



**Australian Medicines Terminology v3 Model
Technical Implementation Guide v2.1**

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1 Introduction

1.1 Purpose

This document's purpose is to provide implementation guidance to software developers and technical consumers that eases the implementation of Australian Medicines Terminology v3 model (AMT v3) for common use cases. In order to do this, this document provides:

- an overview of the AMT;
- an overview of characteristics of SNOMED CT¹ terminologies generally (of which the AMT is one);
- details of the AMT v3 model;
- details of the AMT distribution form;
- guidance on using and interpreting AMT; and
- sample methods of querying AMT data relevant to common use cases.

1.2 Intended audience

This document is intended for technical healthcare vendors and healthcare professionals. This includes developers and testers who are responsible for producing, assuring or maintaining products that integrate with AMT.

1.3 Scope

This document is limited to discussing technical aspects of the AMT, data files and implementation considerations.

It does not cover a business overview of the AMT product or drivers for implementing the AMT product in general. These topics are covered by the *AMT v3 Overview and Use Cases* (NEHTA, 2013).

1.4 How to use this document

This is a long document containing a considerable amount of detailed information. However, it is not necessary to know all of the content of this document in order to usefully work with AMT.

Please use the following table to determine the sections of this document most relevant to your needs.

Note: Unless specified otherwise, all instances of "AMT" from here on refer to "AMT version 3" (AMT v3).

¹ SNOMED and SNOMED CT are registered trademarks of the International Health Terminology Standards Development Organisation (IHTSDO).

Table 1: Document overview

Section	Description	Target audience
2.1 AMT overview	Provides an overview of AMT the product, its purpose and uses.	Those new to AMT.
2.2 SNOMED CT terminologies	Provides a foundation in SNOMED CT as a basis for understanding the AMT model.	Those with little knowledge of SNOMED CT seeking to understand the AMT model.
2.3 AMT v3 model	Details of the elements and construction of the AMT v3 model.	Those wishing to work with AMT v3 product data.
3.1 Overview of Release Format 2 (RF2)	Provides an overview of SNOMED CT RF2 – the release format used to release AMT.	Those unfamiliar with RF2 who will work directly with AMT release files.
3.2 Concrete domains and data type properties	Provides detail of the Concrete domain reference sets used in AMT to express datatype properties. These reference sets are an extension to SNOMED CT RF2.	Those unfamiliar with concrete domains who wish to work with the description logic underpinning the AMT model, or simply access the numeric data properties associated with AMT components.
3.3 Dose Based Prescribing and associated reference sets	Describes reference sets that provide standardised terminology concepts that can be used for three common data elements within healthcare software systems that support dose-based prescribing.	Those wishing to work with AMT and SNOMED CT-AU to support dose based prescribing or medicines ordering in acute care settings.
3.4 RF2 distribution types	Describes the three release forms RF2 releases can provide – Full, Snapshot and Delta.	Those unfamiliar with these three release forms planning on downloading and processing AMT release files regularly.
3.5 Distribution Normal and Stated Forms	Describes the differences between the Distribution Normal Form and Stated Form ² of SNOMED CT terminologies and how this may affect AMT distributed relationships in future.	Those planning on writing code or processes that depend upon the relationships in AMT.
3.6 Transitive closure	Describes what a transitive closure is and how it may be used when querying AMT product data or reporting.	Those planning on writing code or queries to manipulate, transform or report on AMT product data.
3.7 Modules	Details the modules used in the AMT RF2 release files and their meaning.	Those planning on processing AMT release files regularly, particularly if being used in combination with SNOMED CT-AU or SNOMED CT International.
3.8 Meaning of the active field	Describes the behaviour of active and inactive AMT components, and their intended usage.	Those who are implementing and maintaining AMT data.
3.9 effectiveTime field	Describes the intent of the effectiveTime field, its format and its usage in conjunction with the active field.	Those who are implementing and maintaining AMT data.

² Please note that Stated Form is not published in AMT v3 at the time of writing.

Section	Description	Target audience
3.10 History tracking mechanism	Describes the history tracking mechanism used in SNOMED CT and how it is rendered in RF2 and hence AMT.	Those planning on taking regular updates of AMT data.
4.1 Mapping	Describes a mapping based approach to implementing AMT.	Those considering a mapping based implementation of AMT.
4.2 Native implementation	Describes options for implementing AMT natively in an implementation.	Those considering a native implementation of AMT.
4.3 Designing for data updates	Describes principles behind designing implementations of terminology and specifically AMT for regular updates.	Those planning on taking regular updates of AMT data.
4.4 Searching and capturing input	Describes key concepts and considerations when designing and implementing a system capturing terminology encoded data input.	Those planning on using AMT in a clinical user interface for data entry.
4.5 Recording and rendering recorded data	Concepts and considerations when recording AMT encoded clinical records and rendering those records back to clinical users.	Those planning on using AMT to record clinical data.
4.6 Retrieval and analytics	Describes ways to use AMT product data to retrieve and report on AMT encoded records.	Those needing to report on or analyse AMT encoded records.
5 Sample code and scripts	Provides sample schema, queries and scripts to educate about the AMT model and data through tangible demonstration queries.	Those needing to work intensively with AMT product data as release in the RF2 release files.
6 Additional guidance, requirements and test cases on adopting clinical terminologies	Provides additional information on various aspects of terminology adoption including mapping considerations, management of people and processes, software considerations, testing and clinical information exchange.	Those planning on implementing AMT in a system, or sending or receiving clinical messages containing AMT data with other systems.
7 Implementation considerations	Provides AMT product information and implementation related considerations useful to consider when planning an implementation.	Those planning an implementation of AMT.
Appendix A Subpacks and combination packs	Provides further details on multi-component products in AMT; specifically subpacks, combination/component packs.	Those adopting AMT multi-component products who are interested in their modelling.
Appendix B AMT Reference Set Descriptor	Provides an excerpt of the AMT reference set descriptor file.	Those interested in working with machine computable metadata used to define the attributes of AMT reference sets.
Appendix C AMT v3 model diagram conventions	Describes the combination of UML syntax and <i>SNOMED CT Diagramming Guideline</i> (IHTSDO, 2013) used in the AMT v3 model diagram.	Those interested in understanding the AMT v3 model.

Section	Description	Target audience
Appendix D AMT product model diagrams	Includes diagrams that show the detailed modelling of different categories of AMT products.	Those wanting to understand the detailed modelling of some sample AMT products, including stated and inferred relationships.

1.5 Sample scripts

Please note that the sample scripts provided in this document and associated release materials are provided solely as aids to assist in understanding AMT in more depth. These scripts should not be construed as suggested bases for implementation.

1.6 Questions and feedback

NCTIS's product development relies on the input and co-operation of the healthcare community. We value your feedback and encourage questions, comments or suggestions about our products.

To provide feedback, or for further information regarding licensing, please contact us via email at help@nehta.gov.au.

2 AMT model technical overview

2.1 AMT overview

This section provides a very brief overview of the AMT. For a more detailed description please refer to the *AMT v3 Overview and Use Cases* (NEHTA, 2013) .

2.1.1 Aims and objectives of the AMT

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

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

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

The following objectives are of primary importance:

- the consistent identification of branded and generically equivalent medicines; and
- the use of consistent naming conventions and terminology to describe medicines and to facilitate searching for medicines in clinical information systems.

NEHTA continues to work with relevant stakeholders, as well as national and international clinicians and terminology experts, to further refine the specifications, editorial rules, standards and infrastructure necessary to achieve these aims and objectives.

2.1.2 Scope of the AMT

2.1.2.1 In scope

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

- medicines registered by the TGA;
- medicines listed by the TGA; and
- other medicines and therapeutic products required to support AMT use cases. The AMT also includes non-approved therapeutic goods, such as medicines available under the Special Access Scheme.

At present the AMT does not contain all of the products in the categories listed above. The addition of new products is prioritised based on feedback from end users.³

2.1.2.2 Out of scope

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

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

- Adverse effects
- Cautionary and advisory label recommendations
- Contraindications
- Counselling instructions
- Dose checking
- Drug:Allergy interactions
- Drug:Drug interactions
- Drug:Food interactions
- Indications
- Normal dose ranges
- Physiological equivalence
- Precautions for use
- Storage or supply chain related information
- Excipients

Please note that excipients will not be modelled in the AMT unless presented with a clear use case that is agreed to by the relevant NEHTA governance body or bodies.

A Medicinal Product will only define inactive (inert) ingredients where these are part of sequential multi-component products, or diluents provided for the preparation of the actual administrable form of a product.

2.1.3 What the AMT contains

The AMT contains identifiers and descriptions for the majority of “Registered” (AUSTR) products contained in the Australian Register of Therapeutic Goods (ARTG). Many “Listed” (AUSTL) products are also included. Some AUSTR products are available only by prescription whereas AUSTL products can be purchased over-the-counter.

These medications are represented at a containered pack, pack or unit of use level. The trade product (essentially the brand name) is also represented. For example:

³ See the NCTIS request submission page at <http://www.nehta.gov.au/our-work/clinical-terminology/request-submission-product-content-changes>.

Table 2: Example trade product levels

Containered pack level (CTPP)	Amoxil 500 mg capsule: hard, 20, blister pack
Pack level (TPP)	Amoxil 500 mg capsule: hard, 20
Unit of use level (TPUU)	Amoxil 500 mg capsule: hard
Trade product level (TP)	Amoxil

AMT also derives generic representations of the branded (trade) products so that medications may be referred to generically. Taking the above examples:

Table 3: Example medicinal product levels

Pack level (MPP)	amoxycillin 500 mg capsule, 20
Unit of use level (MPUU)	amoxycillin 500 mg capsule
Generic product level (MP)	amoxycillin

AMT's relationships link the generic and branded concepts together, such that it is possible to find the generic form or a branded product, or find all the branded products for a given generic product.

Finally AMT includes defining attributes of these generic and branded products as atomically accessible data. These attributes include:

- Ingredients⁴
- Strength
- Unit of use size
- Form
- Unit of use quantity
- Sub/combination packs
- Container types

2.2 SNOMED CT terminologies

AMT v3 is a SNOMED CT terminology. It shares the same format and top level hierarchy as SNOMED CT, and hence the same "semantic space". Therefore to fully understand AMT, its model and structure, it is useful to first understand the SNOMED CT terminology.

The following sections provide a very brief overview of the components of SNOMED CT terminology, their purpose, and how they work. The AMT, being a SNOMED CT terminology, contains the same terminology components. Where examples are provided they reflect data included in the AMT. Sections on AMT's

⁴ Ingredients represented in AMT v3 are limited to the intended active ingredients and Basis of Strength Substances (BoSS), not the pharmaceutical ingredients of the medicines – for more detail please refer to the *AMT v3 Model Editorial Rules* (NEHTA, 2014).

model further on in this document (Section 2.3) should be read in context of this foundation.

More detailed information about SNOMED CT terminology can be found in the *SNOMED CT Technical Implementation Guide* (IHTSDO, 2014) (hereafter: "SNOMED TIG").

2.2.1 Concepts

Concepts identify and represent a category or class of thing needed to be recorded within health care.

AMT concepts can be very specific for example, *|Aciclovir Intravenous (DBL) 250 mg/10 mL injection: solution, 5 x 10 mL vials|*, or much more general *|aciclovir|*.

General concepts whose meaning encompasses more specific concepts are said to "subsume" the latter. Similarly a specific concept whose meaning falls completely within another concept's meaning is said to be "subsumed by" the other concept.⁵

2.2.2 Descriptions

Every concept has two or more descriptions. Concepts must have a "Fully Specified Name" (FSN) description, which represents the formal, unambiguous meaning of the concept. Consequently the FSN may be quite long, cumbersome and/or formal – not generally the way most clinicians usually refer to the concept. An example FSN is *|Abilify (aripiprazole 10 mg) tablet: uncoated, 30 tablets (trade product pack)|*.

Additionally concepts must have one or more "Synonyms", one of which must be declared as the preferred way of referring to the concept (refer to Section 3.1.7). The preferred Synonym description is also referred to as the Preferred Term (PT). An example is *|Abilify 10 mg tablet: uncoated, 30|*.

Unlike formal FSNs, Synonyms are common names for concepts. However as humans use some common names for different concepts depending on their contexts, Synonyms in SNOMED CT are not unique for a concept. That is, two concepts may both have Synonyms with the same text (note they would still have differing description identifiers). Synonyms thereby introduce some ambiguity for the sake of usability. As an example the concepts *|captopril (medicinal product)|* and *|captopril (AU substance)|* both have a preferred Synonym of the identical text "captopril". However the concepts' meanings differ: the first concept is a Medicinal Product concept while the second concept is a *Medicinal substance* concept.

Note that preferred Synonyms (Preferred Terms) for concepts are unique within each hierarchy in AMT, however are not necessarily unique across hierarchies. For example:

- Within the *Substance* hierarchy only one concept has the Preferred Term "captopril".
- Within the Medicinal Product hierarchy only one concept has the Preferred Term "captopril".
- However, across AMT the Preferred Term "captopril" is not unique – it is the Preferred Term text for both a *Substance* (1901011000036103) and a Medicinal Product (21533011000036102) concept.

⁵ See Section 2.2.4 for more information about subsumption.

Preferred Terms in AMT reflect the common way a medicinal concept is described in the Australian healthcare context. Any number of alternate terms (Synonyms) may be included if required to support various clinically acceptable ways of naming the medicinal concept. A set of editorial rules that govern the consistent way of naming AMT concepts is available via the *AMT v3 Model Editorial Rules* (NEHTA, 2014).

2.2.3 Relationships

Relationships in SNOMED CT terminologies, and hence AMT, link two concepts and have a “relationship type”. Each relationship for a concept is actually an individual logical assertion about the concept. Taken together, the relationships originating from a concept form a set of statements that define the meaning of the concept relative to the other concepts in the terminology.

These relationships attempt to represent the meaning of the concept’s FSN description. Where there is a discrepancy the FSN is always considered to be correct.

An example of an AMT relationship is the source MPUU concept *|aciclovir 5% cream|* HAS MANUFACTURED DOSE FORM relationship to the target *Form* concept *|cream|*.

2.2.4 Subtypes/Supertypes

SNOMED CT uses a special type of relationship, known as IS A, to represent subtype/supertype (or child/parent) relationships between concepts. This relationship is used where a concept is wholly subsumed by another concept.

For example *|Panadol 500 mg tablet: film-coated|* IS A subtype (child) of *|paracetamol 500 mg tablet|* (parent).

Any statements (relationships in SNOMED CT) made by the parent concept are also true of the child concept. Taking the same example, all statements made of *|paracetamol 500 mg tablet|* are true of *|Panadol 500 mg tablet: film-coated|*. For example, the parent concept *|paracetamol 500 mg tablet|* has the following defining attributes:

- A medicinal substance (or active ingredient) of *|paracetamol|*;
- A strength (amount of the medicinal substance) of “500 mg”; and
- A dose form of *|tablet|*.

The child concept *|Panadol 500 mg tablet: film-coated|* inherits all these three attributes (that is, these statements are equally true for the child concept) but it also has a greater specificity in its dose form of *|film-coated tablet|*.

2.2.5 Defined and Primitive concepts

In SNOMED CT concepts may be considered “defined” or “primitive”, which indicates if the concept’s set of relationships⁶ are sufficient to define the concept. This is SNOMED CT’s mechanism for representing necessity and sufficiency.⁷

⁶ The set of relationships where the concept is the source of the relationship form the concept’s relationships.

⁷ See http://en.wikipedia.org/wiki/Necessity_and_sufficiency for a useful overview of these concepts.

Defined concept: The concept's set of relationships is necessary and sufficient to define the concept in terms of the other concepts in the terminology (that is, none of its defining characteristics are missing from its set of relationships).

Primitive concept: While necessary, the concept's set of relationships is not sufficient to define the concept in terms of the other concepts in the terminology.

An example of a defined concept in AMT is *|paracetamol (medicinal product)|*. This concept's definition consists of:

- a relationship to the concept *|paracetamol (substance)|* to define the ingredient it contains; and
- a relationship to the concept *|medicinal product|* to define it as a type of product.

This definition means that any concept that contains paracetamol and is also a type of medicinal product is therefore a subtype of the concept *|paracetamol (medicinal product)|*.

However the concept *|paracetamol (substance)|* is declared as primitive in AMT as its definition only has one relationship stating it is a subtype of *|Australian substance|*.

To define *|paracetamol (substance)|* within AMT would require adding relationships and concepts defining the molecular structure of paracetamol, which is not relevant to AMT's use cases. Therefore these relationships are omitted and *Substance* concepts in AMT are declared primitive.

Similarly *Form* concepts like *|tablet|* and *Unit of measure* concepts like *|milligram|* are also primitive in AMT.

2.2.6 Translation to common knowledge representation languages

Most implementations will not need to reason with the content of AMT or SNOMED CT, however it is possible if required.

The set of concepts, relationships and primitive/defined status can be translated into a common knowledge representation language for this purpose. The IHTSDO provides scripts to translate between SNOMED CT release formats and common knowledge representation formats such as OWL (Web Ontology Language) and KRSS (Knowledge Representation System Specification).

Note that at present these IHTSDO scripts cannot be used on AMT, as AMT uses an additional description logic feature not yet implemented in these scripts – concrete domains. The IHTSDO scripts will be updated as the *RF2 Concrete Domains Specification* (IHTSDO, 2011) proceeds through the IHTSDO standards process.⁸

⁸ This resource can be accessed by IHTSDO Collaborative Space account holders. Registration is free. See: <http://www.ihtsdo.org/about-ihtsdo/collaborative-space/>.

2.2.7 Open versus closed world assumption

Unlike most information models and databases, which operate under a “closed world assumption”, SNOMED CT terminologies like AMT operate under an “open world assumption”. The following wikipedia pages provide useful overviews:

- http://en.wikipedia.org/wiki/Open_world_assumption
- http://en.wikipedia.org/wiki/Closed_World_Assumption

Under a closed world assumption, any statement not known to be true is implicitly false. However under an open world assumption, the omission of a statement simply means that it is unknown – and could be true or false. For example:

Statement: Mary is a citizen of France.

Question: Is Paul a citizen of France?

“Closed world” (for example, SQL) answer: No.

“Open world” answer: Unknown.

SNOMED CT and AMT concepts simply represent what is known, and do not include or preclude other conditions that may be true or false.

For example in SNOMED CT *|fracture of tibia|* obviously does not mean a fracture of the fibula or femur can be assumed. However the omission of a statement about the fibula and femur does not rule out a fracture of fibula or femur either. The statement *|fracture of tibia|* simply states that a tibia fracture exists, and any state of the fibula, femur or any other bone in the body is unknown.

Similarly for AMT, the concept *|paracetamol (medicinal product)|* has a relationship HAS INTENDED ACTIVE INGREDIENT to *|paracetamol (substance)|*. This states the presence of at least paracetamol in the product; however it makes no statement about the presence or absence of any other ingredients (active or otherwise).

Therefore *|paracetamol + codeine (medicinal product)|* is a subtype of *|paracetamol (medicinal product)|* because at least paracetamol is present.

This differs from a closed world model which would assume *|paracetamol (medicinal product)|* contained only paracetamol and no other ingredients because no others were stated. To achieve the closed world semantics of *|paracetamol (medicinal product)|* in an open world model would require the addition of a statement that *|paracetamol (medicinal product)|* contains only *|paracetamol (substance)|* and a renaming of the concept to *|paracetamol only (medicinal product)|*.

2.2.8 Existential and universal restrictions

All SNOMED CT (hence AMT) relationships are expressed using existential restrictions. Universal restrictions are currently not supported in SNOMED CT’s subset of description logic features.

Put simply, existential restrictions mean “at least” or “some”, whereas universal restrictions mean “for all” or “only”.

To illustrate, consider the concept *|paracetamol (medicinal product)|* which is defined with a HAS INTENDED ACTIVE INGREDIENT relationship to *|paracetamol (substance)|*. The existential restriction applies to this relationship, and means “at

least an intended active ingredient of paracetamol must be present". Therefore *|paracetamol (medicinal product)|* is really defined as "paracetamol containing product" – that is, any concept that contains at least paracetamol (such as "paracetamol and codeine") is a subtype of *|paracetamol (medicinal product)|*.

If this relationship was modelled with a universal restriction instead, the concept would mean "paracetamol only product". If this was the case, only concepts containing paracetamol and no other ingredients would be considered to be subtypes of *|paracetamol (medicinal product)|*. However, universal restrictions are not in use in SNOMED CT or AMT. All relationships encountered in AMT have the abovementioned "at least" semantics.

2.2.9 Concept models

SNOMED CT terminologies define concept models for different hierarchies of content which define patterns and rules for concepts in those hierarchies. Concept models play a similar role for terminology that schemas do for relational data.

Each concept model essentially specifies the pattern of logic used to define concepts within that domain. For example, concept models define rules for a hierarchy or group of hierarchies that govern:

- the types of relationships used to define concepts;
- the combinations and groupings of relationships used to define concepts; and
- which types of concepts will be "defined" and which will be "primitive".

SNOMED CT contains numerous concept models for different types of content. AMT contains only one concept model.⁹

2.3 AMT v3 model

This section provides a technical description of the AMT model. In particular, it explains the various elements of the model, how they relate to one another and what can be expected of the data conforming to this model. For a more detailed business description of the model, why it is modelled as it is, and the use cases it supports, please refer to the *AMT v3 Overview and Detailed Business Use Cases* (NEHTA, 2013).

2.3.1 AMT v3 model diagrams

The AMT v3 model illustrated in Figure 1 on p.19 uses a combination of UML notation and the *SNOMED CT Diagramming Guideline* (IHTSDO, 2013).

Note that while this notation has been adapted from UML in an attempt to convey the structure of AMT, the closed world semantics implied by UML class diagrams cannot be assumed in the actual semantics of AMT. A key difference worth noting is:

- Individual concepts in SNOMED CT (and hence AMT) do not represent instances (that is, things); they are classes (that is, types/categories of things). For example *|medicinal product|* is an AMT concept which is the parent of many specific products such as *|paracetamol (medicinal*

⁹ The AMT v3 model is available as a standalone document via <http://www.nehta.gov.au/implementation-resources/ehealth-foundations/australian-medicines-terminology-common>.

product)|. However *|paracetamol (medicinal product)|* is not an instance, it is itself a class that is a subclass of *|medicinal product|*.

The different types of entities in Figure 1 are represented as follows:

- A purple box denotes an AMT concept that is fully defined.
- A blue box denotes an AMT concept that is primitive (that is, not fully defined).
- A white box denotes an AMT reference set member (Section 2.3.5).

Note that the referencing relationships of Concrete domain reference sets have specific semantics that are described in the *RF2 Concrete Domains Specification* (IHTSDO, 2011).

- A grey box provides additional information about a particular AMT component but is not itself a model component.

More details regarding the diagramming notation used in Figure 1 can be found in Appendix C.

Although the AMT model is typically drawn with the most abstract concepts at the top, it is most easily understood by reading in the opposite direction to the typical reading order, that is: from the bottom right-hand corner upwards and to the left. Reading bottom-right to top-left takes the reader from the concepts representing the physical real world entities steadily up to higher levels of abstraction, that is, to more generic forms.

The descriptions of each component are assembled based on consistent editorial rules. For more details of these rules, and for full definitions of all AMT concepts, particularly in relation to policies on describing active ingredients and salts, please refer to the *AMT v3 Model Editorial Rules* (NEHTA, 2014).

Figure 1 should be read in context of AMT v3 being a SNOMED CT terminology – refer to Section 2.2 SNOMED CT terminologies.

Figure 2 represents the AMT clinical sub-hierarchy.

Figure 3 describes the key concepts of the AMT metadata sub-hierarchy. The components included in Figure 3 are ones that relate to AMT reference sets; however the full metadata hierarchy (*SNOMED CT Model Component*) contains a larger set of metadata concepts that are common to both AMT and SNOMED CT-AU.

