8.2 Continuous Clinical Drug Examples

Figure 31: Continuous Clinical Drug oral liquid example

62030011000036100| Cetirizine hydrochloride 10 mg / 1 mL oral liquid, 1 mL measure (clinical drug)|

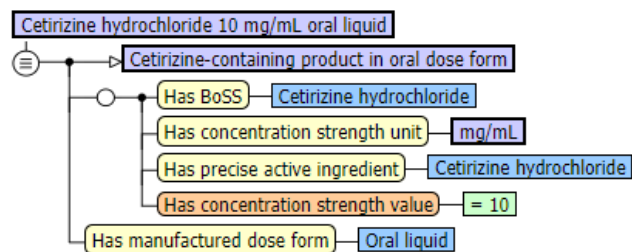


Figure 32: Continuous Clinical Drug lotion oral liquid example

61061000036105| Calamine 150 mg / 1 mL + zinc oxide 50 mg / 1 mL lotion (clinical drug)|

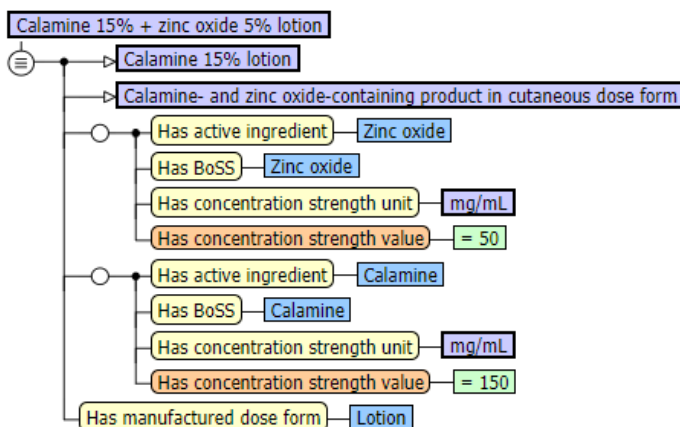
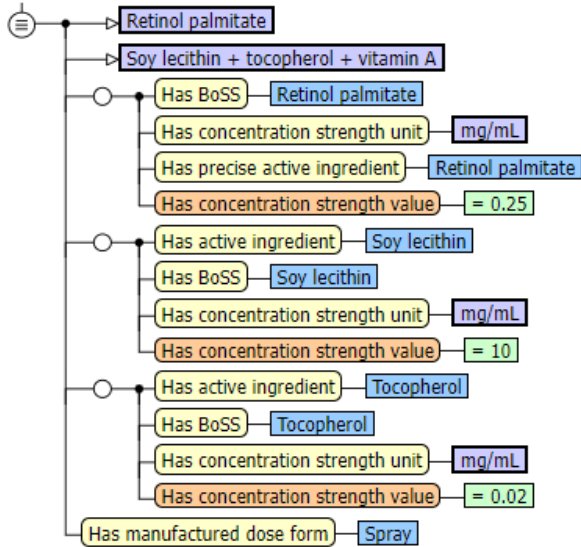


Figure 33: Continuous Clinical Drug spray example

79105011000036102|Soy lecithin 10 mg / 1 mL + tocopherol 20 microgram / 1 mL + vitamin A palmitate 250 microgram / 1 mL spray (clinical drug)|

Soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% spray



A.8.3 Quantities of Continuant forms in containers (Injections)

Figure 34: Quantities of continuous forms in pen device example

1241661000168105|Insulin isophane human 100 international units / 1 mL injection, 3 mL pen device (clinical drug)|

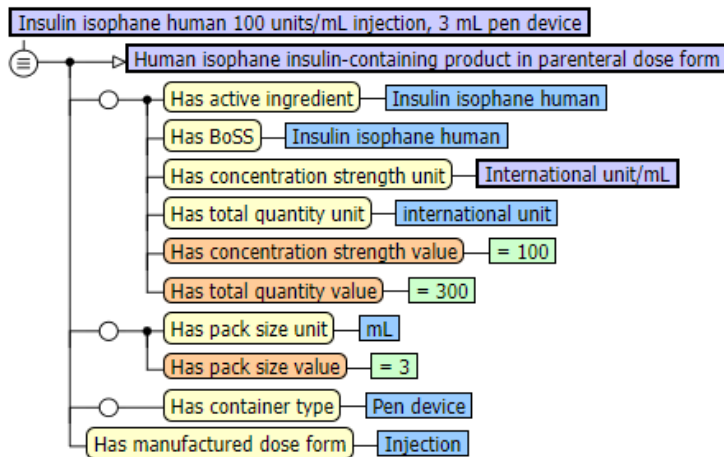
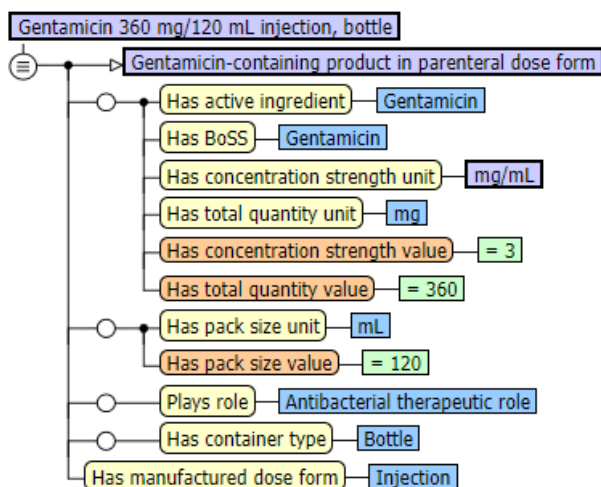


Figure 35: Quantities of continuous forms in bottle example

1336961000168101|Gentamicin 360 mg / 120 mL injection, 120 mL bottle (clinical drug)|



These concepts are currently modelled as “CD” AMTv4 (as they were MPUUs in AMTv3). There is potential for inclusion of supertype, only describing the concentration; i.e. No pack size, total quantity, or container. This “boundless” supertype is not currently authored within AMTv4 – concentration only, no pack size, or container type. This content will be reviewed as part of the AMTv4 roadmap. Consider these two concepts and a third possible (new) concept that subsumes then:

- 45382011000036102| paracetamol 1 g / 100 mL injection, 100 mL vial (Clinical Drug)|
- 1309421000168101|paracetamol 500 mg / 50 mL injection, 50 mL bottle (Clinical Drug)|.

Table 46: Clinical Drug supertype

Attribute	Paracetamol 1 g/100 mL injection, vial	Paracetamol 500 mg/50 mL injection, bottle	Paracetamol 10 mg/mL injection (new concept)
Has manufactured dose form	Injection	Injection	Injection
Has active ingredient	Paracetamol	Paracetamol	Paracetamol
Has precise active ingredient			
Has basis of strength substance	Paracetamol	Paracetamol	Paracetamol
Has concentration strength unit value	10	10	10
Has concentration strength unit	mg/mL	mg/mL	mg/mL
Has total quantity value	1000	500	
Has total quantity unit	mg	mg	
Has container type	Vial	Bottle	
Has pack size value	100	50	
Has pack size unit	mL	mL	