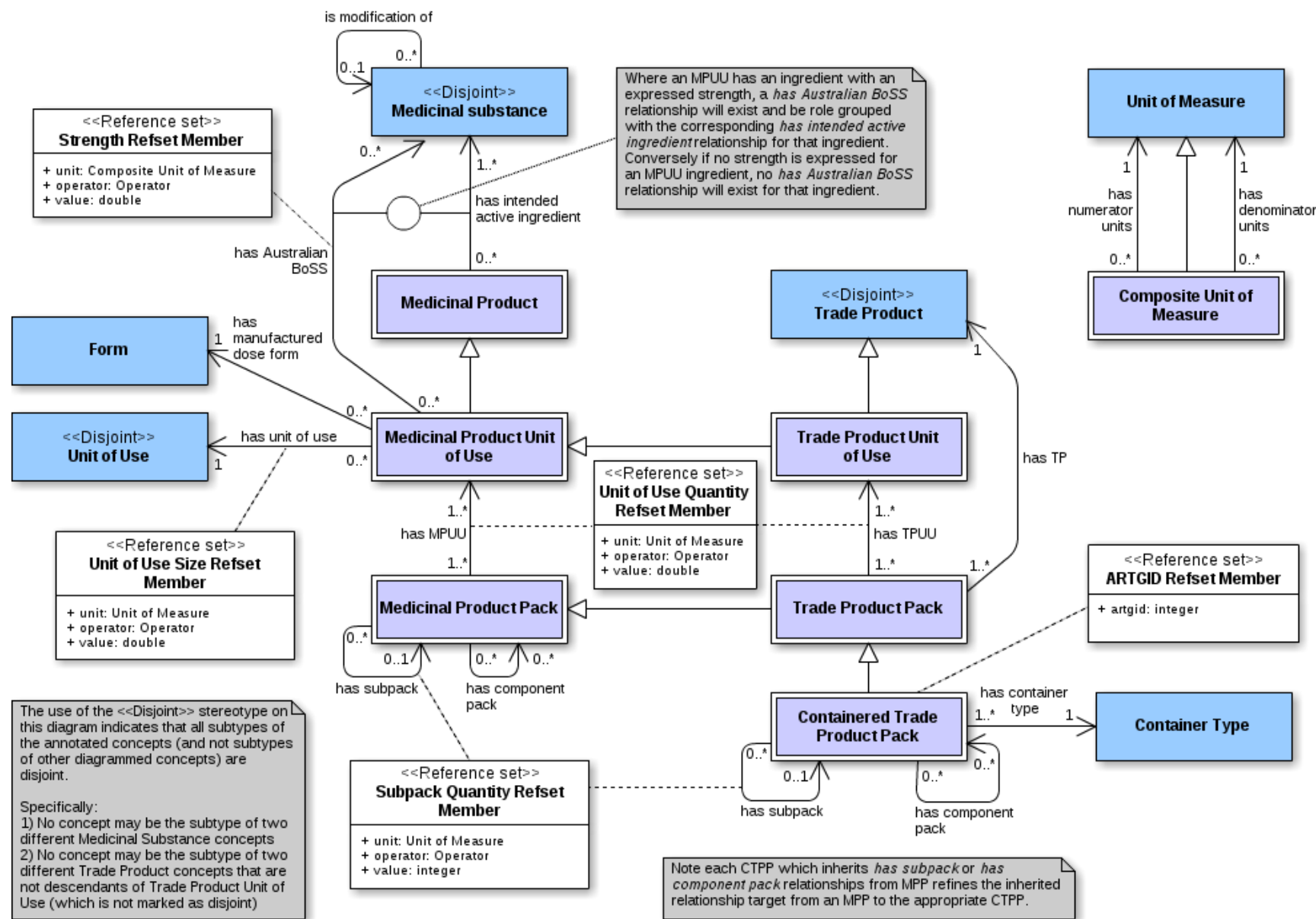


Figure 1: AMT v3 model

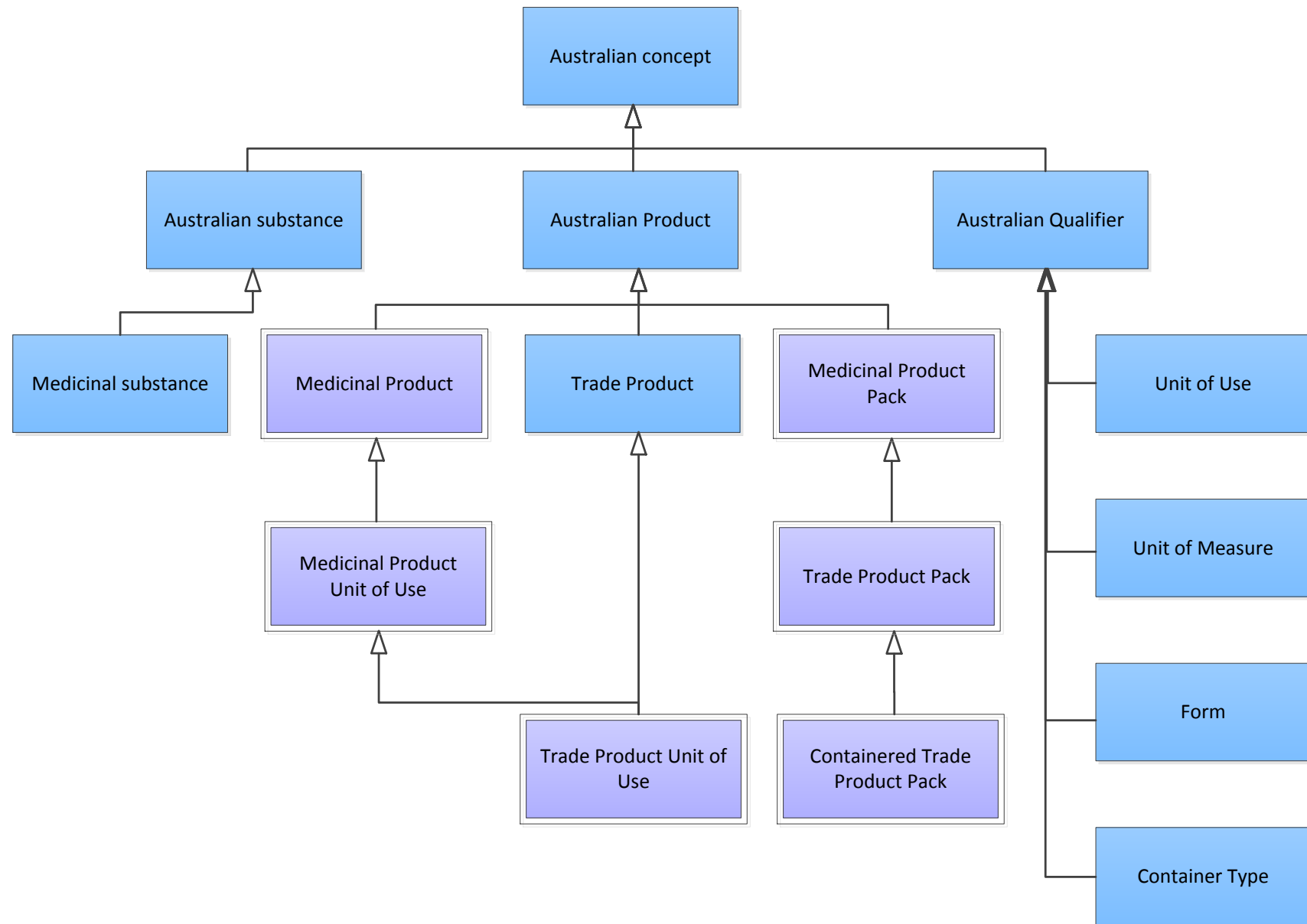


Figure 2: AMT clinical sub-hierarchy

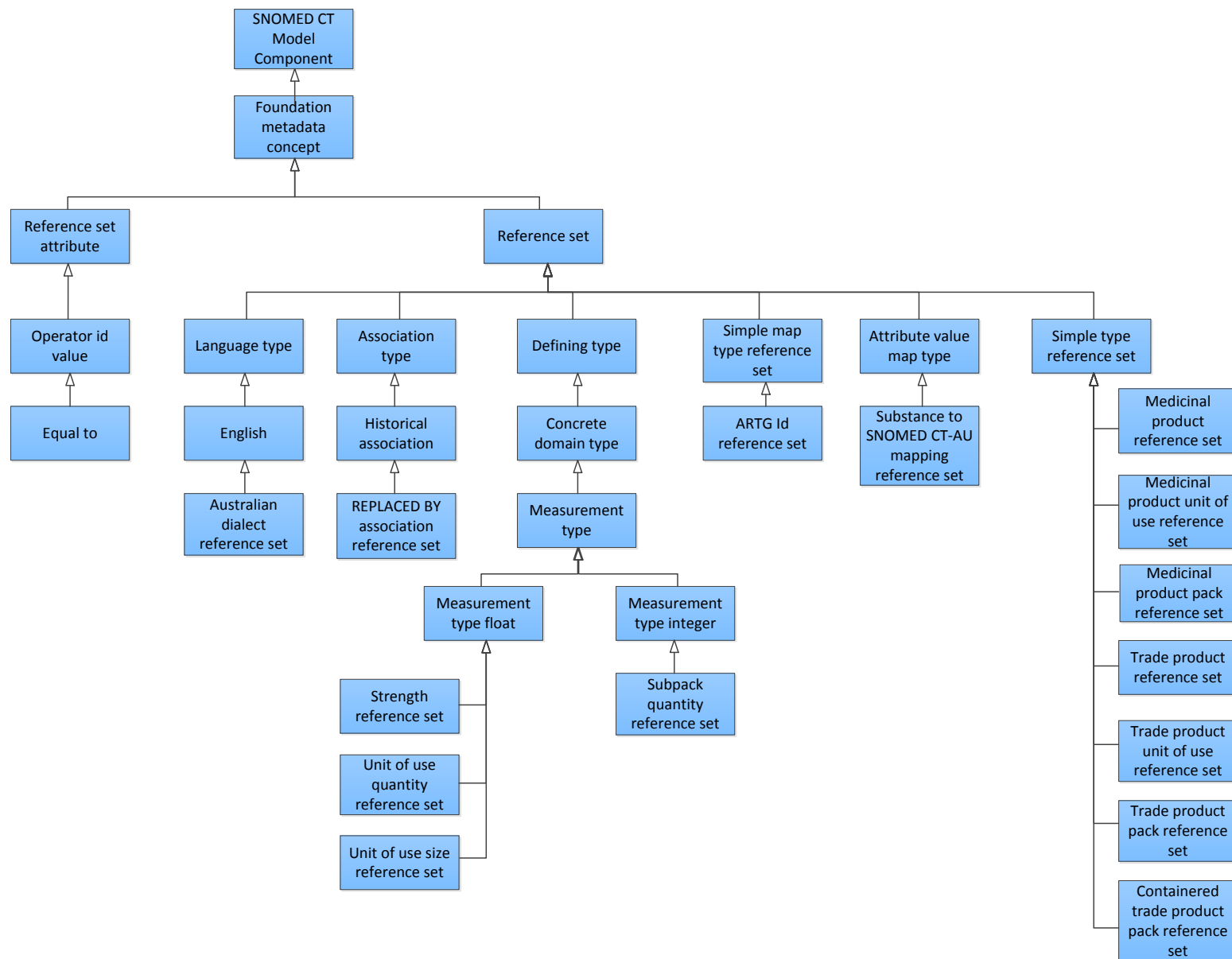


Figure 3: Key concepts of the AMT metadata sub-hierarchy

2.3.2 “Notable concepts”

AMT’s model is based around seven concept classes known as the “seven notable concepts”.¹⁰ These concept classes head hierarchies of concepts representing different abstractions of branded products and their generic product equivalents at various levels of granularity.

The following sections describe each of these concept classes and their relationships, and are intended to be read in combination with Figure 1.

Note that the left hand side of the “seven notable concepts” are all prefixed “Medicinal” and the right hand side “Trade”. This indicates that the concept classes on the left represent generic medicines, whereas the concept classes on the right represent trade or branded medicines. See Figure 4 below for an example.

It is also worth noting that each concept class’s relationships have been pushed up to the most abstract concept, however they are “inherited” down to all descendants. For example the HAS INTENDED ACTIVE INGREDIENT relationships of a Medicinal Product concept are inherited by child concepts (which in this case are Medicinal Product Unit of Use and Trade Product Unit of Use concepts). See Section 2.2.4 Subtypes/Supertypes, which explains that all statements (relationships) true of a parent class are by definition true of the child.

Each of the following sections is illustrated by reference to the same five medicines, as defined below:

Table 4: Illustrative medicines

A	A simple oral solid medication – amoxycillin with a brand of Amoxil.
B	A brand name used across multiple generic medicines – Canesten (in this case Canesten Clotrimazole).
C	A combination pack Nexium Hp7 (one of the more complex examples likely to be encountered).
D	A manufacturer’s generic – 0.9% sodium chloride solution manufactured by Baxter.
E	A medicine where two active ingredients are combined into the same formulation – paracetamol + codeine branded as Panadeine Forte.

The following diagram shows a simple example of how these concepts relate to each other for a single product.

Note that descriptions for examples used in this section follow AMT editorial rules. This includes the use of:

- “+” to separate multiple ingredients of a multi-ingredient product; and
- “(&)” to separate components of a multi-component product.

Refer to the *AMT v3 Model Editorial Rules* (NEHTA, 2014) for more details of these rules.

Note that the following sections describe the Stated Form of AMT data. Note that expected cardinality of relationships expressed in the following sections will change

¹⁰ That is: Medicinal Product (MP), Medicinal Product Unit of Use (MPUU), Medicinal Product Pack (MPP), Trade Product (TP), Trade Product Unit of Use (TPUU), Trade Product Pack (TPP), and Containered Trade Product Pack (CTPP).

in a Distribution Normal Form rendering of the same data. For more details refer to Section 3.5 Distribution Normal and Stated Forms.

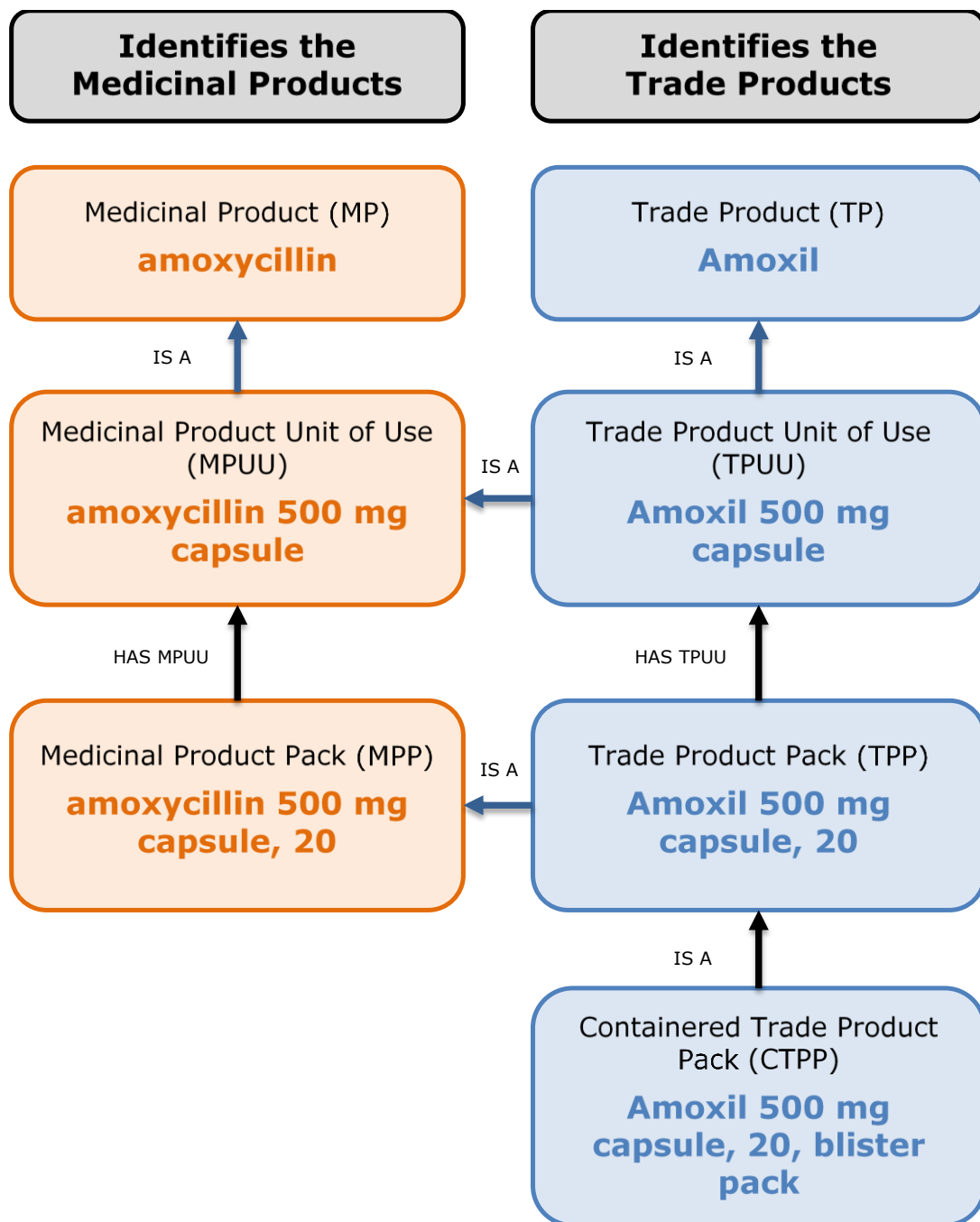


Figure 4: AMT seven notable concepts example

2.3.2.1 Medicinal Product

Medicinal Product (MP) is the abstract formulated representation of the therapeutic active ingredients that are used in the treatment of human patients in Australia.

A Medicinal Product represents the abstract notion of one or more substances combined into a product intended for medicinal use, whereas a *Substance* concept represents an individual substance of some undefined quantity.

The MP class represents the therapeutic intent of an abstract formulation (collection of active substances using non-proprietary names) intended for use as a product. For example, this corresponds to a medicine typically recorded during generic

prescribing. The substances represented in an MP concept are always base active ingredients (that is, the active moiety). If a modification to the base (such as salts, esters and waters of hydration) changes the base in a clinically significant way according to clinical evidence, the modified base is represented in the MP instead. Refer to the *AMT v3 Editorial Rules* for further details of the naming conventions.

While the Medicinal Product concept 21433011000036107 *|paracetamol|* and the *Substance* concept 2442011000036104 *|paracetamol|* have the same Preferred Term string, they are distinct concepts with different meanings. The Medicinal Product concept 21433011000036107 *|paracetamol|* means “paracetamol containing product” whereas the *Substance* concept 2442011000036104 *|paracetamol|* means “some undefined quantity of paracetamol molecules”. The major difference between the concepts is that a Medicinal Product concept includes the abstract formulation of the *Substance(s)* into a Medicinal Product.

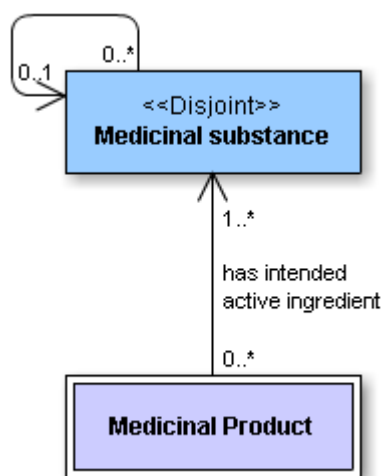


Figure 5: Medicinal Product (with direct relationships)

As an example the Medicinal Product 21433011000036107 *|paracetamol|* represents an abstraction of the MPUU concepts *|paracetamol 500 mg tablet|* or *|paracetamol 665 mg tablet: modified release|*. The *Substance* concept “paracetamol” represents an undefined quantity of paracetamol molecules.

In the Stated Form, each MP concept:

- Is a subtype of the concept 30497011000036103 *|medicinal product|* that is, has an IS A relationship to this grouper concept.
- Has one or more HAS INTENDED ACTIVE INGREDIENT relationships to *Substance* concepts.
 - An “intended active ingredient” (*Substance* concept) represents a base active ingredient, or a modified base (for example, salt) active ingredient if the modified base is deemed clinically significant. For example, *|paracetamol|* is a base ingredient and *|calcium carbonate|* is a modified base ingredient. Refer to the *AMT v3 Model Editorial Rules* (NEHTA, 2014) for further definitions of base/modified base ingredients and clinical significance rules.

Examples of MPs include:

Table 5: Medicinal Product examples

A	amoxycillin
B	clotrimazole
C	<ul style="list-style-type: none">• esomeprazole• clarithromycin• amoxycillin
D	sodium chloride
E	paracetamol + codeine

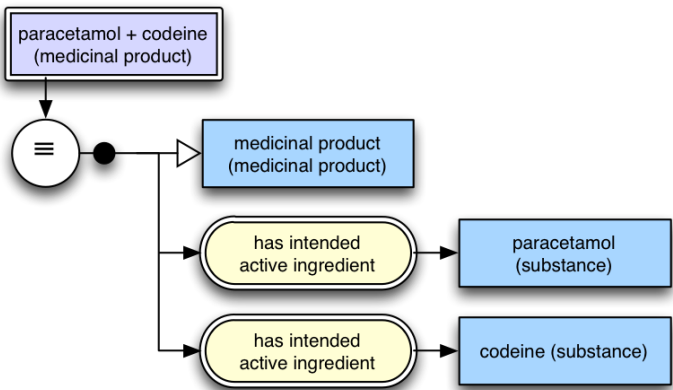


Figure 6: Example MP Stated Form modelling

Note that the Distribution Normal Form is identical to the Stated Form for the example shown in Figure 6 above.

2.3.2.2 Medicinal Product Unit of Use

Medicinal Product Unit of Use (MPUU) concepts represent an abstract formulation containing active ingredient, strength and form in a single dose form or a unit of use component of a multi-component formulation, devoid of brand.

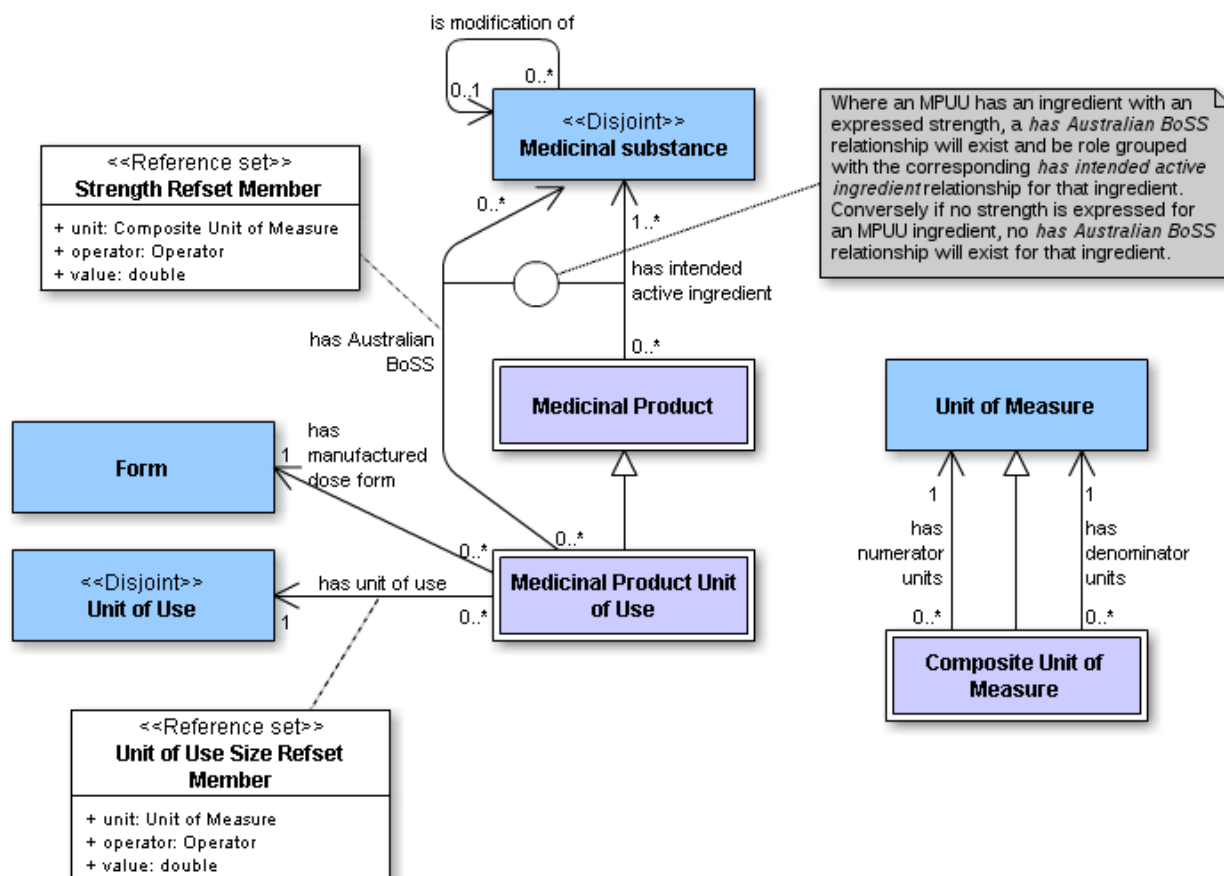


Figure 7: Medicinal Product Unit of Use (with direct relationships)

In the Stated Form, each MPUU concept:

- Is a subtype of the concept 30450011000036109 |*medicinal product unit of use*| that is, has an IS A relationship to this grouper concept.
- Has an IS A relationship to a Medicinal Product concept.
- Has one or more HAS INTENDED ACTIVE INGREDIENT relationships to Substance concepts, which is restated from its supertype Medicinal Product concept's HAS INTENDED ACTIVE INGREDIENT relationships.
 - The target |*Substance*| concepts of these HAS INTENDED ACTIVE INGREDIENT relationship(s) exactly match the target |*Substance*| concepts of the HAS INTENDED ACTIVE INGREDIENT relationship(s) inherited from the supertype Medicinal Product concept.
- Has one HAS AUSTRALIAN BoSS relationship for each HAS INTENDED ACTIVE INGREDIENT relationship with each pair "role grouped" together (refer to Section 3.1.4.1).
 - Each HAS AUSTRALIAN BoSS relationship represents the Basis of Strength Substance (BoSS) used to express the strength of the intended active ingredient to which it is "role grouped".
 - The BoSS is derived from the product registration details and Product Information document, as developed by the product sponsor in collaboration with the TGA. The BoSS is the substance that corresponds to the strength of a product as reported in official product documentation. (The definition of a BoSS is more fully described in the *AMT v3 Editorial Rules*.)

- The strength of each ingredient (numeric value and unit of measure) is attached to the HAS AUSTRALIAN BoSS relationship using the *Strength reference set* (see Section 2.3.5.1).
 - Note that strength details expressed in the *Strength reference set* are normalised to a denominator of one, whereas MPUU descriptions remain in a non-normalised representation closest to clinical usage. For example an MPUU description may express “300 mg/20 mL” which will be “15 mg/mL” in the *Strength reference set*.
 - The strength unit of measure represented in the *Strength reference set* is always a *Composite unit of measure* concept, for example, “mg/mL”.
 - Every *Composite unit of measure* has a relationship to its numerator and denominator components via the HAS NUMERATOR UNITS and HAS DENOMINATOR UNITS relationships, for example, “mg/mL” has numerator units “mg” and has denominator units “mL”.
- Has exactly one HAS MANUFACTURED DOSE FORM relationship to a *Form* concept that represents the concept’s dose form, for example, tablet.
- Has exactly one HAS UNIT OF USE relationship to a *Unit of use* concept that represents the concept’s *Unit of use*.
 - The HAS UNIT OF USE relationship is quantified by a member of the *Unit of use size reference set*, which specifies the overall size of the MPUU (refer to Section 2.3.5.2).

Medicinal Product Unit of Use concepts are a generic form of one or more equivalent Trade Product Unit of Use (TPUU) concepts, for example:

Table 6: Trade Product Unit of Use examples

A	amoxycillin 500 mg capsule
B	clotrimazole 1% cream
C	<ul style="list-style-type: none"> • esomeprazole 20 mg tablet: enteric • clarithromycin 500 mg tablet • amoxycillin 500 mg capsule
D	sodium chloride 0.9% (9 g/1 L) injection, bag
E	paracetamol 500 mg + codeine phosphate 30 mg tablet

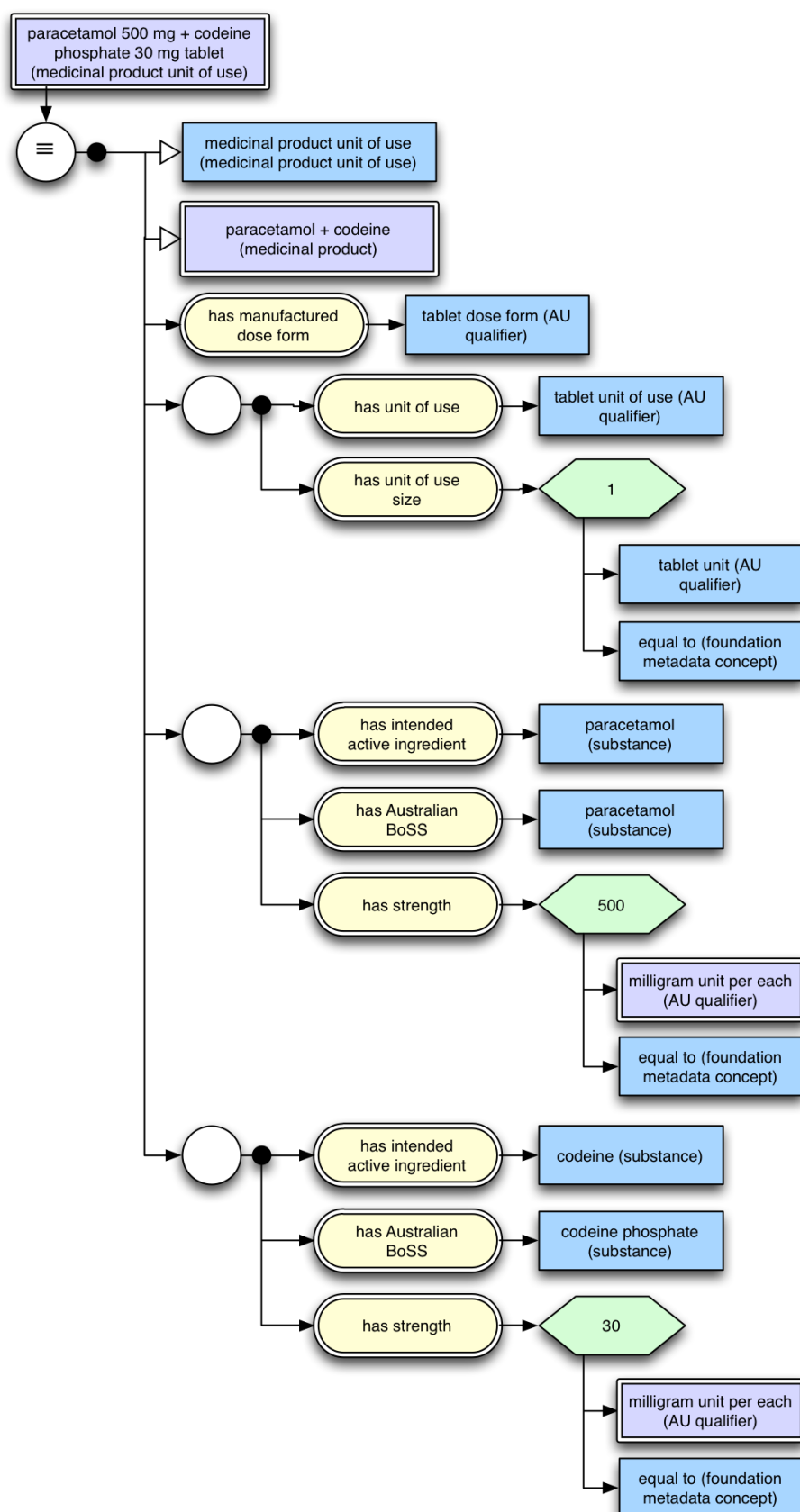


Figure 8: Example MPUU Stated Form modelling

The Distribution Normal Form (DNF) modelling for MPUU concept is different to its Stated Form modelling because in the DNF, each MPUU inherits the defining relationships of its supertype MP concept. (These relationships are part of the logical definition of an MPUU). The figure below illustrates this.

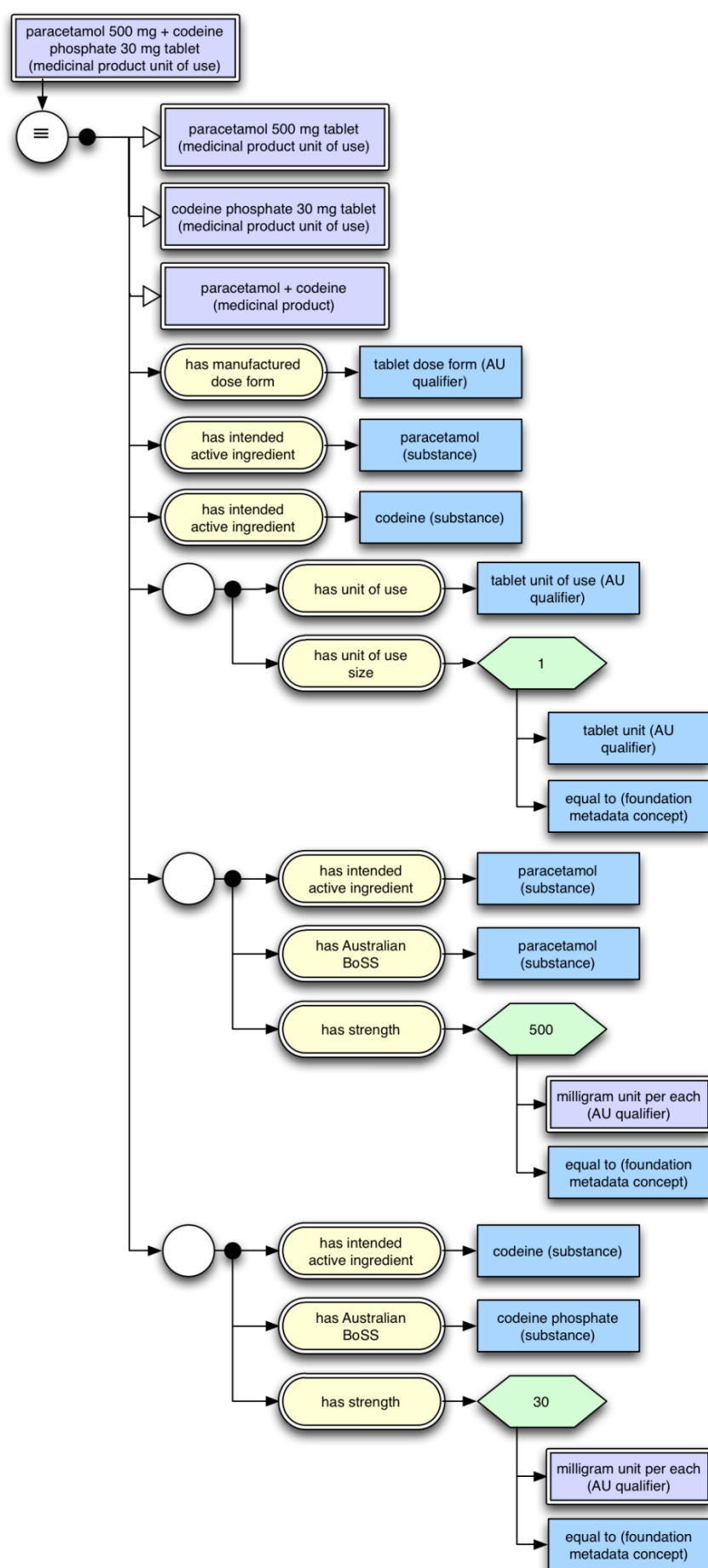


Figure 9: Example MPUU Distribution Normal Form modelling

2.3.2.3 Medicinal Product Pack

Medicinal Product Pack (MPP) concepts represent the abstract concept of a marketable medicinal entity available for patient use, devoid of brand and container type. Each MPP concept is the generic version of a set of one or more equivalent Trade Product Pack concepts. MPP concepts also contain generic information about subpacks and combination packs, corresponding to the subpack and combination packs at the Containered Trade Product Pack (CTPP) level.

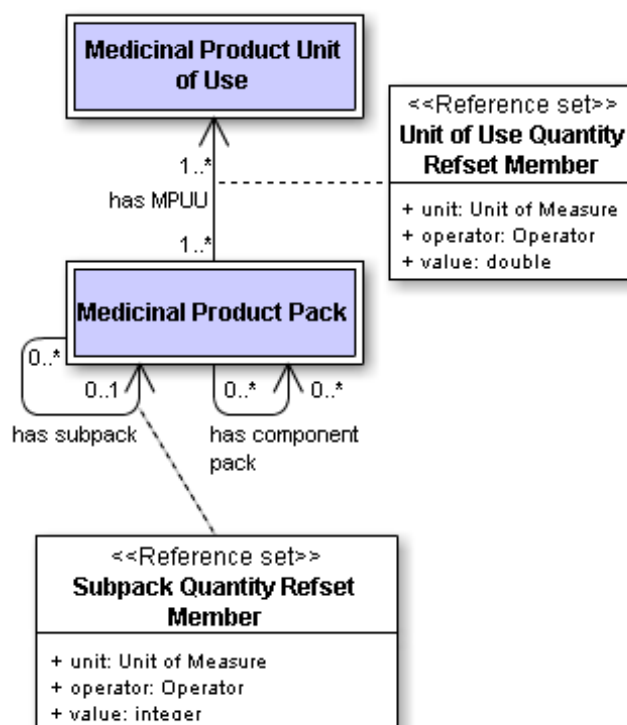


Figure 10: MPP (with direct relationships)

Each MPP concept:

- Is a subtype of the concept 30513011000036104 |*medicinal product pack*|, that is, has an IS A relationship to this grouper concept.
- Has one or more HAS MPUU relationships to each of the Medicinal Product Unit of Use concepts it contains.
 - Each HAS MPUU relationship is quantified by the *Unit of use quantity reference set*, which specifies the quantity of the MPUU instances the MPP contains (refer to Section 2.3.5.3).
- Optionally, has multiple HAS COMPONENT PACK relationships to other MPP concepts if the concept is a combination pack.¹¹
- Optionally, has one HAS SUBPACK relationship to another MPP concept if the concept is a pack containing subpacks.
 - Each HAS SUBPACK relationship is quantified by the *Subpack quantity reference set*, which specifies the number of subpacks contained within each pack containing subpacks (see Figure 25 on p.44).

¹¹ Refer to Figure 24 on p.43 for further information on component packs and combination packs.

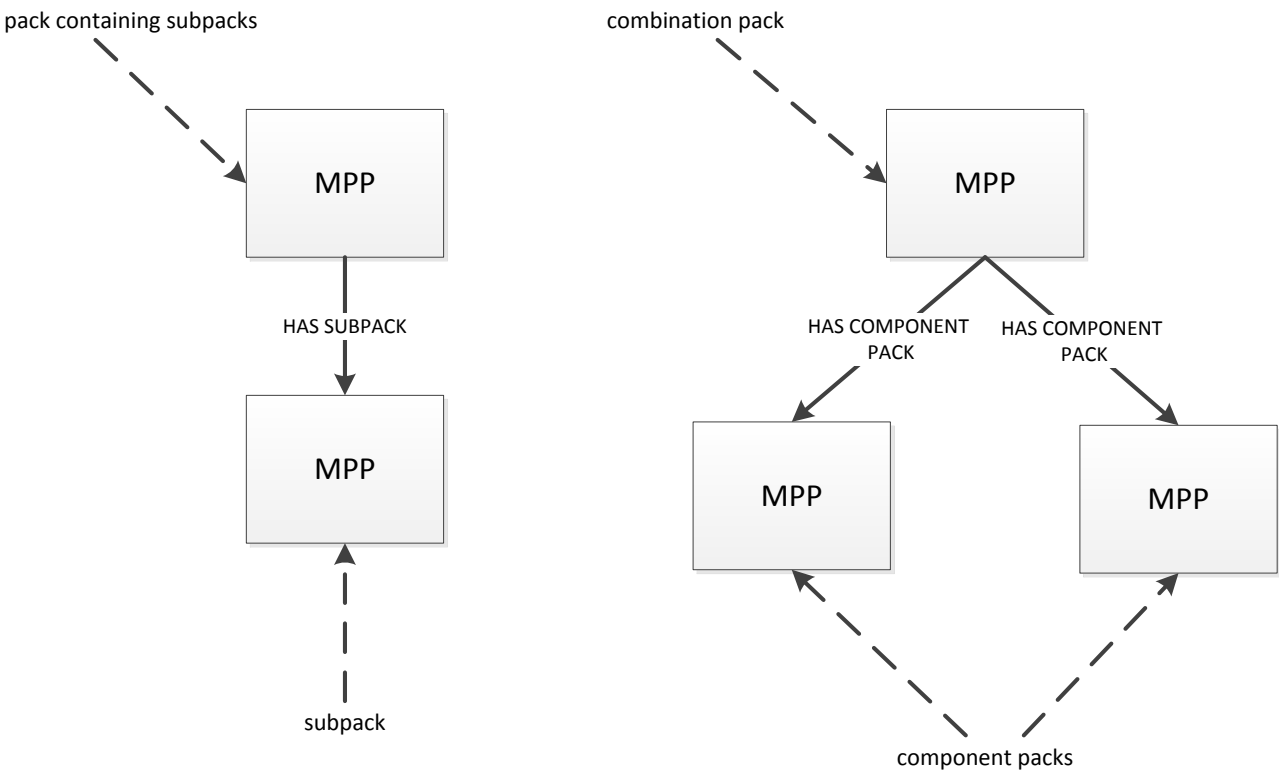


Figure 11: MPP subpack and component pack relationships

Examples of MPPs include:

Table 7: Medicinal Product Pack examples

A	amoxicillin 500 mg capsule, 20
B	clotrimazole 1% cream, 20 g
C	<ul style="list-style-type: none">esomeprazole 20 mg tablet: enteric [14] (&) clarithromycin 500 mg tablet [14] (&) amoxicillin 500 mg capsule [28], 1 packclarithromycin 500 mg tablet, 14esomeprazole 20 mg tablet: enteric, 14amoxicillin 500 mg capsule, 28
D	sodium chloride 0.9% (9 g/L) injection, 1 L
E	paracetamol 500 mg + codeine phosphate 30 mg tablet, 20

Examples of component pack MPPs are:

- esomeprazole 20 mg tablet: enteric, 14
- clarithromycin 500 mg tablet, 14
- amoxicillin 500 mg capsule, 28

Which are component packs of the combination pack MPP:

- esomeprazole 20 mg tablet: enteric [14] (&) clarithromycin 500 mg tablet [14] (&) amoxicillin 500 mg capsule [28], 1 pack

An example of a subpack MPP is:

- ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [6] (&) ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [5] (&) ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet [10] (&) inert substance tablet [7], 28

Which is a subpack of the MPP pack containing subpacks:

- ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [24] (&) ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [20] (&) ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablets [40] (&) inert substance tablets [28], 112 tablets [4 x 28]

For a full definition of subpacks and combination packs and how they are differentiated please refer to Appendix A.

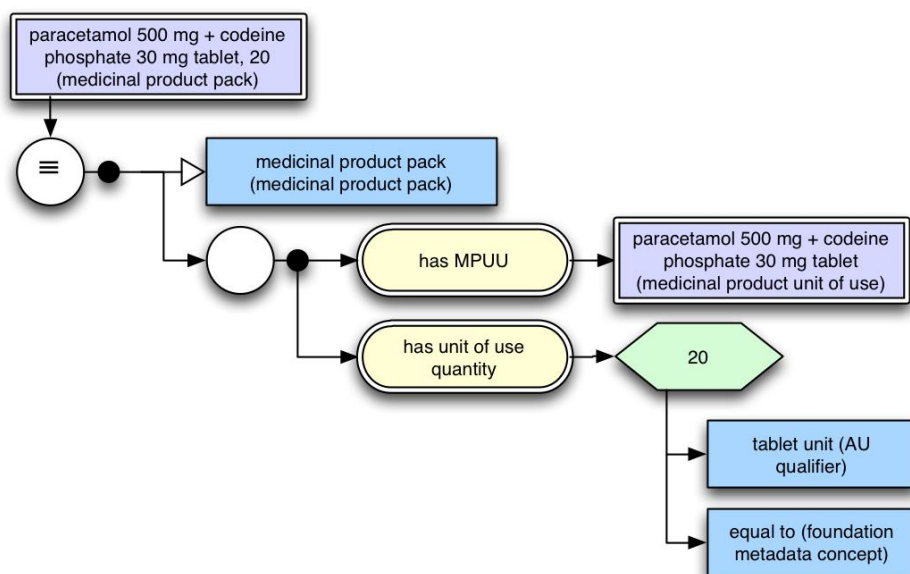


Figure 12: Example MPP Stated Form modelling

Note that the Distribution Normal Form is identical to the Stated Form for the example shown in Figure 12 above.

2.3.2.4 Trade Product

The Trade Product (TP) represents the product brand name, for either single component products, or components of multi-component products regardless of ingredients. The TP may also include any additional detail necessary for identification. For example: strength representation for multi-ingredient products (where this is necessary for differentiation); proprietary form, delivery device or container; an alternate name which has market recognisability.

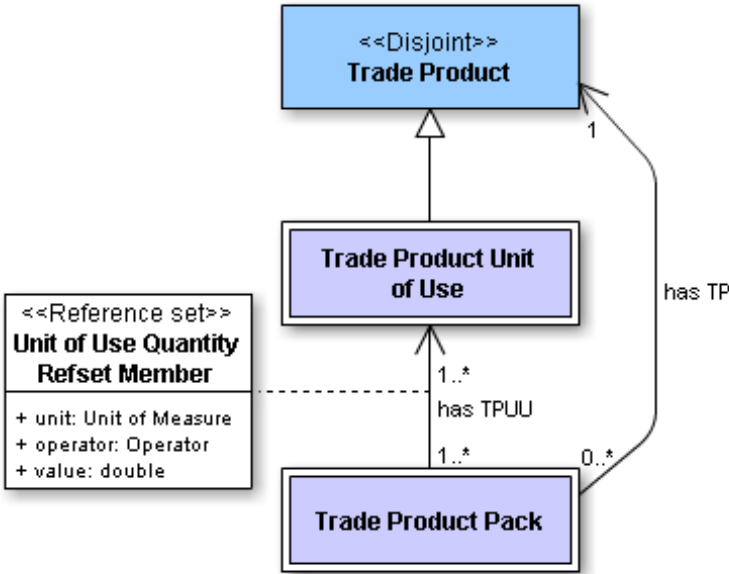


Figure 13: Trade Product (with direct relationships)

Each TP concept is a subtype of the concept 30560011000036108 |*trade product*| that is, it has an IS A relationship to this grouper concept.

Trade Product concepts are always primitive and are used to define the brand name details of the “notable concepts” and distinguish them from the generic, medicinal concepts.

Examples of TPs include:

Table 8: Trade Product examples

A	Amoxil
B	Canesten Clotrimazole
C	<ul style="list-style-type: none">• Nexium• Klacid• Amoxil• Nexium Hp7
D	Sodium Chloride (Baxter)
E	Panadeine Forte

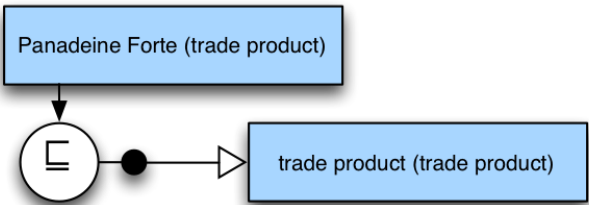


Figure 14: Example TP Stated Form modelling

Note that the Distribution Normal Form is identical to the Stated Form for the example shown in Figure 14 above.

2.3.2.5 Trade Product Unit of Use

Trade Product Unit of Use (TPUU) represents a marketable formulation containing trade name, active ingredient, strength and form in a single dose form or a unit of use component of a multi-component pack.

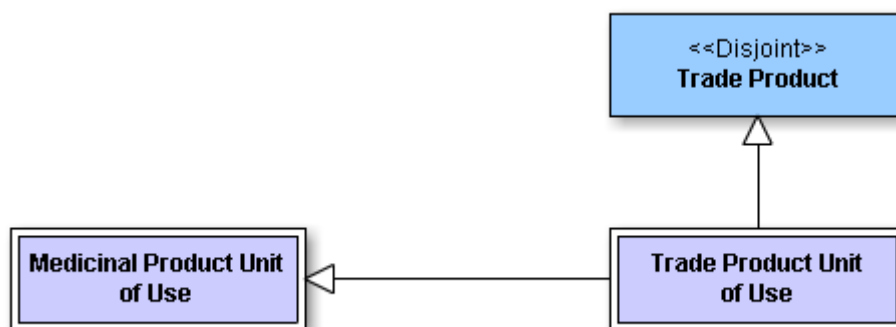


Figure 15: TPUU (with direct relationships)

Each TPUU concept is:

- A subtype of the concept 30425011000036101 |trade product unit of use|, that is, it has an IS A relationship to this grouper concept.
- Always a subtype of a single Trade Product, from which its “brand” is inherited.
- Always a subtype of a Medicinal Product Unit of Use, from which it inherits its:
 - Ingredients
 - Ingredient strengths, including BoSS
 - Form (manufactured dose form)
 - Unit of use
- Optionally has a MANUFACTURED DOSE FORM relationship if the Form is more specific than the Form usually inherited from its parent MPUU.

Most TPUU concepts are fully defined as their set of attributes are sufficient to distinguish otherwise similar products. However in rare occurrences, it is possible for two different TPUU concepts to have the same ingredients, strength, form and brand and still be a different product. Examples of this are products with different flavours or other un-modelled characteristics.

For example the following two TPUU concepts are distinct concepts, yet have the same set of relationships in AMT. As a result they are declared primitive as the additional defining information is not modelled in AMT (refer to Section 2.2.5 for more detail on primitive versus defined concepts). Their FSN and PT descriptions are textually distinct and their conceptIds are also distinct. An example of this is:

- |Neulasta 6mg/0.6 mL injection: solution, syringe|
- |Neulasta with Automatic Needle Guard 6mg/0.6mL injection: solution, syringe|

Examples of TPUUs include:

Table 9: Trade Product Unit of Use examples

A	Amoxil 500 mg capsule: hard
B	Canesten Clotrimazole 1% cream
C	<ul style="list-style-type: none">• Nexium 20 mg tablet: enteric• Klacid 500 mg tablet: film-coated• Amoxil 500 mg capsule: hard
D	Sodium Chloride (Baxter) 0.9% (9 g/L) injection: intravenous infusion, 1 L bag
E	Panadeine Forte tablet: uncoated

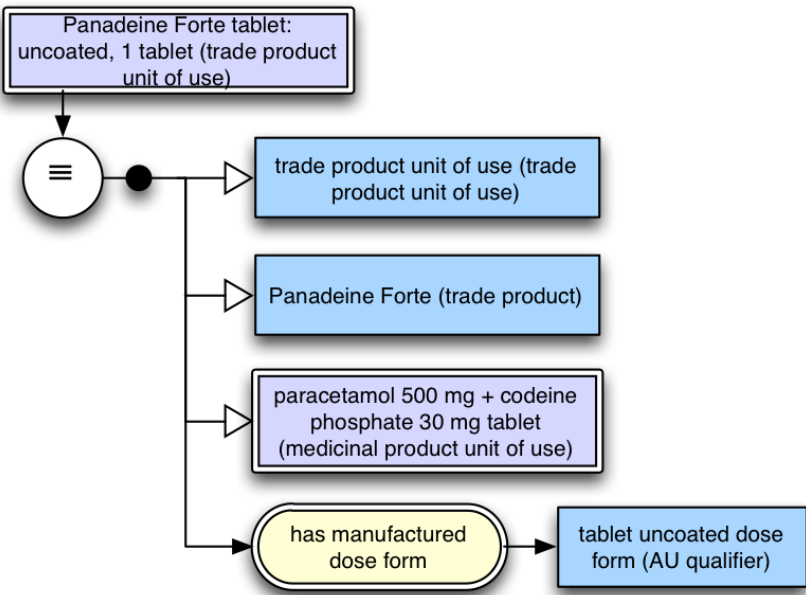


Figure 16: Example TPUU Stated Form modelling

The Distribution Normal Form (DNF) modelling for TPUU concepts is different to its Stated Form modelling because in the DNF, each TPUU restates the defining relationships of its supertype MPUU concept. (These relationships are part of the logical definition of a TPUU.) The figure below illustrates this.

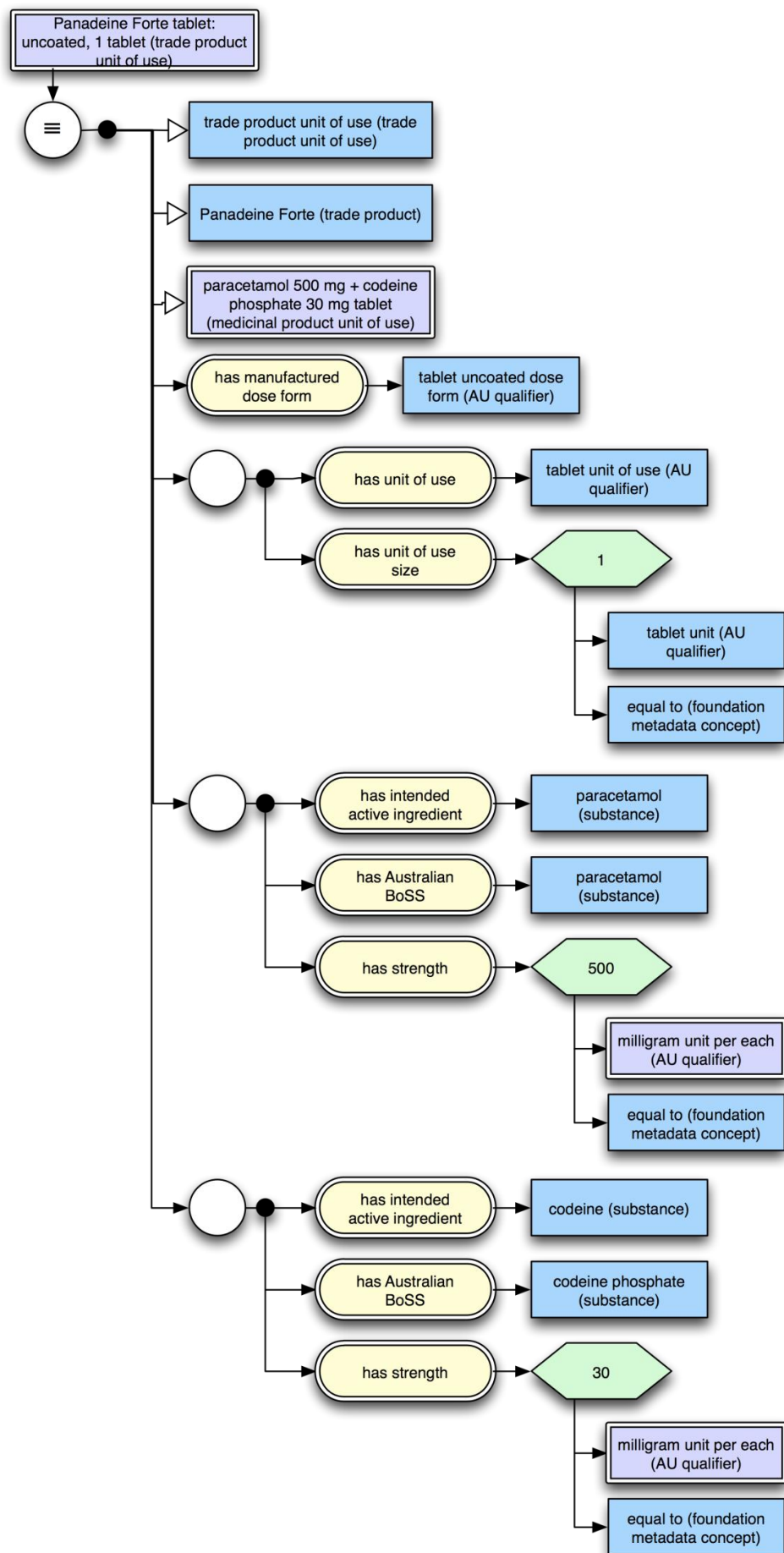


Figure 17: Example TPUU Distribution Normal Form modelling

2.3.2.6 Trade Product Pack

Trade Product Pack (TPP) represents the marketable medicinal entity available for patient use devoid of container type.

For details of when to use a TPP concept versus a CTPP concept, refer to Section 7.6.

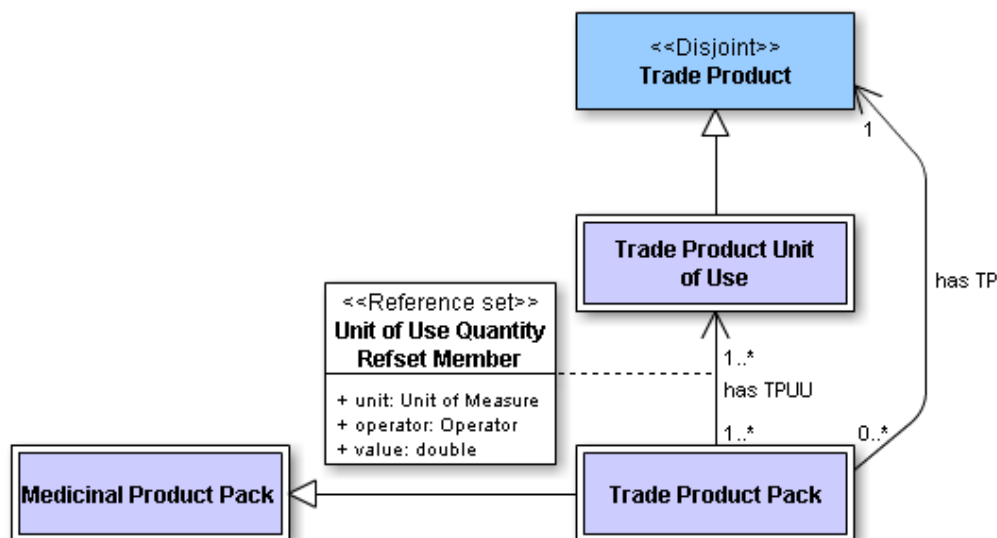


Figure 18: TPP (with direct relationships)

Each TPP concept:

- Is a subtype of the concept 30404011000036106 *[trade product pack]* that is, has an IS A relationship to this grouper concept.
- Is always a subtype of a single MPP, from which it inherits:
 - One or more HAS MPUU relationships to the Medicinal Product Unit of Use concepts it contains.
 - Optionally, multiple HAS COMPONENT PACK relationships to MPP concepts if the concept is a combination pack.
 - Optionally, one HAS SUBPACK relationship to a MPP if the concept is a pack containing subpacks.
- Has exactly one HAS TP relationship to a Trade Product which represents its brand.
 - Note that this Trade Product may or may not be the same as the Trade Product parents of the TPP's Trade Product Units of Use.
 - Specifically, TP concepts for combination pack TPPs and their TPUUs can be different (Nexium Hp7 is one example). Refer to Appendix D.8 to see how this product is modelled.
- Has one or more HAS TPUU relationships to the Trade Product Unit of Use concepts of which this TPP represents the collection.
 - Each HAS TPUU relationship refines a HAS MPUU relationship inherited from the parent MPP, where the target of the HAS TPUU relationship must be a subtype of the target of the inherited HAS MPUU relationship.

- Each HAS TPUU relationship is quantified by the *Unit of use quantity reference set*, which specifies the quantity of the Trade Product Unit of Use instances that the TPP contains (refer to Section 2.3.5.3). Note that the Unit of Use quantity value is identical for the HAS MPUU relationship refined by the HAS TPUU relationship.

Examples of TPPs include:

Table 10: Trade Product Pack examples

A	Amoxil 500 mg capsule: hard, 20
B	Canesten Clotrimazole 1% cream, 20 g
C	<ul style="list-style-type: none"> • Nexium Hp7 (14 x 20 mg enteric tablets, 14 x 500 mg tablets, 28 x 500 mg capsules), 1 pack • Nexium 20 mg tablet: enteric, 14 • Klacid 500 mg tablet: film-coated, 14 • Amoxil 500 mg capsule: hard, 28
D	Sodium Chloride (Baxter) 0.9% (9 g/L) injection: intravenous infusion, 1 L bag
E	Panadeine Forte tablet: uncoated, 20

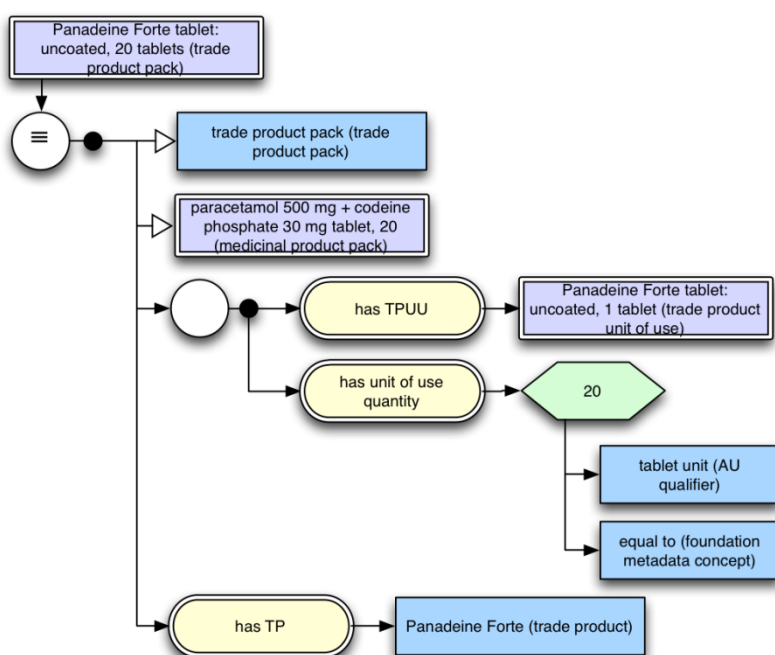


Figure 19: Example TPP Stated Form modelling

Note that the Distribution Normal Form is identical to the Stated Form for the example shown in Figure 19 above.

2.3.2.7 Containered Trade Product Pack

The Containered Trade Product Pack (CTPP) represents the marketable medicinal entity available for patient use, with details of the container type. Its attributes include the brand, the types and number of units it contains, and container type.

For details of when to use a TPP concept versus a CTPP concept, refer to Section 7.6.

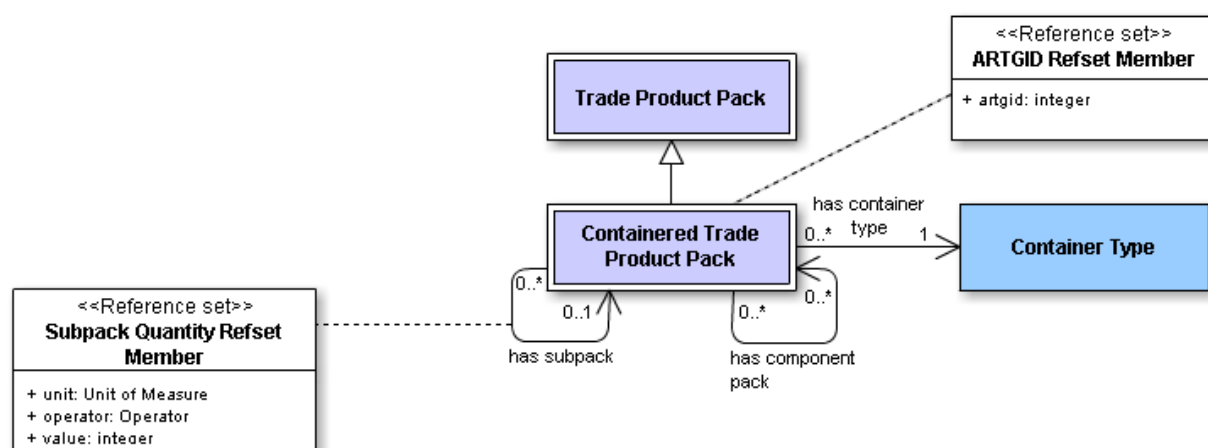


Figure 20: CTPP (with direct relationships)

Each CTPP concept:

- Is a subtype of 30537011000036101 |*containered trade product pack*| that is, has an IS A relationship to this grouper concept.
- Is always a subtype of a single Trade Product Pack, from which it inherits:
 - Exactly one HAS TP relationship to a Trade Product concept, which represents its brand.
 - One or more HAS TPUU relationships to the Trade Product Unit of Use concepts it contains.
 - Each HAS TPUU relationship is quantified by the *Unit of use quantity reference set*, which specifies the quantity of the Trade Product Unit of Use instances that the TPP contains (refer to Section 2.3.5.3).
 - An IS A relationship to a MPP concept, which represents the generic (unbranded) equivalent of the TPP.
- Has exactly one HAS CONTAINER TYPE relationship to a *Container type* concept, which represents the primary (non-ingestible) container which immediately envelops the product.
- Optionally, has multiple HAS COMPONENT PACK relationships to other CTPPs if the concept is a combination pack.
 - Note that if present these relationships will correlate to and refine the HAS COMPONENT PACK relationships inherited from the parent MPP concept.
 - Refer to Section 2.3.3 for further information on component packs and combination packs.
- Optionally, has one HAS SUBPACK relationship to another CTPP if the concept is a pack containing subpacks.
 - Note that if present this relationship will correlate to and refine the HAS SUBPACK relationship inherited from the parent MPP concept.
 - Each HAS SUBPACK relationship is quantified by the *Subpack quantity reference set*, which specifies the number of subpacks contained within each pack containing subpacks (see Section 2.3.5.4). The subpack quantity value will be identical to the subpack quantity of the HAS SUBPACK relationship from the parent MPP being refined.
 - Refer to Section 2.3.3.2 and Figure 21 below for further information on pack containing subpacks and subpacks.

Optionally, a CTPP may be mapped to one or more Australian Register of Therapeutic Goods Identifiers (ARTG Ids) provided in the *ARTG Id reference set*.

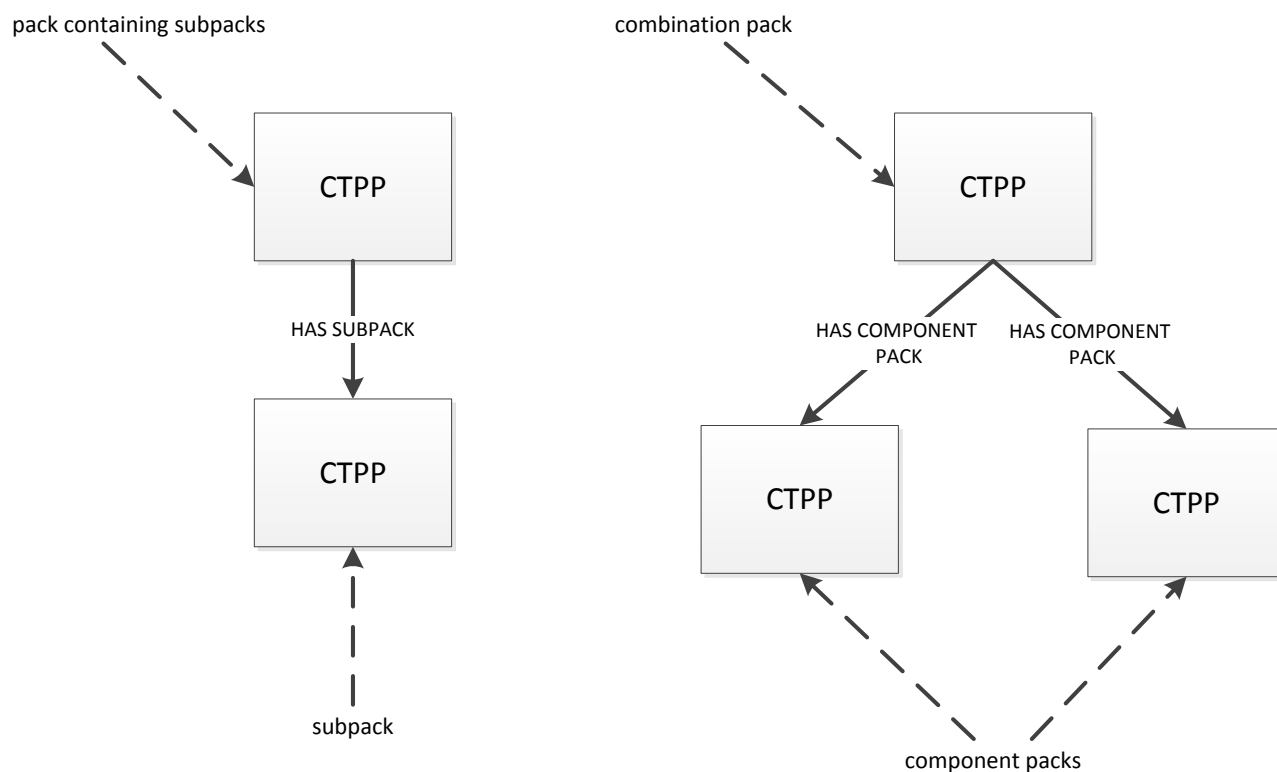


Figure 21: CTPP subpack and component pack relationships

Examples of CTPPs include:

Table 11: Containered Trade Product Pack examples

A	Amoxil 500 mg capsule: hard, 20, blister pack
B	Canesten Clotrimazole 1% cream, 20 g, tube
C	<ul style="list-style-type: none"> Nexium Hp7 (14 x 20 mg enteric tablets, , 28 x 500 mg capsules, 14 x 500 mg tablets), 1 pack, composite pack Amoxil 500 mg capsule: hard, 28, blister pack Klacid 500 mg tablet: film-coated, 14, blister pack Nexium 20 mg tablet: enteric, 14, blister pack
D	Sodium Chloride (Baxter) 0.9% (9 g/L) injection: intravenous infusion, 1 L bag
E	Panadeine Forte tablet: uncoated, 20, blister pack

Examples of component pack CTPPs are:

- Nexium 20 mg tablet: enteric, 14, blister pack
- Klacid 500 mg tablet: film-coated, 14, blister pack
- Amoxil 500 mg capsule: hard, 28, blister pack

The above are component packs of the combination pack CTPP:

- Nexium Hp7 (14 x 20 mg enteric tablets, 28 x 500 mg capsules, 14 x 500 mg tablets), 1 pack, composite pack

An example of a subpack CTPP is:

- Trifeme, 28 tablets, blister pack

Which is a subpack of the CTPP pack containing subpacks:

- Trifeme, 112 tablets [4 x 28], blister pack

For a full definition of subpacks and component packs and how they are differentiated please refer to Appendix A.

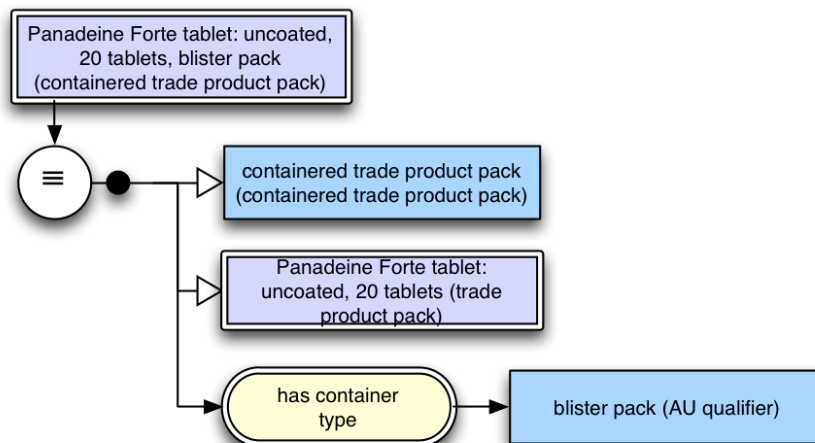


Figure 22: Example CTPP Stated Form modelling

The Distribution Normal Form (DNF) modelling for CTPP concepts is different to its Stated Form modelling because in the DNF, each CTPP restates the defining relationships of its supertype TPP concept. (These relationships are part of the logical definition of a CTPP.) The figure below illustrates this.

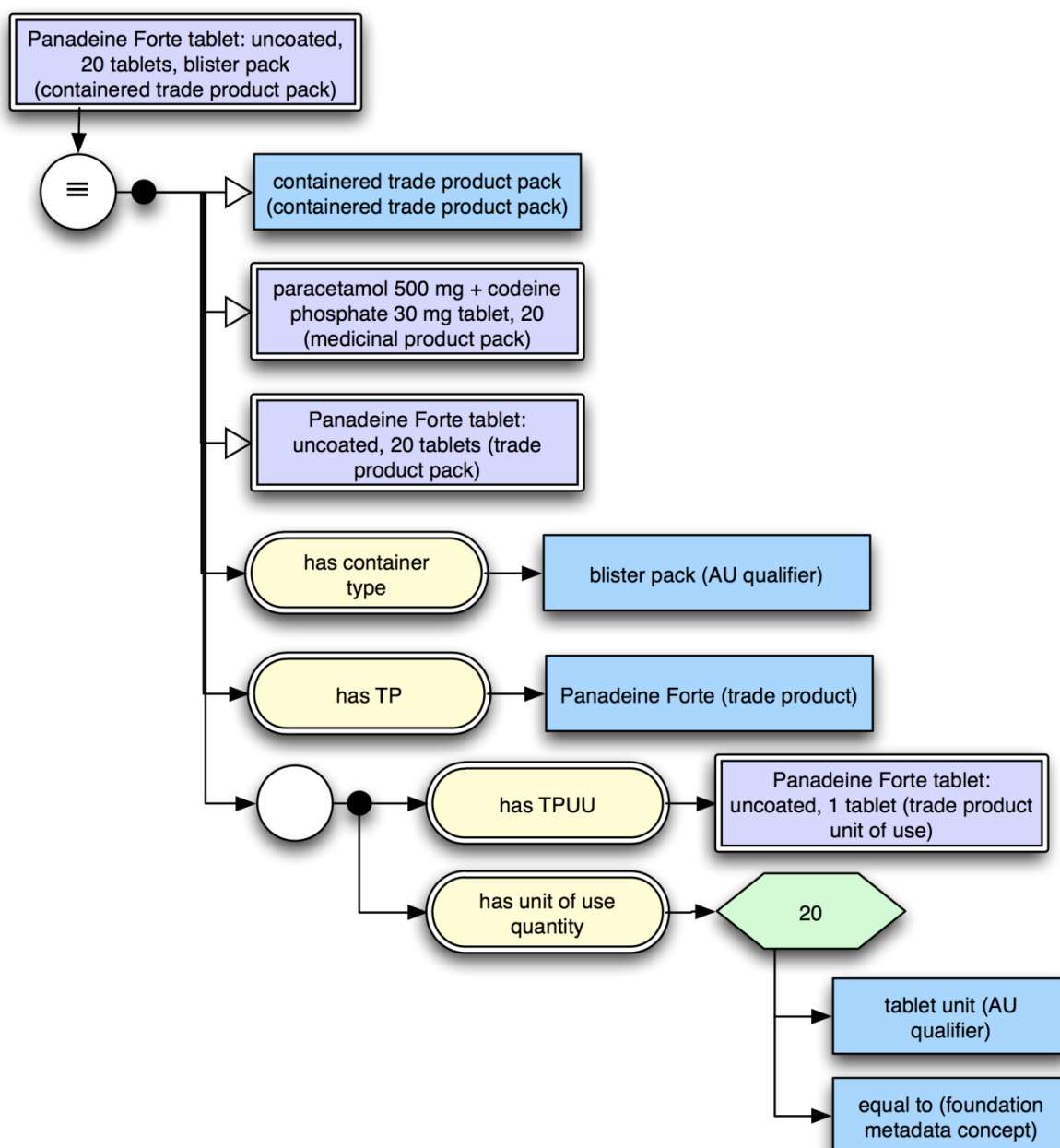


Figure 23: Example CTPP Distribution Normal Form modelling

2.3.3 Packs

2.3.3.1 Combination packs

In AMT, component packs and combination packs pertain only to multi-component products. The structure of CTPP combination packs mirrors the MPP structure of combination packs.

The HAS COMPONENT PACK relationship is not stated for TPP concepts, however the MPP subpack is inherited by the TPP concepts from their MPP parents (where the relationship exists) in the DNF modelling of AMT. See the figure below.

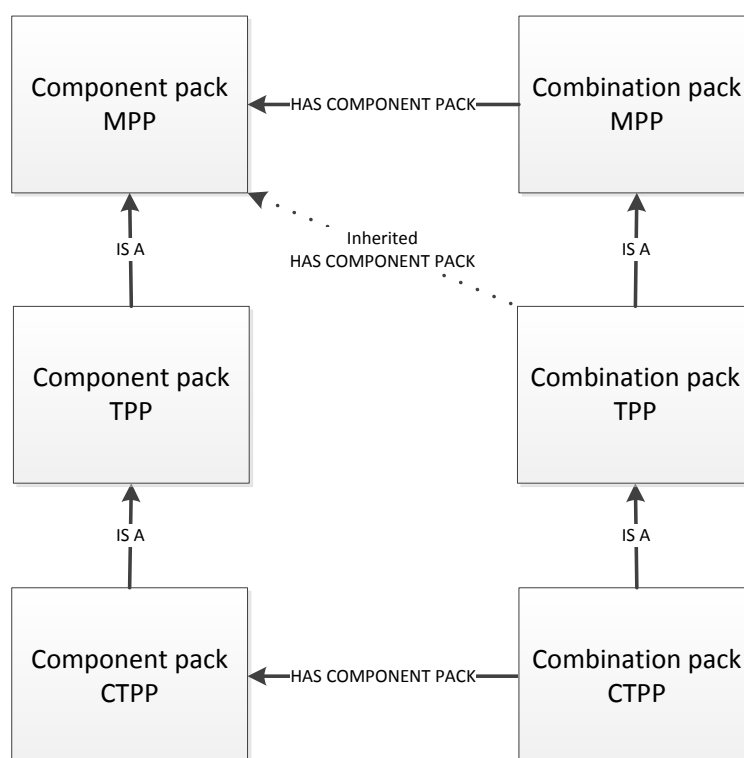


Figure 24: Mirrored structure of MPP, TPP and CTPP combination packs

In addition, the following rules apply:

- All combination pack CTPPs have an IS A relationship to a combination pack TPP concept.
- All combination pack TPPs have an IS A relationship to a combination pack MPP concept.
- All combination pack CTPPs and MPPs have multiple HAS COMPONENT PACK relationships to component pack CTPPs and component pack MPPs respectively. Combination pack TPPs have inherited HAS COMPONENT PACK relationships from their parent MPP.
- The number of component pack concepts is consistent across a relevant CTPP and its associated TPP and MPP.
- Combination pack TPPs and their corresponding component pack TPPs share the same TPUUs.
- Combination pack MPPs and their component pack MPPs share the same MPUUs.

For a full definition of combination and component packs and how they are differentiated please refer to Appendix A. Refer to Appendix D.8 for an example of how they are modelled for the product Nexium Hp7.

2.3.3.2 Subpacks

In AMT, subpacks are included for oral contraceptives, hormone replacement therapy products and any other multi-pack products that are presented in multiple identical subpacks. These products may be single or multi-component.

The structure of CTPP packs containing subpacks mirrors the MPP structure of packs containing subpacks.

The HAS SUBPACK relationship is not stated for TPP concepts; the relationship is inherited by the TPP from its MPP parent (where the relationship exists) based on the DNF modelling of AMT. The following figure provides an example.

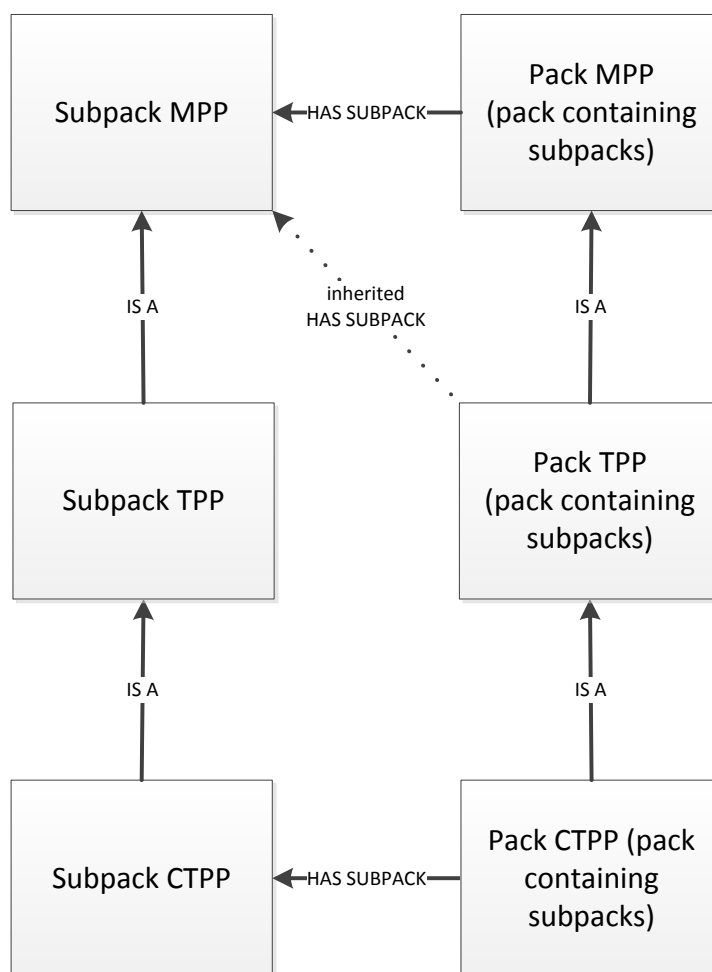


Figure 25: Mirrored structure of MPP, TPP and CTPP packs containing subpacks

Additionally the following rules apply:

- All CTPP packs containing subpacks have an IS A relationship to one TPP pack containing subpacks concept only.
- All TPP packs containing subpacks have an IS A relationship to one MPP pack containing subpacks concept only.
- All CTPP/MPP packs containing subpacks have only one HAS SUBPACK relationship to a subpack CTPP or a subpack MPP respectively. TPP packs containing subpacks have HAS SUBPACK relationships inherited from their parent MPPs.
- The number of subpack concepts is always one across a relevant CTPP and its associated TPP and MPP.
- TPP packs containing subpacks and their subpack TPPs share the same TPUUs.
- MPP packs containing subpacks and their subpack MPPs share the same MPUUs.

For a full definition of subpacks and how they are differentiated, please refer to Appendix A. Refer to Appendix D.9 for an example of how they are modelled for the product Triphasil.

2.3.4 Other concept classes

The other concepts that exist in the AMT model provide the necessary concepts to support the definition of the main “notable concepts”. This section contains an overview of these concepts. More information can be found in the *AMT v3 Model Editorial Rules* (NEHTA, 2014).

2.3.4.1 Medicinal substance

Medicinal substance concepts are primitive and identify chemical elements, compounds, and mixtures. They are contained under the *[Australian substance]* hierarchy in AMT.

Substance concepts may have an IS MODIFICATION OF relationship to another *Substance*. If present, this means that the concept is a chemical compound incorporating the other substance. For example the *Substance* concept *[calcium carbonate]* has an IS MODIFICATION OF relationship to the *Substance* concept *[calcium]*. Using this relationship in reverse it is possible to find all the modified forms of a base substance.

AMT’s *Medicinal substance* concepts represent a parallel set of *Substance* concepts overlapping meaning with parts of SNOMED CT’s *Substance* hierarchy. AMT products reference AMT *Medicinal substances* as ingredients rather than SNOMED CT concepts, as SNOMED CT’s *Substance* hierarchy is under review and likely to change in the future. The *Substance to SNOMED CT-AU mapping reference set* is developed for the implementers of AMT and SNOMED CT-AU to enable integration with SNOMED CT content. It will contain all AMT substances that are used in a modelled AMT product with a corresponding equivalent or supertype¹² map to a substance in SNOMED CT-AU. Refer to Section 2.3.5.6 for further information on this reference set. More information on AMT substances (for example, base and salt) and rules on naming them is available in the *AMT v3 Model Editorial Rules* (NEHTA, 2014).

AMT substances are currently independent of SNOMED CT substances, but will align with SNOMED CT after the SNOMED CT *Substance* hierarchy redesign has been completed.

2.3.4.2 Form

Form concepts are contained under the *[Australian qualifier]* hierarchy in AMT. Each *[form]* concept represents a dose formulation, such as tablet, capsule or eye drop. These *Form* concepts are used in AMT to define the manufactured dose form of medicines concepts.

The administered dose form of medicines is not represented for AMT products, where this is different to the manufactured dose form. For example, the product *[Lemsip Max Flu Strength Daytime oral liquid: powder for, 1 sachet]* has a manufactured dose form of *[oral liquid: powder for]* but when reconstituted for use

¹² That is, the nearest relevant parent concept.

prior to or upon administration will have an administered dose form of *|oral liquid: solution|*.

Form concepts may also be subtypes of (have IS A relationships to) other *Form* concepts. This creates a hierarchy of *Form* concepts, with more specific types of forms towards the bottom of the hierarchy. The top level *Form* concepts have an IS A relationship to the AMT concept *|form|*.

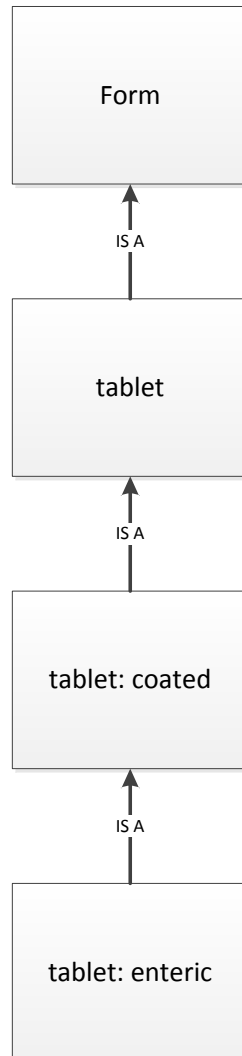


Figure 26: Example form hierarchy

For some products the TPUU form may be more specific than the MPUU form. Where this occurs, different HAS MANUFACTURED DOSE FORM relationships exist for the MPUU and TPUU concepts, however the target of the TPUU's HAS MANUFACTURED DOSE FORM relationship must always be a subtype of the MPUU's form. For example, the product *|Ablavar 2.44 g/10 mL injection: solution, 10 mL vial|* has a TPUU form of *|injection: solution|* while the MPUU form is *|injection|*. This is illustrated in the following figure.

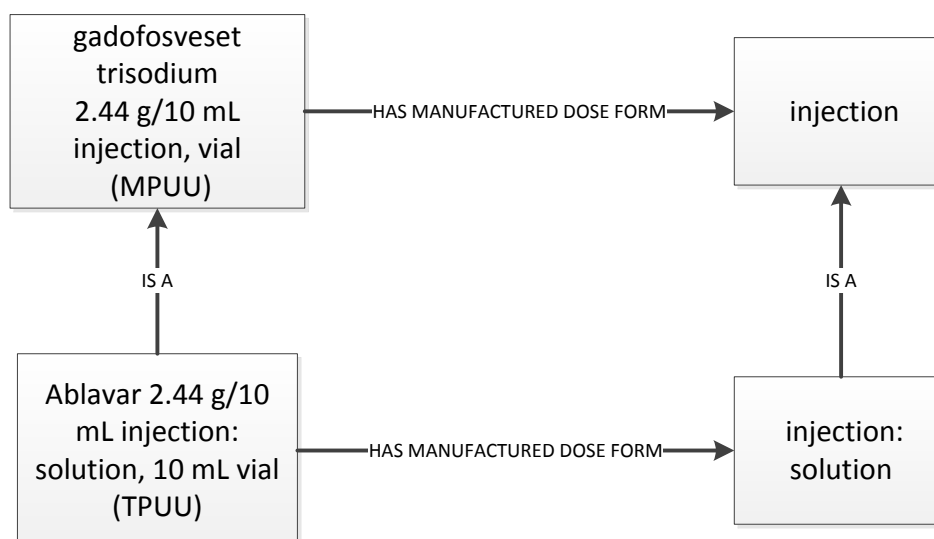


Figure 27: Example of different MPUU and TPUU forms

Some equivalent *Form* concepts can be found between AMT and SNOMED CT-AU. A mapping of *Form* concepts between these terminologies has not been developed at the time of writing. When full integration between AMT and SNOMED CT-AU occurs as part of the development roadmap, where an equivalency is determined the SNOMED CT-AU *Form* concept will be retained as the primary *Form* concept.

2.3.4.3 Unit of measure

Unit of measure concepts are contained under the *[Australian qualifier]* hierarchy in AMT. Under the concept *[unit of measure]*, AMT contains a hierarchy of concepts that represent units used to measure quantities in AMT – for example *[mg]*.

Units of measure are sourced from the TGA data for the medications included in AMT and are defined in the TGA Approved Terminology for Medicines¹³.

This hierarchy also includes units of measure known as “composite units of measure”. A *Composite unit of measure* is used to express units that have a numerator and denominator component. It is currently used to represent the unit field within the *Strength reference set*. For example *[mg/mL]*, where *[mg]* is the numerator unit and *[mL]* is the denominator unit.

Composite unit of measure concepts will have:

- exactly one HAS NUMERATOR UNIT relationship to a *Unit of measure* concept; and
- exactly one HAS DENOMINATOR UNIT relationship to a *Unit of measure* concept.

Unit of measure concepts do not have HAS NUMERATOR UNIT or HAS DENOMINATOR UNIT relationships.

¹³ TGA publishes their Approved Terminology for Medicines at <http://www.tga.gov.au/industry/medicines-approved-terminology.htm>.

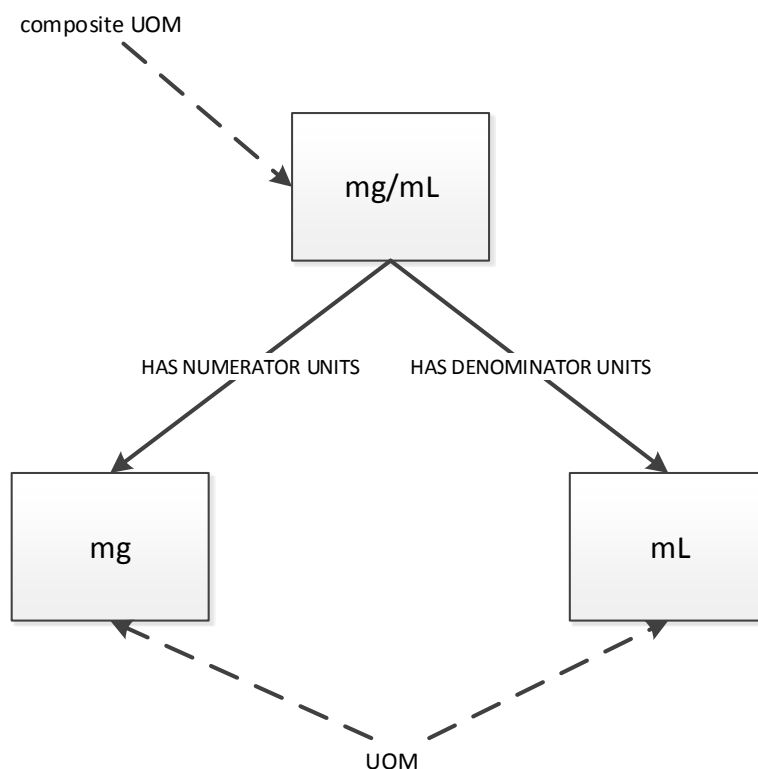


Figure 28: Example Composite unit of measure

Some equivalent *Unit of measure* concepts can be found between AMT and SNOMED CT-AU. A mapping of *Unit of measure* concepts between these terminologies has not been developed at the time of writing. When full integration between AMT and SNOMED CT-AU occurs as part of the development roadmap, where an equivalency is determined, the SNOMED CT-AU *Unit of measure* concept will be retained as the primary *Unit of measure* concept.

2.3.4.4 Unit of use

Unit of use concepts are contained under the [Australian qualifier] hierarchy in AMT. The *Unit of use* describes a discrete unit dose form (such as tablet or capsule) or a continuous form where a consistent physically measurable unit or sub-unit cannot be identified (such as cream or eye drops). It is an MPUU attribute, which is inherited by the TPUU.

The HAS UNIT OF USE relationship is quantified by the *Unit of use size reference set*, which specifies the size of each unit of use.

2.3.4.5 Container type

Container type concepts are contained under the [Australian qualifier] hierarchy in AMT. AMT *Container type* concepts represent the types of container that immediately cover a medicine. Examples include *ampoule*, *bottle*, *blister pack*, *vial* and so on. These concepts are largely derived from TGA Approved Terminology for Medicines.

2.3.5 Reference sets

AMT includes:

- reference sets that carry some of the semantics in the AMT model; and
- reference sets containing convenient enumeration of the “Notable concepts”.

The reference sets specific to AMT are described in this section. In addition, Section 3.1 includes a description of the other reference sets distributed with AMT which form part of the RF2 representation of AMT. Section 3.1 also describes the reference set patterns of all AMT reference sets along with the purpose and format of each reference set field.

2.3.5.1 Strength reference set

The *Strength reference set* is a “concrete domain” reference set (refer to Section 3.2) that includes numerical datatype properties used in the definition of Medicinal Product Unit of Use concepts.

Specifically, members of the *Strength reference set* refer to HAS AUSTRALIAN BoSS relationships and add a property including:

- a value (for example, 500);
- a reference to the unit of measure for the value (for example, mg/each); and
- a reference to an operator, at present only 700000051000036108 |*Equal to*|.

This has the effect of further qualifying the HAS AUSTRALIAN BoSS relationship by specifying the quantity of the ingredient included – from the example above “equal to 500 mg/each”.

Note that the strength of the intended active ingredient is expressed in terms of the “Australian BoSS”, not the intended active ingredient itself if this differs. For example if a concept is defined with:

- HAS AUSTRALIAN BoSS |*morphine sulfate*|;
- HAS INTENDED ACTIVE INGREDIENT |*morphine*|; and
- Strength of “10 mg/each”.

This is specifying that while |*morphine*| is the active portion of the ingredient that provides the therapeutic effect, the strength specified is equivalent to 10 mg worth of |*morphine sulfate*| that is, the strength always qualifies the BoSS. Note that this is **not** necessarily saying that |*morphine sulfate*| is present, but |*morphine sulfate*| is just being used to express the quantity of |*morphine*| that is present. The actual quantity of |*morphine*| present would be less than 10 mg due to the higher molecular weight of |*morphine sulfate*|.

As described in an earlier chapter, the BoSS is always derived from formal documentation developed by the sponsor and the TGA. The BoSS represents one or more substances within a product, which is usually how it is described clinically and how it is dosed. While the intended active ingredient represents only the ingredient portion that provides the known therapeutic effect.

Refer to the *AMT v3 Model Editorial Rules* (NEHTA, 2014) for a fuller definition of the BoSS and Section 2.3.6.8 for more information on the intended active ingredient.

Concentration based strengths and those with numerator and denominator components are represented using “composite units of measure”, such as “mg/mL” or “mg/each”. Medicinal concept Preferred Terms may still use the most preferred human representation, however the *Strength reference set* will always represent normalised strength values using a denominator of one. For example “50 mg/5 mL” might be the human readable strength, whereas the *Strength reference set* will contain “10 mg/mL”.

While the *Strength reference set* will typically represent normalised strength values, there are some exceptions (mainly for patches) whereby the strength value and units represent the relevant release rate (as this is the clinically relevant attribute). See Appendix D.3 for an example modelled patch product and Section 5.4.2 for an example of how to access ingredient strength.

Where different MPUU concepts share the same BoSS (that is, have the same destination *Substance* for the HAS AUSTRALIAN BoSS relationship), and different *Composite units of measure* are used (say “microgram/mL” and “mg/mL”), the *Composite unit of measure* is normalised to only a single unit (for example, only to “microgram/mL”). This is to allow easier strength comparisons across similar products. Refer to Section 3.2.6 for further details on unit conversion.

While the normalised strength in the *Strength reference set* may be “microgram/mL”, the denormalised human friendly strength as displayed within the concept’s Preferred Terms may be “mg/mL” per clinical documentation.

Every active HAS AUSTRALIAN BoSS relationship will be referenced by a single active member of the *Strength reference set* – that is, there is a strength associated with every BoSS. Products where no strength exists for the ingredient will not have a HAS AUSTRALIAN BoSS relationship and no associated *Strength reference set* member. Some examples of these products are:

- Foods/nutritional supplements (such as vitamins, minerals and trace elements with carbohydrate).
- Diagnostic strips (for example, glucose indicator blood).
- Non-medicated dressings/bandages (such as bandage tubular; bandage retention cohesive heavy).
- Inert substances, diluents.

Some MPUU concepts have an alternate strength representation displayed within their Preferred Term for example, “3%” and “1 in 10 000”. There are plans to publish this information in a future release.

For details of the structure and datatypes refer to Section 3.2.

2.3.5.2 Unit of use size reference set

The *Unit of use size reference set* is a “concrete domain” reference set (refer to Section 3.2) that specifies the quantity of a Medicinal Product Unit of Use that constitutes a “unit of use”. This is usually the administrable dose unit (for example, 1 tablet or 5 mL) however for continuous products (creams, for example) a measurable administrable dose unit does not exist.

For Medicinal Product Unit of Use concepts with premeasured, measured or indivisible forms, this reference set will simply indicate a single unit of this form. For example the unit of use size for a *|paracetamol 500 mg tablet|* is "1 tablet". Other examples are "1 patch" or "1 suppository".

For concentration based products, the unit of use size is the total quantity of the medicine in the Medicinal Product Unit of Use concept. For example a *|benztropine mesylate 2 mg/2 mL injection, ampoule|* has its strength in the *Strength reference set* as "1 mg/mL" and in the *Unit of use size reference set* its value is "2 mL".

The combination of the *Unit of use size reference set* and the *Strength reference set* provide the ability to calculate the total ingredient quantity for a unit – refer to Section 5.4.3 for an example of this. Note that there are rounding issues to consider, which are discussed further in Section 7.15.

All MPUU concepts will have an entry in the *Unit of use size reference set*. It is not possible to sensibly provide a unit of use size as a precise amount for continuous form products such as solutions, creams, ointments or some inhalations. These products will have a unit of use size of "1 each" intended to ease total pack quantity calculations by consistently providing a value.

For details of the structure and datatypes refer to Section 3.2.

2.3.5.3 Unit of use quantity reference set

The *Unit of use quantity reference set* is a "concrete domain" reference set (refer to Section 3.2) that includes numerical datatype properties used in the definition of MPP and TPP concepts. Unit of use quantity represents the pack quantity for a given medicinal or trade pack concept. Some examples are "100 capsule", "20 tube", "30 sachet" and "10 vial".

Members of the *Unit of use quantity reference set* refer to HAS MPUU/HAS TPUU relationships between MPP/TPP and MPUU/TPUU concepts and add a property including:

- An integer value (for example, 30).
- A reference to the unit of measure (for example, tablet).
- A reference to an operator, at present only 700000051000036108 *|Equal to|*.

This has the effect of quantifying the HAS MPUU/HAS TPUU relationship to specify how many of each type of Medicinal Product Unit of Use/Trade Product Unit of Use concepts a Medicinal Product Pack/Trade Product Pack concept contains. In the example above this would be "equal to 30 tablets".

Every active HAS MPUU relationship between a Medicinal Product Pack concept and a Medicinal Product Unit of Use concept will be referred to by a single active member of the *Unit of use quantity reference set*. Similarly, every active HAS TPUU relationship between a TPP concept and a TPUU concept will be referred to by a single active member of the *Unit of use quantity reference set*.

For details of the structure and datatypes refer to Section 3.2.

2.3.5.4 Subpack quantity reference set

The *Subpack quantity reference set* is a "concrete domain" reference set (refer to Section 3.2) that quantifies the HAS SUBPACK relationship a Medicinal Product Pack

containing subpacks has with each subpack Medicinal Product Pack. That is, for each HAS SUBPACK relationship, the *Subpack quantity reference set* specifies how many of the subpack Medicinal Product Packs are included in the Medicinal Product Pack concept containing the subpacks.

Similarly, the reference set quantifies the HAS SUBPACK relationship from a CTPP pack containing subpacks with each subpack CTPP. This specifies how many of the subpack CTPPs are included in the CTPP pack containing subpacks.

For example the HAS SUBPACK relationship between the subpack MPP:

- ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [6] (&) ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [5] (&) ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet [10] (&) inert substance tablet [7], 28

and the MPP pack containing subpacks:

- ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [24] (&) ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [20] (&) ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablets [40] (&) inert substance tablets [28], 112 tablets [4 x 28]

is referred to by the *Subpack quantity reference set* with the value “4 each”, indicating the MPP pack containing subpacks contains four of the subpack MPP instances. Each CTPP descendant of an MPP pack containing subpacks will have a HAS SUBPACK relationship to a CTPP which is a descendant of the parent MPP’s subpack, and the specified subpack quantity (in this case four) will match the subpack quantity specified for the MPP parent.

For details of the structure and datatypes refer to Section 3.2.

2.3.5.5 “Notable concept” reference sets

AMT also contains a reference set for each of the “Notable concepts” – a total of seven reference sets, namely:

- *Medicinal product reference set*
- *Medicinal product unit of use reference set*
- *Medicinal product pack reference set*
- *Trade product reference set*
- *Trade product unit of use reference set*
- *Trade product pack reference set*
- *Containerised trade product pack reference set*

These are intended to present each AMT “notable class” product concepts in pre-set lists to simplify implementations. These reference sets have the Simple reference set pattern, as specified in the *SNOMED TIG* (IHTSDO, 2014). Each reference set represents all the concepts from each of the “Notable concept” types; both active and inactive concepts. For example the *Medicinal product unit of use reference set* refers to all the Medicinal Product Unit of Use concepts in AMT – while the vast majority of these concepts are active, some inactive concepts are included as this is the final state of these concepts. Refer to Section 5.3.3 for example SQL scripts that assist in using the AMT notable class concepts for implementation.

If a concept has been inactivated and replaced by a newer active concept an appropriate entry will be included in the *REPLACED BY association reference set*. Refer to the following Section 2.3.5.6.

These reference sets are provided as a convenience and do not have any bearing on the meaning of the AMT content. Each reference set provides the ability to obtain a list of the concepts from each of the “Notable concept” hierarchies without having to use the relationships or a transitive closure. Refer to Section 5.3.3 for other methods of extracting all members of a notable concept class.

2.3.5.6 Historical association reference set

This reference set is intended to capture historical states of AMT concepts, which is important during terminology maintenance. Specifically, the *REPLACED BY association reference set* identifies retired (inactive) concepts in AMT along with their active, replacement concepts (where a replacement exists).

The referenced components within this reference set are AMT concepts only and do not include other components. These other components (that is, descriptions, relationships and reference set members) may change over time, including being retired. One method to identify these changes for terminology updates is to use the Delta release files, as included in the AMT data bundle.

In addition, referenced components within this reference set are only retired concepts that have an active replacement. Some concepts may be retired without an active replacement (for example, if the concept was created erroneously) and these are not included in the reference set. Therefore, the count of reference set members in this reference set will be a lesser number than the count of all inactive concepts in AMT.

Once released this reference set appends new rows as applicable in each subsequent release.

Concepts are retired due to various reasons, such as: a change in source data, a change in editorial policy, an erroneously created concept, or duplicate concepts.

2.3.5.7 Substance to SNOMED CT-AU mapping reference set

The *Substance to SNOMED CT-AU mapping reference set* is developed for the implementers of AMT, SNOMED CT-AU and NEHTA Detailed Clinical Models¹⁴ to enable use of the AMT content integrated with SNOMED CT.

AMT’s *Medicinal substance* concepts represent a parallel set of *Substance* concepts overlapping meaning with parts of SNOMED CT’s *Substance* hierarchy. AMT products reference AMT *Medicinal substances* as ingredients rather than SNOMED CT concepts, as SNOMED CT’s *Substance* hierarchy is under review and likely to change in future. The *Substance to SNOMED CT-AU mapping reference set* will contain all AMT substances that are used in a modelled AMT product with a corresponding equivalent or supertype¹⁵ map to a substance in SNOMED CT-AU. This reference set has the Attribute Value Map type reference set pattern, as specified in Section 3.1.11 below.

¹⁴ Further information on NEHTA Detailed Clinical Models can be obtained from the following link <http://www.nehta.gov.au/implementation-resources/clinical-documents/detailed-clinical-model-library>.

¹⁵ That is, the nearest relevant parent concept.

The map contains both equivalent and supertype maps depending upon the correlation of AMT *Substance* concepts to SNOMED CT *Substance* concepts at the time.

- Equivalent maps are bi-directional and indicate that the AMT *Substance* concept identified is semantically equivalent to the specified SNOMED CT *Substance* concept.
 - For example, the AMT substance 2425011000036109 |*oxazepam*| is equivalent to the SNOMED CT-AU substance 387455006 |*Oxazepam*|.
- Supertype maps of AMT substances that have no equivalent SNOMED CT-AU substances, are mapped to the nearest parent concept (that is, supertype concept) in the SNOMED CT-AU *Substance* hierarchy. This is a directional map and must only be used from AMT to SNOMED CT-AU.
 - For example, the AMT substance 927556011000036108 |*meningococcal group W135 conjugate vaccine*| is more granular than any SNOMED CT-AU substance concept found (at the time of mapping), and is therefore mapped to the nearest SNOMED CT-AU supertype substance concept of 424891007 |*Meningococcus vaccine*|.

Note: Use of the map to integrate AMT with SNOMED CT substances may result in incorrect inferences. This is due to known modelling issues in the SNOMED CT *Substance* hierarchy which is being addressed by an IHTSDO project. However until this work is completed and the International edition of SNOMED CT is updated, care must be taken using the AMT *Substance* to SNOMED CT-AU mapping reference set.

2.3.5.8 Australian Register of Therapeutic Goods Identifier (ARTG Id) reference set

The ARTG Id is the primary identifier used to identify therapeutic goods as included in the Australian Register of Therapeutic Goods (ARTG). It is intended to support implementers for mapping purposes and identification of products.

This is a Simple Map reference set, as described in Section 3.1.10. This reference set allows zero to many ARTG Ids (as a string) to be associated with one or more CTPP concepts. The ARTG Id is an optional identifier from an external identifier scheme (that is, not native to SNOMED CT) and is therefore a non-defining attribute of the CTPP class.

The following ARTG Id maps are possible:

- One ARTG Id is associated with a single CTPP – this accounts for the vast majority of products.
 - For example, ARTG Id 75592 maps to the CTPP concept |*Dicloil 500 mg capsule, 24, blister pack*|.
- One ARTG Id is associated with multiple CTPPs – this occurs typically for products that are marketed in multiple, differing pack quantities.
 - An example is ARTG Id 71816, which maps to two CTPP concepts:
 - |*Aciclovir (GenRx) 200 mg tablet, 50, blister pack*| and
 - |*Aciclovir (GenRx) 200 mg tablet, 90, blister pack*|
 - The above ARTG Id is present in two separate lines in the reference set each referencing different CTPP concepts.

- Multiple ARTG Ids are associated with a single CTPP – this can occur when the same product obtains a new ARTG Id and the previous ARTG Id remains in the source TGA data.
 - For example, the ARTG Ids 120662 and 77830 are mapped to the same CTPP concept *|Seretide MDI 125/25 inhalation: pressurised, 120 actuations, metered dose aerosol can|*.
 - The above ARTG Ids are present in two separate lines in the reference set, each referencing the same CTPP.

This reference set contains ARTG Id strings that are greater than one million. However, as these strings are not strictly ARTG Ids as assigned by the TGA and were created to support AMT v2 legacy administrative processes, these strings are marked as “not active” in the reference set (that is, active field = 0). They are not suitable for use in any clinical system implementation.

2.3.6 Relationship types

AMT uses a variety of relationship types when connecting two concepts to represent different logical statements. This section covers the relationship types in use within AMT, where they are used and what they mean.

Note that the following sections describe the Stated Form of the AMT data. Note that expected cardinality of relationships expressed in the following sections will change in a Distribution Normal Form rendering of the same data. For more details refer to Section 3.5.

2.3.6.1 IS A

116680003 *|Is a|* comes from the parent terminology, SNOMED CT. It is used to represent a supertype relationship, where the destination concept of an IS A relationship is a supertype of the source concept of an IS A relationship.

This means that the source or “child” concept is a subtype of the “parent” concept, and all defining statements that are true of the parent concept are therefore true of the child concept.

2.3.6.2 HAS TPUU

30409011000036107 *|Has TPUU|* is an AMT relationship type used to indicate that a source TPP concept contains one or more specified destination TPUU concepts.

Note: HAS TPUU is a sub-relationship type of HAS MPUU, that is a narrower, more specific specialisation of the HAS MPUU relationship type between an MPP and MPUU.

Therefore each HAS TPUU relationship from a TPP to a TPUU:

- Specialises a HAS MPUU relationship on a parent MPP to an MPUU destination concept.
- Specifies a TPUU destination concept that is a subtype of the MPUU destination concept of the HAS MPUU relationship it specialises.

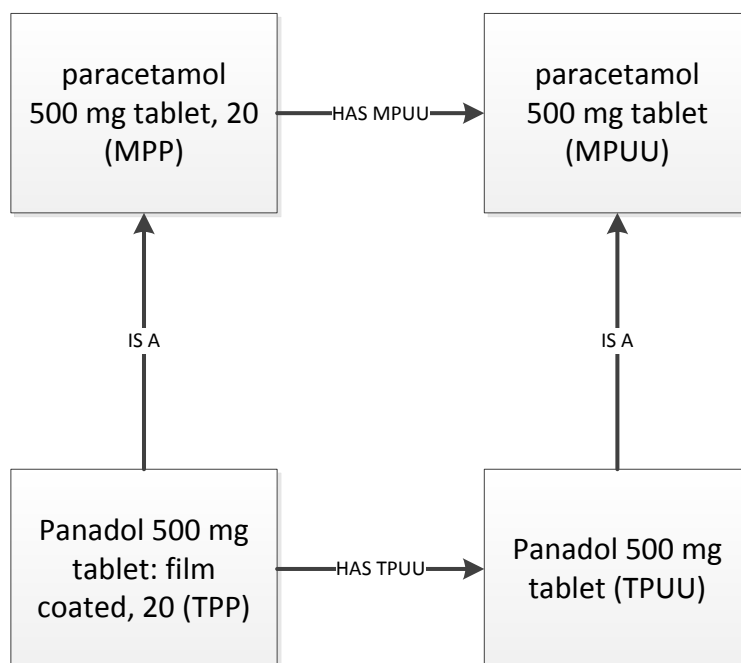


Figure 29: Example HAS MPUU and HAS TPUU sub-role

2.3.6.3 HAS TP

700000101000036108 *[Has TP]* is an AMT relationship type that is used to specify the Trade Product concept representing a product's brand. Each TPP concept is the source of a relationship of this type for this purpose. All CTPPs inherit these relationships from their TPP.

2.3.6.4 IS MODIFICATION OF

30394011000036104 *[Is modification of]* is an AMT relationship type used on *Medicinal substance* concepts to indicate that the source *Substance* concept is a chemical compound that incorporates the destination *Substance* concept.

This relationship only exists if:

- a *Substance* concept incorporates another *Substance* concept; **and**
- the source *Substance* concept of the relationship has been used by an AMT product (that is, the *Substance* is the destination of any HAS INTENDED ACTIVE INGREDIENT or HAS AUSTRALIAN BoSS relationship).

This relationship represents a modification to an active moiety (that is, the base ingredient). The modification could be a primary modification to the base (such as salts, esters, or waters of hydration) or a secondary modification to the base (such as waters of hydration or salts).

The source concepts within the following examples describe a "primary modified base" and a "secondary modified base" respectively:

- *[ipratropium bromide]* IS MODIFICATION OF *[ipratropium]*.
- *[ipratropium bromide monohydrate]* IS MODIFICATION OF *[ipratropium bromide]*.

This relationship may be used to determine the base ingredient for a given primary modified base ingredient or salt ingredient for a given secondary modified base ingredient of AMT product concepts. See Section 2.3.4.1 for more details.

2.3.6.5 HAS CONTAINER TYPE

30465011000036106 |*Has container type*| is an AMT relationship type used to indicate a CTPP concept's container type where the source of the relationship is the CTPP concept and the destination of the relationship is the *Container type* concept. Each CTPP concept has exactly one HAS CONTAINER TYPE relationship.

The container type represents the primary (non-ingestible) packaging that immediately envelops the product such as bottle, blister pack, ampoule and bag.

For multi-component products where different layers of packaging exist and the container types may be different (that is, combination pack CTPPs), the container type is designated as |*pack*| for example, for the CTPP |*Actonel Combi D, 1 pack*|.

Note: The container type of "pack" is not displayed in the CTPP Preferred Term as it is repeating the same text that is offered by the unit of use quantity (that is, "1 pack"). The "pack" container information will be displayed in the CTPP Fully Specified Name. Refer to the *AMT v3 Editorial Rules* for further rules on modelling containers.

The primary packaging for the individual CTPP concepts (that is, composite packs) contained within each combination pack CTPP is represented to the specific container type. For example |*Actonel Combi D, 1 pack*| has two composite packs of |*Actonel Once-a-Week 35 mg tablet: film-coated, 4, blister pack*| and |*Calcium carbonate / colecalciferol (Sanofi-Aventis) granules: effervescent, 24 sachets*|. These composite pack concepts have a container type of |*blister pack*| and |*sachet*| respectively.

Refer to Section 2.3.3 for more information on combination and composite packs.

2.3.6.6 HAS SUBPACK

30454011000036104 |*Has subpack*| is an AMT-specific relationship type used to indicate the subpack MPP and CTPP concepts belonging to certain MPP and CTPP concepts. The MPP or CTPP packs containing subpacks is the source of the relationship, and the subpack CTPP or MPP is the destination of the relationship. This is an optional relationship for MPP and CTPP concepts.

For more details on packs containing subpacks as well as subpacks refer to Section 2.3.3.2.

2.3.6.7 HAS COMPONENT PACK

700000061000036106 |*Has component pack*| is an AMT-specific relationship type similar to HAS SUBPACK. HAS COMPONENT PACK is used to indicate where a destination MPP or CTPP concept is a component pack of an MPP or CTPP combination pack (respectively). This is an optional relationship for MPP and CTPP concepts.

For more details on combination packs refer to Section 2.3.3.

2.3.6.8 HAS INTENDED ACTIVE INGREDIENT

700000081000036101 |*Has intended active ingredient*| is an AMT relationship used to indicate the ingredients of an MP or MPUU concept that are intended to have a therapeutic effect. AMT does not model excipient ingredients of products.

Every MP concept will be the source of at least one relationship of this type, and the destination concept is a *Substance* concept that represents the ingredient. MPUU concepts have one HAS INTENDED ACTIVE INGREDIENT for each of its parent MP's HAS INTENDED ACTIVE INGREDIENT relationships with a matching destination *Substance* concept.

The *Substance* concept that is the target of the HAS INTENDED ACTIVE INGREDIENT relationship is the base of the contained active ingredient concept or the precise ingredient (with salt), where this is therapeutically necessary or clinically significant.

Within the AMT a "base" is defined as the active moiety of the ingredient name (that is, the segment of the molecule which has an intended therapeutic effect on the body). A "primary modified base" is defined as an additional segment which is combined with the base (but does not have an intended therapeutic effect on the body). A "secondary modified base" is a base which has been further modified in some way (but this modification does not have an intended therapeutic effect on the body). This modification frequently indicates the hydration status of the ingredient or another salt. Refer to the *AMT v3 Editorial Rules* (NEHTA, 2014) for a fuller definition of the MP concept.

Note that in AMT inert ingredients have been added to medicines using the HAS INTENDED ACTIVE INGREDIENT relationship type. For example, *[inert substance]*.

2.3.6.9 HAS AUSTRALIAN BoSS

30364011000036101 *[Has Australian BoSS]* is an AMT-specific relationship type. It is used to represent the Australian BoSS for each HAS INTENDED ACTIVE INGREDIENT from an MPUU concept to a *Substance* concept. The pairing of HAS AUSTRALIAN BoSS and HAS INTENDED ACTIVE INGREDIENT relationships for each MPUU is represented using relationship groups – refer to Section 3.1.4.1.

The HAS AUSTRALIAN BoSS relationship is used as part of the representation of the strength of the ingredient indicated by the paired HAS INTENDED ACTIVE INGREDIENT relationship. The other facet to the strength of the ingredient is a member of the *Strength reference set* that exists for each HAS AUSTRALIAN BoSS relationship and provides the quantity of the *Substance* concept targeted by the HAS AUSTRALIAN BoSS relationship. See Section 2.3.5.1 for more detail.

2.3.6.10 HAS MANUFACTURED DOSE FORM

30523011000036108 *[Has manufactured dose form]* is an AMT relationship type used to indicate the manufactured dose form of an MPUU. Every MPUU concept is a source of exactly one relationship of this type, with the destination being a *Form* concept which indicates the MPUU's manufactured dose form.

Every TPUU inherits the same form from its parent MPUU, but may further refine this inherited form by stating a HAS MANUFACTURED DOSE FORM relationship to a more specific Form. When this occurs, the TPUU *Form* is always a subtype of the MPUU *Form*. Figure 27 on p.47 illustrates an example of this.

2.3.6.11 HAS UNIT OF USE

30548011000036101 *[Has unit of use]* is an AMT relationship type that indicates the *Unit of use* concept that represents the *Unit of use* for an MPUU.

Each MPUU concept has exactly one active relationship of this type, where the MPUU concept is the source and the *Unit of use* concept is the destination of the relationship. Each TPUU concept inherits the *Unit of use* from its parent MPUU.

2.3.6.12 HAS MPUU

30348011000036104 |*Has MPUU*| is an AMT relationship type used to indicate the MPUU concepts contained within an MPP concept. Each MPP concept is the source of one or more HAS MPUU relationships, where the destinations of the relationships represent the MPUU concepts contained within the MPP. Figure 29 on p.56 provides an example of a HAS MPUU relationship.

2.3.6.13 HAS NUMERATOR UNITS

700000091000036104 |*Has numerator units*| is an AMT-specific relationship type used to indicate the numerator *Unit of measure* concept for a *Composite unit of measure* concept.

For example, given the *Composite unit of measure* |mg/mL|, this concept will be the source of a HAS NUMERATOR UNITS relationship to a destination |mg| concept.

A *Unit of measure* concept will only be the source of a HAS NUMERATOR UNITS relationship if it is a *Composite unit of measure*. If a *Unit of measure* concept is the source of a HAS NUMERATOR UNITS relationship, it will also be the source of a HAS DENOMINATOR UNITS relationship. See also Section 2.3.6.14.

See Section 2.3.4.3 for more details on composite units of measure.

2.3.6.14 HAS DENOMINATOR UNITS

700000071000036103 |*Has denominator units*| is an AMT-specific relationship type with similar purpose to HAS NUMERATOR UNITS. It is used to indicate the denominator *Unit of measure* concept for a *Composite unit of measure* concept.

For example, given the *Composite unit of measure* |mg/mL|, this concept will be the source of a HAS DENOMINATOR UNITS relationship to a destination |mL| concept.

A *Unit of measure* concept will only be the source of a HAS DENOMINATOR UNITS relationship if it is a *Composite unit of measure*. If a *Unit of measure* concept is the source of a HAS DENOMINATOR UNITS relationship, it will also be the source of a HAS NUMERATOR UNITS relationship. See also Section 2.3.6.13.

See Section 2.3.4.3 for more details on composite units of measure.

2.3.7 Relationship range and domain

The following sections summarise the applicable domains and ranges for AMT relationship types. This has been expressed using the same format used in Section 5.1 of the *SNOMED TIG* (IHTSDO, 2014).

2.3.7.1 Relationship types by domain

The following table shows the type of source relationships (other than IS A relationships) allowable for concepts broken down by the hierarchies in AMT. Concepts may belong to multiple hierarchies in AMT, and in this case the union of the relationship types allowable for each hierarchy are allowed.

The allowable relationships described here represent both the Stated Form and the Distribution Normal Form (DNF) of AMT. The AMT is currently published only in DNF, which includes inherited and inferred relationships for concepts. Refer to Section 3.5.3 for further information on Distribution Normal Form.

Note: See Section 2.3.6 for descriptions of each of these types of relationships.

Table 12: Allowable source relationships

AMT hierarchy	Inferred relationships (Distribution Normal Form) – Current AMT releases	Stated relationships
<i>Composite unit of measure</i>	HAS NUMERATOR UNITS HAS DENOMINATOR UNITS	HAS NUMERATOR UNITS HAS DENOMINATOR UNITS
<i>Medicinal Product</i>	HAS INTENDED ACTIVE INGREDIENT	HAS INTENDED ACTIVE INGREDIENT
<i>Medicinal substance</i>	IS MODIFICATION OF	IS MODIFICATION OF
<i>Medicinal Product Unit of Use</i>	HAS INTENDED ACTIVE INGREDIENT HAS AUSTRALIAN BoSS HAS MANUFACTURED DOSE FORM HAS UNIT OF USE	HAS INTENDED ACTIVE INGREDIENT HAS AUSTRALIAN BoSS HAS MANUFACTURED DOSE FORM HAS UNIT OF USE
<i>Medicinal Product Pack</i>	HAS MPUU HAS SUBPACK HAS COMPONENT PACK	HAS MPUU HAS SUBPACK HAS COMPONENT PACK
<i>Trade Product Unit of Use</i>	HAS INTENDED ACTIVE INGREDIENT HAS AUSTRALIAN BoSS HAS MANUFACTURED DOSE FORM HAS UNIT OF USE	HAS MANUFACTURED DOSE FORM
<i>Trade Product Pack</i>	HAS TP HAS TPUU HAS SUBPACK HAS COMPONENT PACK	HAS TP HAS TPUU
<i>Containerized Trade Product Pack</i>	HAS TP HAS TPUU HAS CONTAINER TYPE HAS SUBPACK HAS COMPONENT PACK	HAS CONTAINER TYPE HAS SUBPACK HAS COMPONENT PACK

2.3.7.2 Allowable ranges

The following table shows the possible range (values) for each relationship type, represented in the Stated Form of AMT. The values are AMT concepts.

Note: See Section 2.3.6 for descriptions of each of these types of relationships, and Sections 2.3.2 and 2.3.4 for descriptions of the concept classes cited in the range.

Table 13: Ranges of relationship types

Relationship Type	Range
HAS NUMERATOR UNITS	<i>Unit of measure</i>
HAS DENOMINATOR UNITS	<i>Unit of measure</i>
HAS INTENDED ACTIVE INGREDIENT	<i>Medicinal substance</i>
IS MODIFICATION OF	<i>Medicinal substance</i>
HAS AUSTRALIAN BoSS	<i>Medicinal substance</i>
HAS UNIT OF USE	<i>Unit of Use</i>
HAS MANUFACTURED DOSE FORM	<i>Form</i>
HAS MPUU	<i>Medicinal Product Unit of Use</i>
HAS SUBPACK	<i>Medicinal Product Pack</i> <i>Containerised Trade Product Pack</i>
HAS COMPONENT PACK	<i>Medicinal Product Pack</i> <i>Containerised Trade Product Pack</i>
HAS CONTAINER TYPE	<i>Container type</i>
HAS TP	<i>Trade Product</i>
HAS TPUU	<i>Trade Product Unit of Use</i>

3 Distribution form of AMT

AMT is distributed as an RF2 release containing the following Concrete domain reference sets which also form part of the semantics of the AMT content:

- *Strength reference set*
- *Unit of use size reference set*
- *Unit of use quantity reference set*
- *Subpack quantity reference set*

The following sections provide an overview of AMT's distribution form and format, with references to the *SNOMED TIG* (IHTSDO, 2014) where appropriate.

3.1 Overview of Release Format 2 (RF2)

The IHTSDO currently has two release formats for SNOMED CT: Release Format 1 (RF1) and Release Format 2 (RF2). RF1 is the original format SNOMED CT was released in, and has been superseded by the newer RF2 in recent years.

AMT relies on features supported by RF2 but not RF1, therefore AMT is distributed in RF2 only.

For the full definition of RF2 refer to Section 5.3 "Release Format 2" of the *SNOMED TIG* (IHTSDO, 2014), however this section provides an overview of key elements of RF2.

3.1.1 Elements of an RF2 release

An RF2 release consists of four core files as depicted in Figure 30:

- Concepts
- Descriptions
- Relationships
- Identifiers¹⁶

Each of these files is a tab delimited UTF-8 text file with DOS line termination (<carriage return> followed by <line feed>), and together these files provide a relational distribution form for SNOMED CT components.

Each core component (Concepts, Descriptions, Relationships, and Identifiers) are distributed in their own file each with a different format. The columns for each file format are covered in more detail in the following sections, however it is important to note from Figure 30 below:

- Concept identifiers are foreign keys in the relationships file representing the source and destination of relationships.
- Concepts have two or more descriptions in the Descriptions file. The rows in this file use the concept's identifier as a foreign key.

¹⁶ See Section 5.4.3 "ContentType element" of the *SNOMED CT Technical Implementation Guide* (IHTSDO, 2014) for details of these files.

- All four files have a foreign key to a module identifier, which is a concept identifier referencing the module to which the component belongs – refer to Section 3.7.

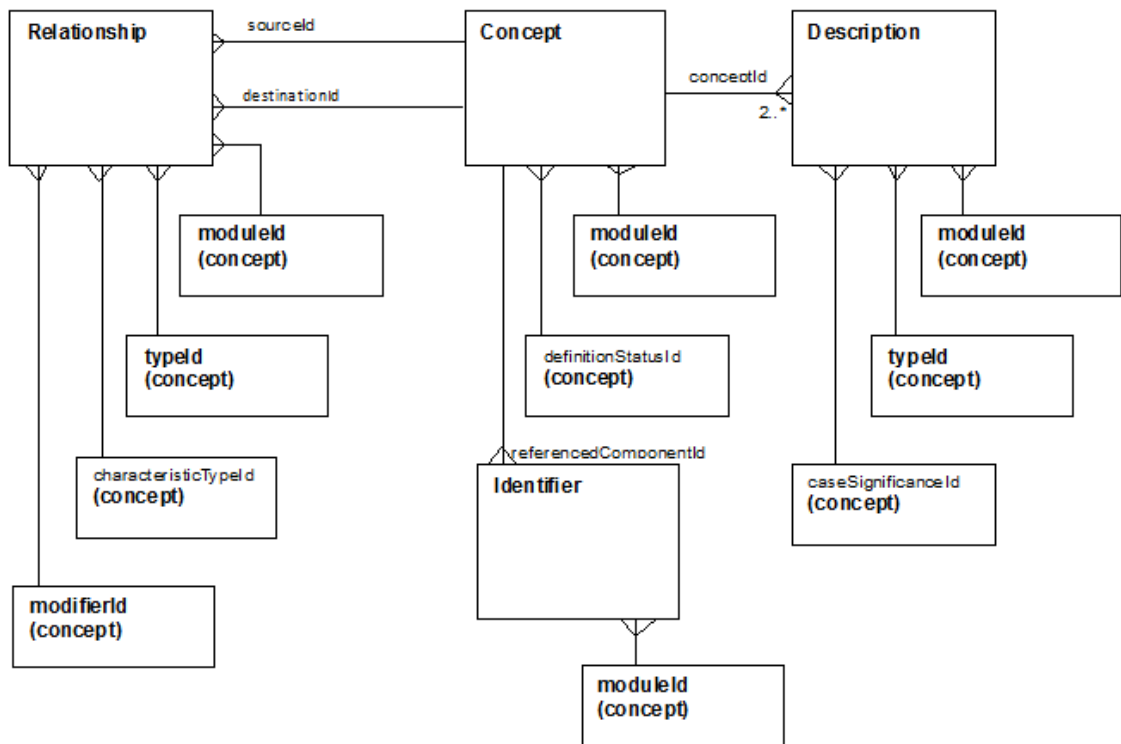


Figure 30: Core RF2 files

3.1.2 Concepts

Concepts are at the core of RF2 and AMT – refer to Section 2.2.1 for more detail on their meaning and purpose.

RF2 provides a file containing concepts which has the following format.

Table 14: RF2 concept file format

Field	Data type	Immutable	Purpose
id	SCTID	Y	Uniquely identifies the concept.
effectiveTime	Time	N	Specifies the inclusive date at which the component version's state became the then current valid state of the component. See Section 3.10 for more details.
active	Boolean	N	Specifies whether the concept's state was active or inactive from the nominal release date specified by the effectiveTime. See Section 3.10 for more details.
moduleId	SCTID	N	Identifies the concept version's module. Set to a descendant of Module within the metadata hierarchy. See Section 3.7 for more details.

definitionStatusId	SCTID	N	Specifies if the concept version is primitive or fully defined. Set to a child of <i> Definition status </i> in the metadata hierarchy. Only necessary if using the description logic definitions of the AMT content: refer to Section 2.2.5.
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Refer to Section 5.4.3.1 “Concept file” of the *SNOMED TIG* (IHTSDO, 2014) for more details.

3.1.3 Descriptions

Each concept must have one, and only one, active

- Fully Specified Name (FSN); and
- Preferred Term (PT).

Additionally other Synonyms may be provided for a concept.

In RF2, and hence AMT, there are currently only two types of descriptions – FSNs and Synonyms (refer to typeId below). PTs are Synonym type descriptions which have been identified by a Language reference set to be preferred in a particular context. To find AMT Preferred Terms it is necessary to use and combine both the Descriptions file and the Language reference set file. Refer to Section 3.1.7 for more detail on this mechanism.

Table 15: RF2 description file format

Field	Data type	Immutable	Purpose
id	SCTID	Y	Uniquely identifies the description.
effectiveTime	Time	N	Specifies the inclusive date at which the component version’s state became the then current valid state of the component. See Section 3.10 for more details.
active	Boolean	N	Specifies whether the description’s state was active or inactive from the nominal release date specified by the effectiveTime. See Section 3.10 for more details.
moduleId	SCTID	N	Identifies the description version’s module. Set to a child of <i> Module </i> within the metadata hierarchy. See Section 3.7 for more details.
conceptId	SCTID	Y	Identifies the concept to which this description belongs. Set to an Identifier of a concept in the <i> SNOMED CT concept </i> hierarchy within the Concept file. Note that versions of descriptions and concepts do not belong to each other. Which version of any given description is combined with which version of its owning concept depends on the point in time at which they are accessed.
languageCode	String	Y	Specifies the language of the description text using the two character ISO-639-1 code. Note that this specifies a language level only, not a dialect or country code.

Field	Data type	Immutable	Purpose
			In AMT this is always “en” for English. The <i>Australian dialect reference set</i> provides the Australian Preferred Terms, essentially declaring them “en-AU”.
typeId	SCTID	Y	Identifies whether the description is an FSN, Synonym or other description type. This field is set to a child of <i> Description type </i> in the metadata hierarchy.
term	String	N	The description version’s text value, represented in UTF-8 encoding.
caseSignificanceId	SCTID	N	Identifies the concept enumeration value that represents the case significance of this description version. For example, the term may be completely case sensitive, case insensitive, or initial letter case sensitive. This field will be set to a child of <i> Case significance </i> within the metadata hierarchy.

The *Description format reference set* (Section 3.1.12.2) specifies the lengths and formats of descriptions in the release. AMT uses only “plain text” descriptions with a maximum length of 2048 characters – note this is longer than SNOMED CT’s default lengths for standard Fully Specified Names and Synonyms. See Section 7.8 for more details.

Refer to Section 5.4.3.2 “Descriptions file” of the *SNOMED TIG* (IHTSDO, 2014) for more details.

3.1.4 Relationships

The relationships file in RF2 contains SNOMED CT relationships which provide a unidirectional connection between two concepts and a relationship type. The combination of this triplet provides a logical statement about the concept that is the “source” of the relationship. See Section 2.2.3 for more detail on the purpose and meaning of relationships.

Table 16: RF2 relationships file format

Field	Data type	Immutable	Purpose
id	SCTID	Y	Uniquely identifies the relationship.
effectiveTime	Time	N	Specifies the inclusive date at which the component version’s state became the then current valid state of the component. See Section 3.10 for more details.
active	Boolean	N	Specifies whether the relationship’s state was active or inactive from the nominal release date specified by the effectiveTime field. See Section 3.10 for more details.
moduleId	SCTID	N	Identifies the relationship version’s module. Set to a child of <i> module </i> within the metadata hierarchy. See Section 3.7 for more details.

Field	Data type	Immutable	Purpose
sourceId	SCTID	Y	Identifies the source concept of the relationship version, that is, the concept the relationship version emanates from. Set to an Identifier of a concept in the <i>SNOMED CT concept</i> hierarchy within the "Concept" file.
destinationId	SCTID	Y	Identifies the concept that is the destination of the relationship version. Set to an Identifier of a concept in the <i>SNOMED CT concept</i> hierarchy within the "Concept" file.
relationshipGroup	Integer	Y	Groups together relationship versions that are part of a logically associated relationship group. All active Relationship records with the same relationshipGroup number and sourceId are grouped in this way. See Section 3.1.4.1 for details relevant to AMT.
typeId	SCTID	Y	A concept enumeration value from the metadata hierarchy that identifies the semantic type of the relationship version. For example <i>Is a</i> , or <i>associated morphology</i> . Section 2.3.6 contains the possible values for this field in AMT and their meaning.
characteristicTypeId	SCTID	Y	A concept enumeration value that identifies the characteristic type of the relationship version (that is, whether the relationship version is defining, qualifying, and so on). This field is set to a descendant of <i>characteristic type</i> within the metadata hierarchy.
modifierId	SCTID	Y	A concept enumeration value that identifies the type of Description Logic (DL) restriction (some, all, and so on.). Set to a child of <i>modifier</i> within the metadata hierarchy.

Refer to Section 5.4.3.3 "Relationships file" of the *SNOMED TIG* (IHSTDO, 2014) for more details.

3.1.4.1 Relationship groups

SNOMED CT uses "relationship groups" (referred to as "role groups") to group together relationships that are relative to each other and must be read as a collective.

This mechanism is used in AMT to group HAS INTENDED ACTIVE INGREDIENT and HAS AUSTRALIAN BoSS relationships for MPUU concepts, and is important for multi-ingredient MPUUs.

Consider the following example HAS INTENDED ACTIVE INGREDIENT and HAS AUSTRALIAN BoSS relationships for the MPUU concept |*paracetamol 500 mg + codeine phosphate 15 mg tablet*|:

Table 17: Example relationship groups

Relationship type	Destination	Relationship group
HAS INTENDED ACTIVE INGREDIENT	paracetamol	1234
HAS INTENDED ACTIVE INGREDIENT	codeine	9876

HAS AUSTRALIAN BoSS	paracetamol	1234
HAS AUSTRALIAN BoSS	codeine phosphate	9876

Without the Relationship Group column, it is impossible for a machine to determine which HAS AUSTRALIAN BoSS relationship relates to which HAS INTENDED ACTIVE INGREDIENT relationship.

Relationship group values are:

- Zero for ungrouped relationships; meaning all relationships with “0” as their relationship group are not grouped with any other relationship and are to be treated individually.
- Non-zero integers for grouped relationships. A relationship with a non-zero relationship group is grouped with other relationships with the same relationship group value and source conceptId.

Relationship group values in themselves are meaningless other than the grouping effect they have. That is there is no significance to a relationship group value of “1” as opposed to “2”.

Relationship group values are only meaningful within the context of relationships with the same source concept identifier.

3.1.5 Identifiers

The RF2 Identifiers file provides a mechanism to associate one or more co-referent identifiers with another RF2 component, such as a concept, description, or relationship.

AMT uses this mechanism to represent the original AMT v2 identifiers for AMT v2 components that have been replaced by their SNOMED CT International and SNOMED CT-AU counterparts. In these cases the identifiers represented in AMT concept, description and relationship files will reflect the SNOMED CT International and SNOMED CT-AU identifiers, and the AMT v2 identifiers will be present in the RF2 Identifiers file referencing the new component. This includes both SCTIDs and UUIDs previously published in AMT v2 for these components. This provides backward compatibility for systems that have implemented these AMT v2 identifiers.

The format of the Identifiers file is shown in the table below.

Table 18: RF2 identifiers file format

Field	Data type	Immutable	Purpose
identifierSchemeId	SCTID	Y	Identifier of the concept enumeration value from the metadata hierarchy that represents the scheme to which the Identifier value belongs. Set to a descendant of <i> Identifier scheme </i> within the metadata hierarchy. In AMT this is: <ul style="list-style-type: none"> • 900000000000002006 <i> SNOMED CT UUID </i> or • 9000000000000294009 <i> SNOMED CT integer ID </i>

Field	Data type	Immutable	Purpose
			depending upon whether the alternateIdentifier is an AMT v2 UUID or SCTID.
alternateIdentifier	String	Y	String representation of the alternateIdentifier in its native scheme. In AMT this is an AMT v2 UUID or SCTID.
effectiveTime	Time	N	Specifies the inclusive date at which the alternateIdentifier was associated with the SNOMED CT component. See Section 3.10 for more details.
active	Boolean	N	Specifies whether the association was active or inactive from the point in time specified by the effectiveTime. See Section 3.10 for more details.
moduleId	SCTID	N	Identifies the source module that this association was created in. Set to a child of Module within the metadata hierarchy. See Section 3.7 for more details.
referencedComponentId	SCTID	Y	Uniquely identifies the SNOMED CT component with which the alternateIdentifier is associated.

Refer to Section 5.4.3.3 “Identifiers file” of the *SNOMED TIG* (IHTSDO, 2014) for more details.

3.1.6 Simple reference sets

AMT is released with seven Simple reference sets, one for each of the “Notable concepts” – refer to Section 2.3.5.5 which explains the purpose of these specific reference sets.

These reference sets adhere to the Simple reference set pattern defined by the IHTSDO in the RF2 specification. Details of this pattern can be found in Section 5.6.2.3 “Simple Reference Set” of the *SNOMED TIG* (IHTSDO, 2014), however an overview of the data structure and expected values in AMT is provided below.

Table 19: RF2 simple reference set file format

Field	Data type	Purpose
id	UUID	A 128 bit unsigned integer, uniquely identifying the reference set member.
effectiveTime	Time	Specifies the inclusive date at which this change becomes effective. See Section 3.10 for more details.
active	Boolean	Specifies whether the member’s state was active or inactive from the nominal release date specified by the effectiveTime field. See Section 3.10 for more details.
moduleId	SCTID	Identifies the member version’s module. Set to a child of Module within the metadata hierarchy.

Field	Data type	Purpose
See Section 3.7 for more details.		
refSetId	SCTID	<p>Set to a child of <i>Simple type reference set</i> in the metadata hierarchy.</p> <p>In AMT this identifies which of the seven reference sets each row is a member of. The values used are:</p> <ul style="list-style-type: none"> 929360021000036102 <i>Trade product reference set</i> 929360031000036100 <i>Trade product unit of use reference set</i> 929360041000036105 <i>Trade product pack reference set</i> 929360051000036108 <i>Containerised trade product pack reference set</i> 929360061000036106 <i>Medicinal product reference set</i> 929360071000036103 <i>Medicinal product unit of use reference set</i> 929360081000036101 <i>Medicinal product pack reference set</i>
referencedComponentId	SCTID	<p>A reference to the SNOMED CT component being tagged with a value.</p> <p>In AMT this is the concept that this membership row is referring to and including in the reference set.</p>

3.1.7 Language reference sets

Language reference sets in RF2 are used to express local language preferences and dialectic differences across descriptions from a parent language; for example British English preferences versus United States English preferences.

RF2 also only provides two types of descriptions:

- Fully Specified Names – the true meaning of the concept.
- Synonyms – other names for a concept useful in a variety of settings.

Language reference sets in RF2 annotate RF2 Synonym descriptions with one of three mutually exclusive values to provide localisation:

Preferred	Indicates that Synonyms annotated with this value are the preferred way of describing the concept (also known as the “Preferred Term”). A Language reference set is required to have only one active “preferred” Synonym for each concept.
Acceptable	Indicates that Synonyms annotated with this value are not the preferred way of describing a concept, however are acceptable in the Language reference set’s context. A Language reference set may refer to zero or more of a concept’s descriptions with this value.
Not Acceptable	Indicates that the Synonym is not an acceptable way to describe the concept in this Language reference set’s context. Language reference sets do not reference Synonyms with this value, rather for brevity they simply do not reference Synonyms that are unacceptable.

Figure 31 on p.70 shows an example taken from SNOMED CT-AU, showing how the *Australian dialect reference set* expresses that:

- “Paracetamol” is preferred (green) and “Acetaminophen” is not acceptable (red).
- “Appendectomy” is preferred (green), while “Appendectomy” is acceptable (blue), as is “Excision of appendix”.

That is, the Language reference set can be joined with the content of the Descriptions file to determine the preferred and acceptable Synonyms for a concept or concepts.

Note that Fully Specified Names are not referenced – they are always acceptable and preference is irrelevant.

Note also that columns have been omitted from the example for brevity.

Note that the *Australian dialect reference set* has content that spans the following modules:

- AMT module
- SNOMED CT-AU module
- Australian common model component module

This allows the same language reference set to be used across SNOMED CT-AU and AMT to simplify implementation. Publications containing only the AMT will contain all *Australian dialect reference set* references on the AMT module and Australian common model component module, which is self-contained and does not require the SNOMED CT-AU module to use AMT.

The AMT *Australian dialect reference set* is also known as the *AMT Australian English language reference set*.

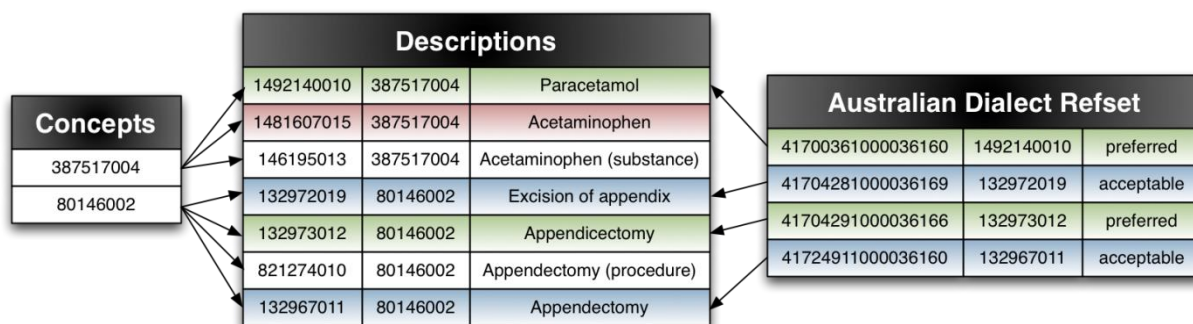


Figure 31: Example of a SNOMED CT-AU Language reference set

The data structure of a Language reference set is as follows.

Table 20: RF2 language reference set file format

Field	Data type	Purpose
id	UUID	A 128 bit unsigned integer, uniquely identifying the reference set member.

Field	Data type	Purpose
effectiveTime	Time	Specifies the inclusive date at which this change becomes effective. See Section 3.10 for more details.
active	Boolean	Specifies whether the member's state was active or inactive from the nominal release date specified by the effectiveTime field. See Section 3.10 for more details.
moduleId	SCTID	Identifies the member version's module. Set to a child of Module within the metadata hierarchy. See Section 3.7 for more details.
refSetId	SCTID	A descendant of Language type in the metadata hierarchy. In AMT this field has the value 32570271000036106 Australian dialect reference set .
referencedComponentId	SCTID	A reference to the Description included in the Language reference set.
acceptabilityId	SCTID	A descendant of Acceptability in the metadata hierarchy. In AMT this is one of: <ul style="list-style-type: none"> 900000000000548007 Preferred ; or 900000000000549004 Acceptable .

3.1.8 Association reference sets

RF2 also provides the Association reference set pattern – refer to Section 5.6.2.11 “Association Reference Set” of the *SNOMED TIG* (IHTSDO, 2014).

This reference set pattern is used in AMT to provide a Historical association reference set, 900000000000526001 |REPLACED BY association reference set| – refer to Section 7.4.2.3 “Historical Association Reference Set” of the *SNOMED TIG* (IHTSDO, 2014).

The *REPLACED BY association reference set* in AMT refers to retired concepts, and provides the identifier of the active, replacement concepts for each referenced concept.

The data structure is outlined below.

Table 21: RF2 association reference set file format

Field	Data type	Purpose
id	UUID	A 128 bit unsigned integer, uniquely identifying the reference set member.
effectiveTime	Time	Specifies the inclusive date at which this change becomes effective. See Section 3.10 for more details.
active	Boolean	Specifies whether the member's state was active or inactive from the nominal release date specified by the effectiveTime field. See Section 3.10 for more details.

Field	Data type	Purpose
moduleId	SCTID	Identifies the member version's module. Set to a child of <i>Module</i> within the metadata hierarchy. See Section 3.7 for more details.
refSetId	SCTID	A descendant of <i>Association type</i> in the metadata hierarchy. In AMT this will be the value 9000000000000526001 <i>REPLACED BY association reference set</i> .
referencedComponentId	SCTID	A reference to the source component of the association. In the context of the AMT <i>Historical association reference set</i> , this will be the identifier of the AMT concept which is now inactive and has been replaced.
targetComponentId	SCTID	A reference to the destination component of the association. In the context of the AMT <i>Historical association reference set</i> , this will be the identifier of the active AMT concept replacing the retired concept, as identified in the referencedComponentId.

3.1.9 Attribute value reference sets

RF2 also provides the Attribute value reference set pattern – refer to Section 5.6.2.5 “Attribute Value Reference Set” of the *SNOMED TIG* (IHTSDO, 2014). This reference set pattern is used in AMT to provide the 9000000000000483008 |*Concept inactivation indicator reference set*|.

The *Concept inactivation indicator reference set* in AMT is used to indicate the reason why a concept has been inactivated. For example, reasons for inactivating concepts may be because the concept is erroneous, duplicated or outdated due to a change in source data.

The data structure is outlined below.

Table 22: Attribute value reference set data structure

Field	Data type	Purpose
id	UUID	A 128 bit unsigned integer, uniquely identifying the reference set member.
effectiveTime	Time	Specifies the inclusive date at which this change becomes effective. See Section 3.10 for more details.
active	Boolean	Specifies whether the member's state was active or inactive from the nominal release date specified by the effectiveTime field. See Section 3.10 for more details.
moduleId	SCTID	Identifies the member version's module. Set to a child of <i>Module</i> within the metadata hierarchy. See Section 3.7 for more details.
refSetId	SCTID	A descendant of <i>Attribute value type</i> in the metadata hierarchy.

Field	Data type	Purpose
		In AMT this takes the value 900000000000489007 <i>Concept inactivation indicator reference set</i> .
referencedComponentId	SCTID	A reference to the component being tagged with a value. In the context of the <i>Concept inactivation indicator reference set</i> , this will be the identifier of the AMT concept which has been inactivated.
conceptInactivationValue Id	SCTID	The tagged value applied to the referencedComponentId. A descendant of <i>Concept inactivation value</i> in the metadata hierarchy. In AMT this is currently one of the following: <ul style="list-style-type: none"> 900000000000485001 <i>Erroneous</i> ; or 900000000000483008 <i>Outdated</i> .

3.1.10 Simple map reference sets

RF2 provides the Simple map reference set pattern – refer to Section 5.6.2.6 “Simple Map Reference Set” of the *SNOMED TIG* (IHTSDO, 2014). This reference set pattern is used in AMT to provide the 11000168105 |*ARTG Id reference set*|.

The *ARTG Id reference set* is used to indicate an optional mapping between a CTPP concept and one or more ARTG Id (as specified by the TGA).

The data structure is outlined below.

Table 23: Simple map reference set pattern data structure

Field	Data type	Purpose
id	UUID	A 128 bit unsigned integer, uniquely identifying the reference set member.
effectiveTime	Time	Specifies the inclusive date at which this change becomes effective. See Section 3.10 for more details.
active	Boolean	Specifies whether the member’s state was active or inactive from the nominal release date specified by the effectiveTime field. See Section 3.10 for more details.
moduleId	SCTID	Identifies the member version’s module. Set to a child of <i>Module</i> within the metadata hierarchy. See Section 3.7 for more details.
refSetId	SCTID	A descendant of <i>Simple map</i> in the metadata hierarchy. In AMT this takes the value 11000168105 <i>ARTG Id reference set</i> .
referencedComponentId	SCTID	The identifier of the concept being mapped. In the context of the <i>ARTG Id reference set</i> , this is the CTPP concept identifier being mapped.
schemeValue	String	The equivalent code in the other terminology, classification or code system.

Field	Data type	Purpose
		In the <i>ARTG Id reference set</i> , this is the ARTG Id that is mapped to the CTPP concept, as identified in the referencedComponentId.

3.1.11 Attribute value map reference sets

This reference set pattern is an extension of the RF2 specifications. It extends a simple map reference set by an additional field of *mapType*, which specifies whether a mapping between a concept and its mapped target is an “equivalent”, “specialise” or “generalise” map.

A specialise map means the target mapped concept is more specialised than (or is a subtype of) the source concept being mapped (referencedComponentId). A generalise map means the target mapped concept is more generalised than (or is a supertype of) the source concept being mapped (referencedComponentId).

It is used in AMT to provide the 281000036105 |*Substance to SNOMED CT-AU mapping reference set*|.

The *Substance to SNOMED CT-AU mapping reference set* in AMT is used to correlate AMT substance concepts that are either equivalent to or more specialised than SNOMED CT substance concepts.

The data structure is outlined below.

Table 24: Attribute value map reference sets data structure

Field	Data type	Purpose
id	UUID	A 128 bit unsigned integer, uniquely identifying the reference set member.
effectiveTime	Time	Specifies the inclusive date at which this change becomes effective. See Section 3.10 for more details.
active	Boolean	Specifies whether the member’s state was active or inactive from the nominal release date specified by the effectiveTime field. See Section 3.10 for more details.
moduleId	SCTID	Identifies the member version’s module. Set to a child of <i>Module</i> within the metadata hierarchy. See Section 3.7 for more details.
refSetId	SCTID	A descendant of <i>Attribute value map type</i> in the metadata hierarchy. In AMT this takes the value 281000036105 <i>Substance to SNOMED CT-AU mapping reference set</i> .
referencedComponentId	SCTID	The identifier of the concept being mapped. In the context of the <i>Substance to SNOMED CT-AU mapping reference set</i> , this will be the AMT substance concept being mapped.

Field	Data type	Purpose
mapType	SCTID	The map type value applied to the targetSnomedCtSubstance when compared to the referencedComponentId. It is a descendant of <i> Map type </i> in the metadata hierarchy. In AMT this is currently one of the following: <ul style="list-style-type: none"> 291000036107 <i> Equivalent </i>; or 301000036106 <i> Generalise </i>.
targetSnomedCtSubstance	SCTID	The identifier of the target concept being mapped to. In the context of the <i>Substance to SNOMED CT-AU mapping reference set</i> , this will be the SNOMED CT-AU substance concept being mapped to.

3.1.12 Metadata reference sets

AMT as an RF2 release also contains a number of metadata reference sets described in the following sections. These reference sets provide metadata about the release format and contained content structure.

3.1.12.1 Module dependency reference set

The *Module dependency reference set* is used to describe:

- the modules included in the release files; and
- the dependencies between the modules in the release files.

This type of reference set is described in Section 7.4.2.4, and specified in Section 5.6.2.12 of the *SNOMED TIG* (IHTSDO, 2014). The following passage is of particular relevance here:

The rows in this Reference Set that originate in a given module (identified by moduleId) indicate a dependency on the module identified by the referencedComponentId. The two string values each contain dates that indicate the version of source module and the required version of the module on which it depends.¹⁷

The *Module dependency reference set* from the AMT data has been provided in the table below as an example. The identifiers in this table have been replaced by Preferred Terms for readability, and some columns have been removed for brevity.

Table 25: Example of AMT's Module dependency reference set

Module name	Referenced component name	Source effective time	Target effective time
Australian Medicines Terminology module	SNOMED CT Model Component	20151130	20150731
Australian common model component extension	SNOMED CT Model Component	20151130	20150731

¹⁷ Section 7.4.2.4, *SNOMED CT Technical Implementation Guide* (IHTSDO, 2014).

Australian Medicines Terminology module	Australian common model component extension	20151130	20151130
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The data columns used in the *Module dependency reference set* are as follows.

Table 26: RF2 module dependency reference set file format

Field	Data type	Purpose
id	UUID	A 128 bit unsigned integer, uniquely identifying the reference set member.
effectiveTime	Time	Specifies the inclusive date at which this change becomes effective. See Section 3.10 for more details.
active	Boolean	Specifies whether the member's state was active or inactive from the nominal release date specified by the effectiveTime field. See Section 3.10 for more details.
moduleId	SCTID	Identifies the member version's module. Set to a child of Module within the metadata hierarchy. See Section 3.7 for more details.
refSetId	SCTID	A reference to the Module dependency concept in the metadata hierarchy.
referencedComponentId	SCTID	A reference to the module that this module is dependent on, a descendant of Module in the metadata hierarchy.
sourceEffectiveTime	String	The effective time of the source module. This allows a specific module version to be selected as having a dependency. The effectiveTime must match exactly.
targetEffectiveTime	String	The effective time of the target module. This allows a specific module version to be selected as being the subject of a dependency. The effectiveTime must match exactly.

For more details on modules refer to Section 3.7.

3.1.12.2 Description format reference set

The Description format reference set is a reference set that provides format and maximum length information for description types used in a release.

AMT contains a Description format reference set that contains the following information:

Table 27: Example of AMT's Description format reference set

Description type	Format	Maximum length
Fully Specified Name	Plain text	2048 bytes
Synonym	Plain text	2048 bytes

If implementation cannot be achieved, please contact the NCTIS.¹⁸ Refer to Section 7.8 for more details.

Section 5.6.2.13 “Description Format Reference Set” of the *SNOMED TIG* (IHTSDO, 2014) specifies Description format reference sets. The columns used in the reference set are provided below.

Table 28: RF2 description format reference set file format

Field	Data type	Purpose
id	UUID	A 128 bit unsigned integer, uniquely identifying the reference set member.
effectiveTime	Time	Specifies the inclusive date at which this change becomes effective. See Section 3.10 for more details.
active	Boolean	Specifies whether the member’s state was active or inactive from the nominal release date specified by the effectiveTime field. See Section 3.10 for more details.
moduleId	SCTID	Identifies the member version’s module. Set to a child of <i>Module</i> within the metadata hierarchy. See Section 3.7 for more details.
refSetId	SCTID	Set to the <i>Description format</i> reference set concept in the metadata hierarchy.
referencedComponentId	SCTID	A reference to a child of <i>Description type</i> in the metadata hierarchy.
descriptionFormat	SCTID	A reference to a child of <i>Description format</i> reference set attribute concept in the metadata hierarchy.
descriptionLength	Integer	The maximum length in bytes for descriptions of this description type.

3.1.12.3 Reference set descriptor

In RF2 the Reference set descriptor is a reference set that holds metadata used to define the following attributes of reference sets included in a release:

- the order of appearance of additional attributes (other than those mandatory for a reference set);
- the name and purpose of the additional attributes; and
- the data types for the additional attributes.

The Reference set descriptor is specified in Section 5.6.2.2 “Reference Set Descriptor” of the *SNOMED TIG* (IHTSDO, 2014).

AMT provides a *Reference set descriptor reference set*; its columns are described in the table below. An example from the reference set descriptor from AMT is included in Appendix B.

¹⁸ See Section 1.6.

Table 29: RF2 reference set descriptor file format

Field	Data type	Purpose
id	UUID	A 128 bit unsigned integer, uniquely identifying the reference set member.
effectiveTime	Time	Specifies the inclusive date at which this change becomes effective. See Section 3.10 for more details.
active	Boolean	Specifies whether the member's state was active or inactive from the nominal release date specified by the effectiveTime field. See Section 3.10 for more details.
moduleId	SCTID	Identifies the member version's module. Set to a child of Module within the metadata hierarchy. See Section 3.7 for more details.
refSetId	SCTID	Indicates that this row is part of a "reference set descriptor". Set to the 900000000000456007 Reference set descriptor reference set (foundation metadata concept) .
referencedComponentId	SCTID	Identifies the reference set (or type of reference set) that is specified by this descriptor. Set to a descendant of 900000000000455006 Reference set (foundation metadata concept) in the metadata hierarchy.
attributeDescription	SCTID	Specifies the name of an attribute that is used in the reference set to which this descriptor applies. Set to a descendant of 900000000000457003 Reference set attribute (foundation metadata concept) in the metadata hierarchy, that describes the additional attribute extending the reference set.
attributeType	SCTID	Specifies the data type of this attribute in the reference set to which this descriptor applies. Set to a descendant of 900000000000459000 Attribute type (foundation metadata concept) in the metadata hierarchy, that describes the type of the additional attribute extending the reference set.
attributeOrder	Integer	Specifies the position of this attribute in the reference set to which this descriptor applies. A zero value identifies the referencedComponentId within the reference set. Other values specify an additional attributes by its position relative to the referencedComponentId. Set to an unsigned integer, providing an ordering for the additional attributes extending the reference set.

3.2 Concrete domains and data type properties

3.2.1 What are concrete domains?

Concrete domains and data type properties are a way of including concrete data values as defining attributes of concepts. The name "concrete domains" stems from research in the late 1970s on mathematical descriptions of the semantics of programming languages in an effort to distinguish data from semantic domains.

The term “concrete domains” is commonly used when describing these capabilities of description logics.

Put simply, while the relationships in SNOMED CT (for AMT specifically the relationships listed in Section 2.3.6) allow a concept to have an attribute with a concept value, data type properties provide attributes which have a concrete data value. That is an attribute value from a concrete domain such as the number “5” as opposed to a concept value such as the concept *[paracetamol]*.

The domains available are really any continuum of concrete data values, such as numbers, time, dates, colours, strings and so on. OWL, for example permits the use of any XML Schema Datatype.

AMT only uses the concrete domains of real numbers and integers. These are used to represent the defining numeric attributes of AMT concepts, specifically:

- Strength – for example, the concentration of an ingredient;
- Unit of use size – for example, the volume of a medicine in an ampoule;
- Unit of use quantity (in a pack) – for example, the number of tablets in a pack; and
- Subpack quantity – for example, the number of subpacks in a pack containing subpacks.

3.2.2 Concrete domains in SNOMED CT

SNOMED CT currently has no support for concrete domains, and only supports a very limited set of description logic features known as EL+.

A proposal has been under development since 2010, defining both the semantic implications and RF2 representation of the introduction of this description logic feature into SNOMED CT’s currently limited set. This proposal is in trial use, but is not yet finalised.

This proposal has been developed specifically in response to needs for increased expressivity to adequately represent the IHTSDO’s new Pharmacy Model, to be used to remodel SNOMED CT’s medicines content. The new IHTSDO Pharmacy Model uses concrete domains as specified to represent ingredient strengths in medicines.

While the current scope in SNOMED CT is limited to the Pharmacy Model, the proposal as specified is very general and may be applied in future in other SNOMED CT content domains.

The proposal is documented in the RF2 Concrete Domains Specification (IHTSDO, 2011). This document includes:

- the specification of the reference set pattern to be used (RF2 data structure);
- implication for description logic semantics;
- handling of units of measure;
- metadata additions; and
- changes to diagramming notation.

3.2.3 Concrete domains in AMT

AMT implements concrete domains as specified in the proposal *RF2 Concrete Domains Specification* (IHTSDO, 2011). This implementation provides:

- defining numeric attributes for AMT concepts modelled within the description logic definition of the concepts; and
- type safe machine-processable access to these numeric attributes without needing to use description logic.

The following AMT reference sets (which conform to the *Concrete Domains Specification*) provide these numeric attributes for AMT and are known as “Concrete domain reference sets”:

- *Strength reference set* (Section 2.3.5.1)
- *Unit of use size reference set* (Section 2.3.5.2)
- *Unit of use quantity reference set* (Section 2.3.5.3)
- *Subpack quantity reference set* (Section 2.3.5.4)

If only type safe access to these numeric attributes is required (without use of the full description logic definition) it is not necessary to read the entirety of the *RF2 Concrete Domains Specification* (IHTSDO, 2011). The information relevant to most implementations has been repeated in Section 3.2.4 below as a convenience. Note that this focuses mainly on structural form of the data. The meaning of the Concrete domain reference sets included in AMT are discussed in Sections 2.3.5.1 to 2.3.5.4.

For details of the description logic implications and semantics please refer to the *RF2 Concrete Domains Specification* (IHTSDO, 2011).

3.2.4 Structure

The table below shows the columns present in the Concrete domain reference sets provided with AMT.

Table 30: RF2 concrete domain reference set file format

Field	Data type	Purpose
Id	UUID	A 128 bit unsigned integer, uniquely identifying the reference set member.
effectiveTime	Time	Specifies the inclusive date at which this change becomes effective. See Section 3.10 for more details.
active	Boolean	Specifies whether the member’s state was active or inactive from the nominal release date specified by the effectiveTime field. See Section 3.10 for more details.
moduleId	SctId	Identifies the member version’s module. Set to a child of Module within the metadata hierarchy. See Section 3.7 for more details.
refSetId	SctId	Set to a child of Concrete domain type in the metadata hierarchy. In the context of AMT this is either:

Field	Data type	Purpose
		<ul style="list-style-type: none"> 700000111000036105 <i>Strength reference set</i> 700000131000036101 <i>Unit of use quantity reference set</i> 700000141000036106 <i>Unit of use size reference set</i> 700000121000036103 <i>Subpack quantity reference set</i>
referencedComponentId	SctId	The component with which the concrete value is to be associated. In the context of AMT this is always a relationship identifier. Refer to Sections 2.3.5.1 to 2.3.5.4 for details of the specific relationship types, sources and destinations used in each case.
unitId	SctId	A child of <i>Unit</i> (SctId 258666001). In AMT this is always a type of AMT ¹⁹ <i>Unit of measure</i> concept.
operatorId	SctId	A child of <i>Operator id value</i> in the metadata hierarchy. Currently in AMT this field will always hold the value 700000051000036108 <i>Equal to</i> . Other values may be introduced into AMT in future to support ranges if necessary (such as “greater than” and “less than”).
value	String	The concrete value to be associated with the referenced component. The precise data type presented in this string is dependent upon the particular subtype of the <i>Concrete domain type</i> concept, which will also be reflected in the specific reference set’s descriptor. For AMT this value is a double precision floating number for the <i>Strength reference set</i> , <i>Unit of use size reference set</i> , and <i>Unit of use quantity reference set</i> . For the <i>Subpack quantity reference set</i> this value will be an integer.

3.2.5 Units of measure

Units are represented as specified in Section 3.2.4 using the “unitId” field to reference *Unit of measure* concepts, for example “milligram”.

Where necessary for concentration and rate based strengths, composite units of measure are used, for example “mg/mL”.²⁰ Where a composite unit of measure is used, the value provided is always in terms of a denominator of one. For example “2 mg per 2 mL” is expressed in the *Strength reference set* as “1 mg / mL”. This allows much easier comparison of strength values.

There are exceptions whereby the value in the *Strength reference set* is represented in terms of a denominator that is not one. Section 2.3.5.1 describes this exception in more detail. Refer also to Appendix D.3 which illustrates a sample product.

There is also a special unit of measure called “each”. This unit means that the value provided in the Concrete domain reference set is simply a count or number of the items the reference set is referring to. For example this is used in the *Unit of use quantity reference set* where MPUUs included in an MPP have a physically countable dose form, such as tablet or capsule.

¹⁹ As distinct from being a child of the SNOMED CT |Unit of measure| concept.

²⁰ Note that composite units of measure are always used for the Strength reference set.

“Each” is also used in the *Unit of use size reference set* where MPUUs with a unit of use of “Continuous” have the UNIT OF USE SIZE attribute of “1 each”. This is to allow machine computation of the denormalised (human readable) strength using a combination of the *Strength reference set* and the *Unit of use size reference set*. Refer to Section 7.15 for more details.

These issues of *Unit of measure* are all discussed in Sections 2.3.4.3, 2.3.6.13 and 2.3.6.14.

3.2.6 Unit conversions

Currently the representation of quantities in the *RF2 Concrete Domains Specification* (IHTSDO, 2011) does not cater for unit conversions. In order to ensure that all strengths are machine comparable without unit conversion, the *Concrete Domains Specification* instructs that all quantities of a single concept use the same units. For example, to determine that “1 g of paracetamol” is the same as “1000 mg of paracetamol” without unit conversion requires that *|paracetamol|* is always referred to using the same unit of measure.

AMT implements this normalisation of units in the *Strength reference set*, whereby a single *Composite unit of measure* is chosen for all available strengths of similar MPUU concepts that share the same BoSS. Section 7.16.2 describes an example of unit conversion in AMT.

Note that this normalisation of units of measure does not affect descriptions. Product descriptions may represent the strength in the most useful form to humans that is equivalent to the machine representation in the *Strength reference set*.

Unit conversion is possible outside of SNOMED CT’s description logic (that is, outside a classifier), however unit conversion factors are not currently published in AMT or SNOMED CT data. SNOMED CT International is working towards publishing a map between SNOMED CT Units of Measure and UCUM units to resolve this issue.

3.3 Dose Based Prescribing and associated reference sets

This chapter provides guidance on the intent of the initial three dose based prescribing reference sets, a brief summary of their content, the rationale for the inclusion/exclusion criteria informing their development and the technical aspects of the reference set files. It does not detail the process of how these reference sets can be used to create a dose-based order. Further details on the content and inclusion/exclusion criteria used for the reference sets can be found in the *SNOMED CT-AU Development Approach for Reference Sets* (NEHTA, 2015).

The current reference sets are:

- *Dose based prescribing dose form reference set;*
- *Dose based prescribing dose frequency and interval reference set; and*
- *Dose based prescribing route of administration reference set.*

The objective of dose based prescribing references sets is to deliver terminology within the AMT and SNOMED CT-AU for the common data elements needed to support the non-product-based prescribing or medication ordering activity typically performed within acute care settings.

While all of the content for the current dose based prescribing reference sets are sourced from SNOMED CT-AU, the process of creating a dose based order

necessarily includes a *Medicine* element, of which values can be drawn from AMT concepts.

Additional terminology, reference sets, product relationships and specific implementation guidance (covering how to use AMT and SNOMED CT-AU to perform a dose-based order) is currently being developed to further extend the usability of the AMT within the acute care settings.

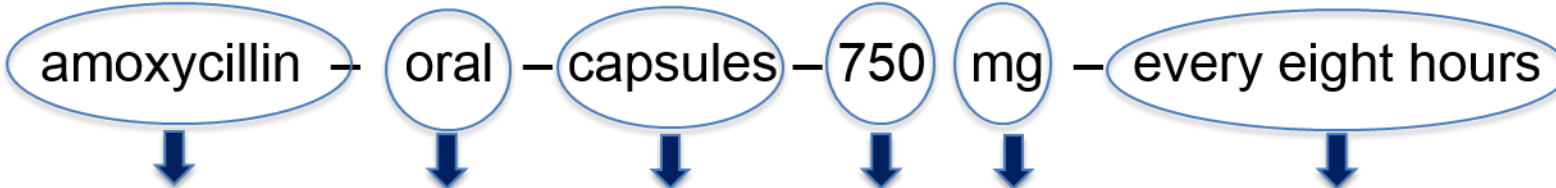
A regular dose-based order commonly includes the following data elements:

- *Medicine*
 - A therapeutic agent comprising an active ingredient or combination of active ingredients; or optionally a product brand name (trade product)
- *Route of Administration*
- *Dose Form*
- *Dose Quantity and Unit of Measure*
- *Dose Frequency*
- *Start Date and Stop Date*

Other optional elements include frequency qualifier, method/site of administration, start/stop times and clinical indication.

The *Medicine* element may optionally also include a dose form or a dose form and strength. A *Medicine* element can be populated with a trade product where generic prescribing may not be warranted, such as products with multiple ingredients or multiple components, or differing bioequivalence.

The following figure depicts an example of a regular dose-based order and its constituents that can be encoded with a combination of AMT and SNOMED CT-AU terminology concepts.



Dose order element	Medicine (or therapeutic agent)	Route of Administration	Dose Form	Dose Quantity	Dose Unit of Measure	Dose Frequency
AMT or SCT-AU encoding	AMT – Medicinal Product	SCT-AU ¹	SCT-AU	NA ²	SCT-AU	SCT-AU
Concept identifier	21415011000036100	26643006	385049006	–	258684004	307439001

1. SCT-AU = SNOMED CT Australian extension
2. NA = Not applicable

Figure 32: Regular dose based order example

The current reference sets provide standardised terminology concepts that can be used for the common data elements of *Dose Form*, *Dose Frequency* and *Route of Administration* within healthcare software systems that support dose-based ordering.

While these reference sets were developed with a focus on dose-based prescribing requirements, this does not preclude them being used for any prescribing (including pack-based prescribing) as there is likely to be a large area of overlap. It is necessary to analyse the suitability of a reference set's content against a system's information model prior to its adoption.

The concepts from the current reference sets are sourced from SNOMED CT-AU and hence are published within the combined SNOMED CT-AU and AMT release bundle. Direct relationships between these SNOMED CT-AU concepts and AMT products are not currently modelled.

3.3.1 Dose based prescribing dose form reference set

The intent of this reference set is to provide concepts that can be used for recording in a *Dose Form* element, which is commonly used in generating a medication order.

The concepts in this reference set are sourced from the SNOMED CT-AU |*Type of drug preparation*| sub-hierarchy. The dose form concepts included are typically general dose forms that are suitable for selection when creating a dose-based order. Examples of general forms are:

- |*tablet*|;
- |*suppository*|; and
- |*injection*|.

Some specific forms are included if they represent a clinically relevant difference to their unmodified forms and the specific forms are expected to be selected by a prescriber when creating a dose-based order. Examples of specific forms include:

- |*enteric tablet*|;
- |*modified release injection*|; and
- |*bladder irrigation*|.

Some SNOMED CT dose forms are excluded from this reference set because they are more important for product differentiation during activities such as dispensing and administration or they are not frequently used in a dose-based order.

While the AMT contains dose form concepts, these have not been used for this reference set because SNOMED CT-AU provides a broader range of suitable concepts. The AMT dose forms will be replaced by equivalent SNOMED CT-AU dose forms as part of the future full integration of both terminologies.

This reference set is a Simple reference set. The "referencedComponentId" field within this reference set corresponds to concept identifiers (SCTId) of SNOMED CT-AU dose form concepts. Refer to Section 3.1.6 for further details of this RF2 reference set pattern.

3.3.2 Dose based prescribing dose frequency and interval reference set

The intent of this reference set is to provide concepts that can be used for recording in a *Dose Frequency* element, which is commonly used in generating a medication order.

The concepts in this reference set are sourced from the SNOMED CT-AU *|Qualifier value|* sub-hierarchy. The concepts included are typically regular frequency intervals and frequencies per unit time that are suitable for selection when creating a dose-based order. Examples of regular frequency intervals are

- *|Every hour|*;
- *|Every day|*; and
- *|Every 12 hours|*.

Examples of frequencies per unit time include

- *|Once a day|*;
- *|Twice a day|*; and
- *|Three times a week|*.

Some SNOMED CT frequencies are excluded from this reference set because they are not regularly used, may be interpreted in more than one way or are not relevant in a dose-based order.

The frequency concepts included exist only in SNOMED CT-AU as there are no equivalent concepts in the AMT.

This reference set is a Simple reference set. The "referencedComponentId" field within this reference set corresponds to concept identifiers (SCTId) of SNOMED CT-AU dose frequency concepts. Refer to Section 3.1.6 for further details of this RF2 reference set pattern.

3.3.3 Dose based prescribing route of administration reference set

The intent of this reference set is to provide concepts that can be used for recording in a *Route of Administration* element, which is commonly used in generating a medication order.

The concepts in this reference set are sourced from the SNOMED CT-AU *|Route of administration value|* sub-hierarchy. The concepts included are routes of administration that are suitable for selection when creating a dose-based order. Examples are

- *|Epidural|*;
- *|Intravenous|*; and
- *|Left ear|*.

Some SNOMED CT routes of administration are excluded from this reference set because they are not regularly used, contains a method of administration, contains multiple routes or are not relevant in a dose-based order.

These routes of administration concepts exist only in SNOMED CT-AU and are independent of the AMT product concepts (and any associated TGA approved

licenced route) as no equivalent concepts or route of administration attribute currently exist in the AMT.

This reference set is a Simple reference set. The "referencedComponentId" field within this reference set corresponds to concept identifiers (SCTId) of SNOMED CT-AU route of administration concepts. Refer to Section 3.1.6 for further details of this RF2 reference set pattern.

3.4 RF2 distribution types

RF2's data structure and history tracking mechanism (refer to Section 3.10) enables three different types of release, as tabulated below.

Table 31: RF2 release types

Release Type	Description
Full	The files representing each type of component contain every version of every component ever released.
Snapshot	The files representing each type of component contain one version of every component released up to the time of the snapshot. The version of each component contained in a snapshot is the most recent version of that component at the time of the snapshot.
Delta	The files representing each type of component contain only component versions created since the previous release. Each component version in a delta release represents either a new component or a change to an existing component.

To demonstrate, Figure 40 below shows a sample of Full content expressed as Snapshot and Delta as well.

Concepts - Full			Concepts - Snapshot			Concepts - Delta		
id	active	effectiveTime	id	active	effectiveTime	id	active	effectiveTime
138875005	1	20070131	138875005	1	20100131	138875005	1	20100131
138875005	0	20090731	404684003	0	20100131	404684003	0	20100131
138875005	1	20100131	162744006	1	20070731	3415004	1	20100131
404684003	1	20030131	3415004	1	20100131			
404684003	1	20090731						
404684003	0	20100131						
162744006	1	20020131						
162744006	1	20070731						
3415004	1	20100131						

Figure 33: Example of Full, Snapshot and Delta formats

RF1 SNOMED CT Releases and AMT v2 were always released in Snapshot format only. AMT production releases are in RF2 format, and are published in Full, Snapshot and Delta release types.

These forms are useful in different contexts. For example the Snapshot form is easiest to query, however, data updates typically require loading a new Snapshot release. Queries written against the Full form are more complex, however data

updates are simplified to appending the next Delta release to the existing Full data. For more details of these considerations refer to Section 4.3.

For more information on the RF2 release types, refer to the *SNOMED TIG* (IHTSDO, 2014).

3.5 Distribution Normal and Stated Forms

The AMT v2 and v3 Beta files were published in “Stated Form”; however v3 production releases are published in “Distribution Normal Form” (DNF).

The DNF will allow easier access to defining relationships and concept attributes (where this is required in an implementation) without users manually navigating to different concept levels. The DNF specifically impacts on the Relationships file and Concrete domain reference sets.

It is therefore important to understand the following sections as any designs or prototype implementations derived from the “Stated Form” files may be impacted.

Please note that the Stated Form is not published in AMT at the time of writing.

Specific impacts for analysis are listed in Section 3.5.4, however generally the AMT v3 Beta “Stated Form” did not contain all the inferable relationships for each concept. Omitted relationships included both IS A and other relationship types.

SNOMED CT is always distributed in what is known as Distribution Normal Form, which is the definitive release. Additionally SNOMED CT is distributed by the IHTSDO in the Stated Form which was used to create the Distribution Normal Form, however the Stated Form is not the definitive release form.

The IHTSDO mandates that publication of SNOMED CT and extensions is in Distribution Normal Form, and distribution in other Inferred Forms or Stated Form is optional.

The following sections explain the differences between Stated Form, Inferred Forms and Distribution Normal Forms.

3.5.1 Stated and Inferred Forms

SNOMED CT and its extension terminologies (such as AMT) have an ontological foundation. This formalised representation of knowledge allows reasoning, and machine processes can be used to infer facts from a collection of stated facts, represented by relationships between concepts in SNOMED CT terminologies.

The collection of relationships representing the statements about each concept in the terminology can take a number of different forms, which in essence break down into two categories:

- | | |
|-----------------------|--|
| Stated Form | This is the set of statements authored by human authors asserting facts about the concepts in the terminology. |
| Inferred Forms | These forms include the statements that can be inferred from the collection of statements made in the Stated Form. This is usually created by a computer using software known as a description logic classifier or reasoner. |

As a simple example the figure below shows the addition of an inferred relationship – that a hybrid car is a type of petrol car because it has the same definition as a petrol-driven car, with an additional relationship that the petrol-driven car does not have.

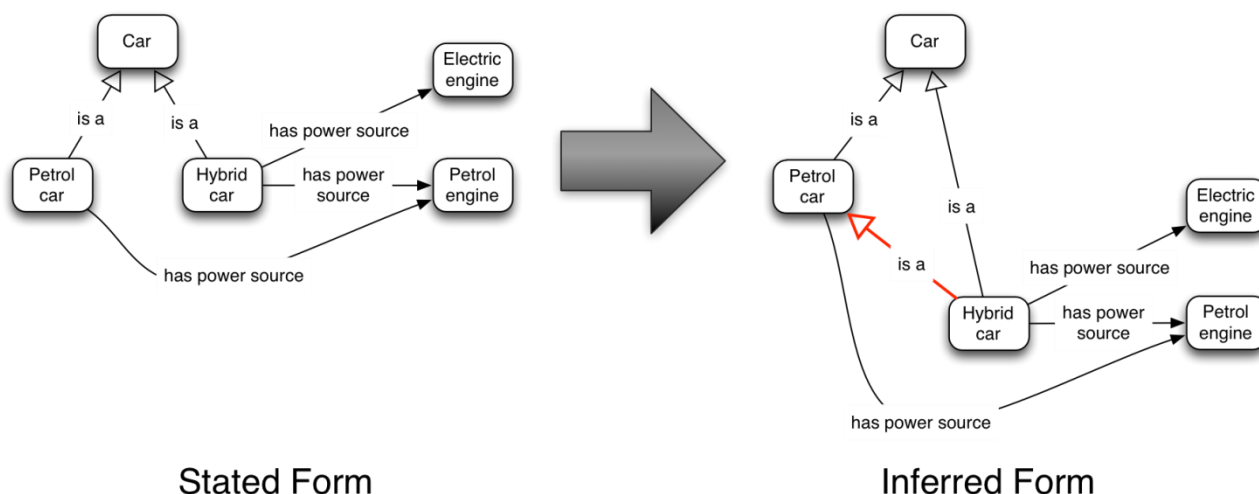


Figure 34: Adding inferred relationships

3.5.2 Normalised forms

Inferred Forms can be further broken down into “normalised” forms, where rules are used to govern the relationships included from the entire set of stated and inferred relationships. Normal forms provide a consistent and dependable structure to code against. The two extremities of these forms are:

- including every possible inferable relationship, which would include many redundant relationships (see Section 3.6); and
- reducing the relationships to the minimum possible number without losing or changing semantics (see the following section).

3.5.3 Distribution Normal Form

The IHTSDO has a defined “Distribution Normal Form” for SNOMED CT, which is an Inferred Form as discussed above.

The Distribution Normal Form is created by:

- 1 Using a description logic classifier on the Stated Form to determine the additional inferable relationships.
- 2 “Normalising” the resulting full set of stated and inferred relationships to:
 - limit the IS A relationships to proximal supertypes (described further below); and
 - remove any redundant inferred relationships (described further below).

The IHTSDO chose this form to distribute because:

- It provides non-redundant inferred and inherited relationships, so consumers of this form do not need to calculate them (that is, have and use a description logic classifier as in point 1 above).
- It minimises the number of IS A relationships to keep the format as compact as possible for distribution. The opposite approach would be to

distribute the full transitive closure, which is very large. The benefit of a more compact form, combined with the ease of generating the transitive closure ²¹ means that the minimal set of IS A relationships is felt to be easier to consume. See Section 3.6 for more details on what a transitive closure is, and how to create it.

The following two rules are applied to create this “normalised” form.

3.5.3.1 Proximal inferred supertypes

This rule applies to the combined stated and inferred IS A relationships, and means that only IS A relationships to “proximal supertypes” of a concept (that is, the closest parent concepts) are included. Other IS A relationships to supertypes of the concept which can be reached by traversing multiple IS A relationships are omitted. This reduces the IS A relationships to the minimal set of inferable parents, with no direct IS A relationships to ancestors, and is the opposite of the Transitive Closure described in Section 3.6.

As an example, Figure 40 below shows a hierarchy of concepts containing redundant IS A relationships on the left being converted to the “proximal supertype view” on the right.

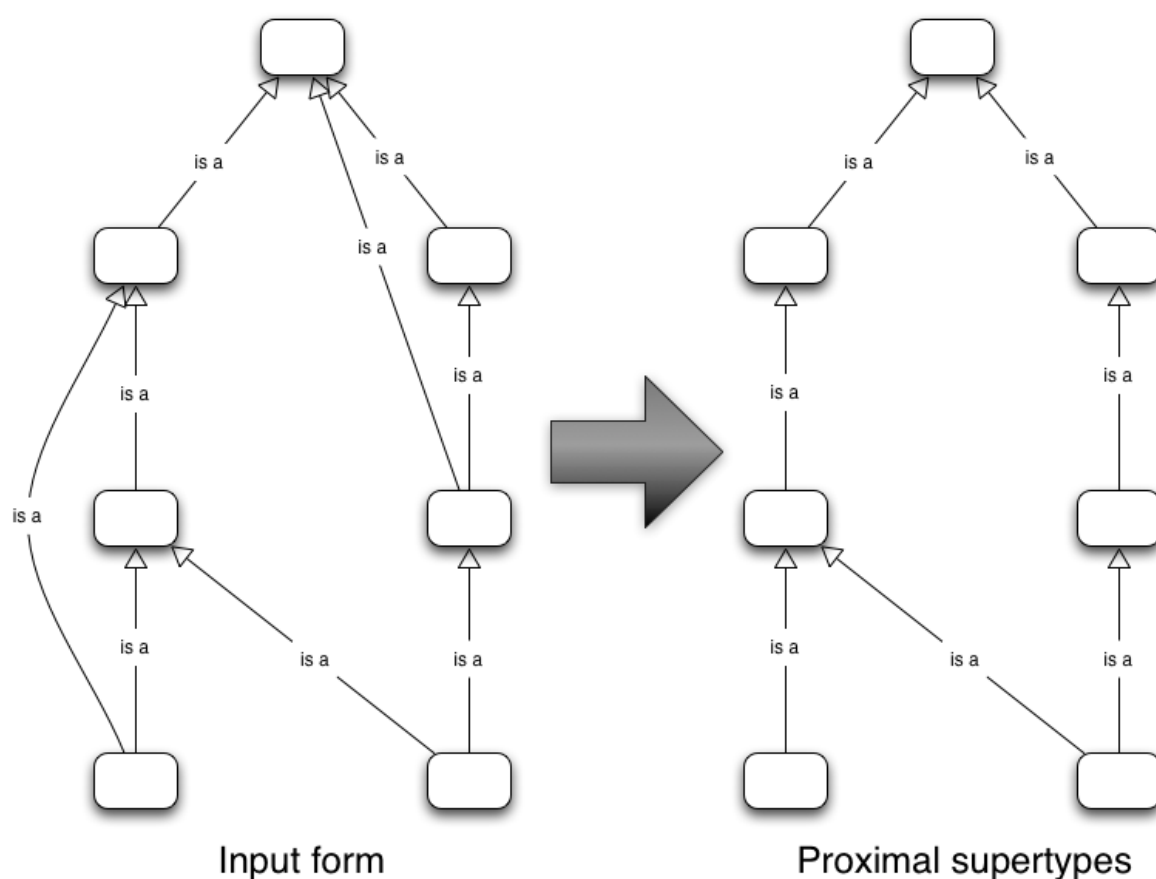


Figure 35: Example conversion to proximal supertypes for Distribution Normal Form

²¹ Many algorithms exist for easily creating a transitive closure, including scripts provided with the same code accompanying this guide, and by the IHTSDO. See Section 3.6 for more details.

3.5.3.2 Non-redundant inferred defining relationships

This rule applies to all stated and inferred relationships a concept has, and means that only non-redundant defining relationships and relationship groups are included. This includes relationships inherited from supertype ancestors (not just direct parents). Relationships or relationship groups that are supertypes of other relationships or relationship groups are omitted (refer to Section 2.3.6.2 as an example of super/sub-relationships).

Figure 40 below shows an example of an incomplete graph of concepts to demonstrate the "non-redundant relationships rule". Assuming the Stated Form on the left hand side of this diagram, all the inferred and inherited relationships are added, and then reduced to their non-redundant set. For example, note that "rel type A" is inherited down to all of the concepts, however "rel type B" is not.

This is because the relationship "rel type C" from B to F is a subtype of the relationship "rel type B" from A to E. Including a "rel type B" relationship from B to E would therefore be redundant, however the "rel type C" relationship to F is inherited by C.

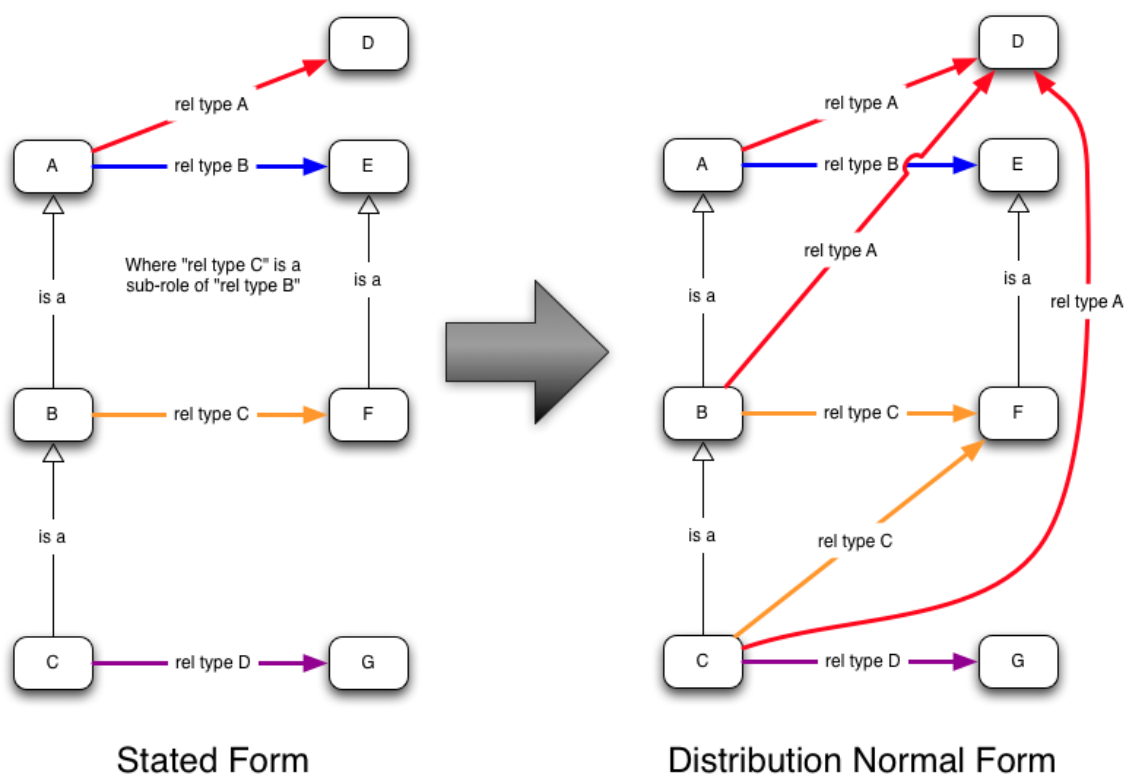


Figure 36: Conversion to non-redundant relationship view

3.5.4 Expected differences between AMT v3 Stated and Distribution Normal Forms

AMT Production files are published in Distribution Normal Form. The Stated Form may be optionally published at a later date. The DNF impacts on the Relationship file as well as the Concrete domain reference sets. The inclusion of inferred and inherited relationships will mean additional rows added to these reference sets.

AMT Distribution Normal Form differs from the Stated Form in a number of ways. The following sub-sections provide individual examples; however these are not the

limit of the differences, just examples of patterns of differences. Refer to Appendix D for some examples of products that include inferred relationships.

3.5.4.1 Missing inferred relationships

A number of inferred IS A relationships are not included in the Stated Form. An example of such a relationship is that the Stated Form includes the statement that

- |*paracetamol 500 mg tablet*| IS A |*paracetamol (medicinal product)*|.

However it does not include the statement:

- |*paracetamol 500 mg + codeine phosphate 30 mg tablet*| IS A |*paracetamol (medicinal product)*|.

This statement is inferred and included in the Distribution Normal Form, because |*paracetamol 500 mg + codeine phosphate 30 mg tablet*| has the same HAS INTENDED ACTIVE INGREDIENT relationship to |*paracetamol (AU substance)*| as |*paracetamol (medicinal product)*|. This is similar to the example shown in Figure 34 on p.89.

3.5.4.2 No inherited relationships

Relationships that are inherited down the hierarchy to child concepts are not included in the Stated Form. An example of this is that the Trade Product Unit of Use concept |*Panadol 500 mg tablet: film-coated*| does not have the relationship HAS INTENDED ACTIVE INGREDIENT to |*paracetamol (AU substance)*| in the Stated Form.

In the Distribution Normal Form, this relationship exists, inherited from the parent MPUU concept |*paracetamol 500 mg tablet*|. Therefore with the Stated Form it is necessary to navigate up to all parent concepts manually to find and use these relationships. In the Distribution Normal Form they are replicated on the child concepts for easier access. This is similar to the example shown in Figure 36 above.

3.5.4.3 Redundant relationships

Some relationships distributed in the Stated Form may become redundant in the Distribution Normal Form and therefore may be retired in the Distribution Normal Form.

For example, Figure 37 below shows the Stated and Distribution Normal Forms for |*paracetamol (medicinal product)*| and |*paracetamol + codeine (medicinal product)*|. Because |*paracetamol + codeine (medicinal product)*| is determined to be a subtype of |*paracetamol product*|, the directly stated IS A relationship from |*paracetamol + codeine (medicinal product)*| to |*medicinal product*| becomes redundant, and is not included in the Distribution Normal Form.

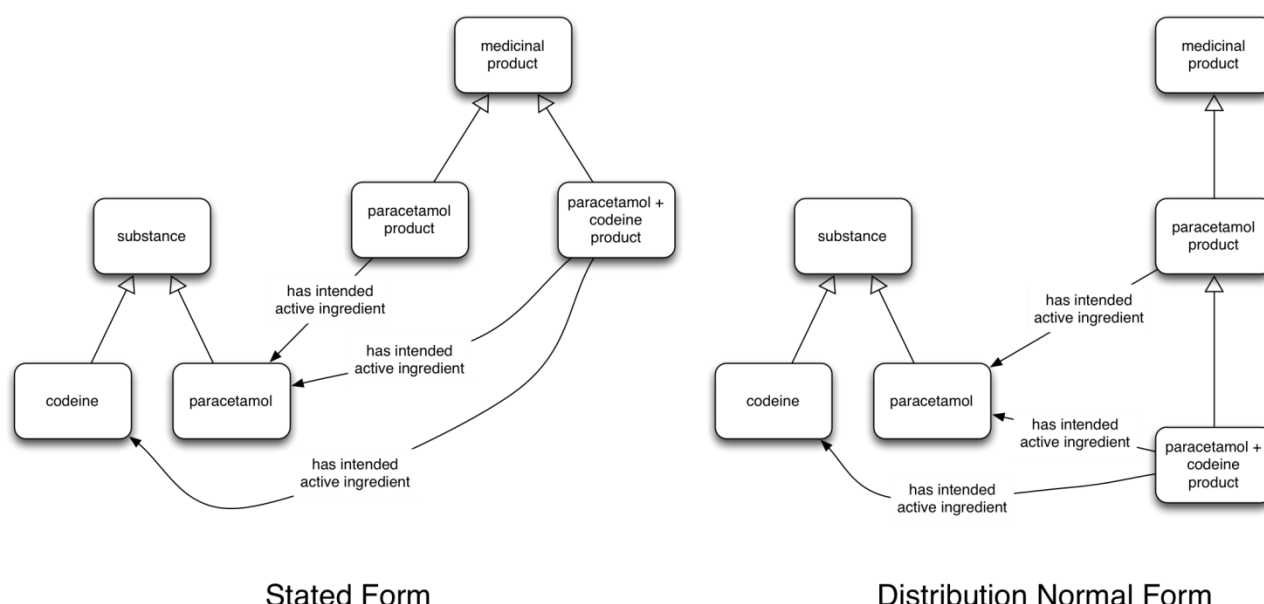


Figure 37: Comparative examples of Stated Form and Distribution Normal Form

3.6 Transitive closure

Generation and use of a transitive closure can be a useful tool in searching terminology data, or in data retrieval/reporting on terminology encoded records.

The following sections explain what a transitive closure is, how to create one, and how to use it.

Note that generating a transitive closure on AMT files in Stated Form will not produce all true subtype relationships. Transitive closure generation (as described below) is based on an initial set of IS A relationships, however the Stated Form of AMT does not include all inferable IS A relationships in “proximal supertype” form. The AMT Distribution Normal Form files do contain all required IS A relationships to correctly calculate a transitive closure.

3.6.1 What is a transitive closure in SNOMED CT?

The opposite of the “proximal inferred supertype” view included in the Distribution Normal Form (refer to Section 3.5.3), a “transitive closure” view includes all possible true IS A relationships between concepts. This effectively adds to the “proximal inferred supertype” view new IS A relationships for every possible multi-relationship traversal.

Best explained using a diagram, the figure below shows the Distribution Normal Form “proximal supertype” view on the left turned into a transitive closure on the right.

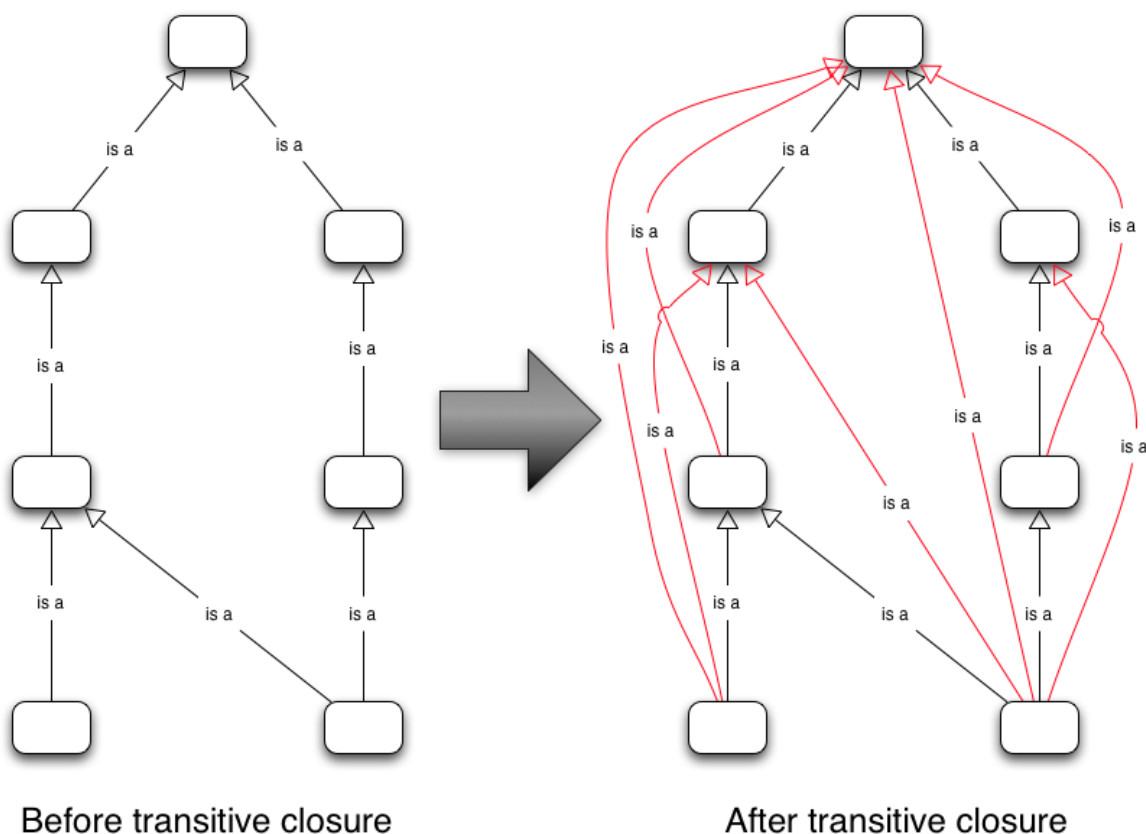


Figure 38: Example of a transitive closure

3.6.2 Purpose

In the context of SNOMED CT terminology implementation (including AMT) a transitive closure can be thought of as an index.

By generating all possible IS A relationships, it is possible to determine if a concept is a descendant of another concept (subsumption testing) with a single relationship. This avoids needing to traverse all possible routes through multiple relationships, which is typically slow and requires more complex code/queries.

Refer to Section 5 for an example of how to create a transitive closure.

3.6.3 Generation

There are a number of algorithms and technologies for calculating a transitive closure from RF2 relationships files. For example it is possible to use a relational database, or even a shell script with text file processing.

The IHTSDO provides a MySQL stored procedure implementation which generates a transitive closure into a MySQL database table. Refer to Section 7.7.5.2 "Transitive closure implementation" of the *SNOMED TIG* (IHTSDO, 2014). The IHTSDO also provides some details of an in-memory representation and algorithm for fast subsumption testing in Section 7.7.5.2.3 "Access to Relationships" of the same document.

Section 5 below also provides a sample schema, load scripts and common queries for AMT as an aid to understanding the distributed AMT data. The sample schema and load scripts also include generation of a transitive closure using the IHTSDO's MySQL stored procedure. The accompanying sample queries demonstrate the use

of the transitive closure to achieve fast subsumption testing and more compact queries.

3.7 Modules

3.7.1 What are modules?

RF2 introduced the concept of “modules” to SNOMED CT. Put simply, a module is a way of segregating content for the purposes of identifying:

- organisational responsibility for content;
- dependencies between content; and
- groupings of content for a particular purpose or separate development/release cycle.

The use of modules allows AMT to be published as a more compact release, with only metadata content from SNOMED CT and SNOMED CT-AU. Without this modularisation of SNOMED CT and SNOMED CT-AU, it would be necessary to publish AMT with all of SNOMED CT and SNOMED CT-AU.

Modules are typically more important for terminology authors (such as national release centres and extension builders) rather than for implementations and clinical end users. It may be important to consider modules if an organisation develops and maintains a SNOMED CT extension terminology.

In RF2 each component has a “moduleId” attribute which indicates the module to which that component belongs. The “moduleId” can change over time to indicate that its ownership has changed, or that it is being grouped with a different set of content. Changes to a module are tracked over a component’s life using the same history tracking mechanism used for all RF2 content – refer to Section 3.10.

3.7.2 AMT modules

AMT contains three modules, as summarised below.

Table 32: AMT modules

SNOMED CT Identifier	Name	Description
9000000000000012004	SNOMED CT Model Component	IHTSDO module used to denote all metadata content used as a foundation for RF2 and SNOMED CT – that is, non-clinical content.
161771000036108	Australian common model component extension	NEHTA module used to denote content that is common to Australian extensions i.e. SNOMED CT-AU and AMT.
900062011000036108	Australian Medicines Terminology module	NEHTA module used to denote AMT-specific content.

Modules have dependencies expressed in the *Module dependency reference set* (refer to Section 3.1.12.1). The figure below expresses the dependencies between NEHTA and IHTSDO modules with modules included in AMT, as expressed in the *Module dependency reference set*, highlighted in orange.

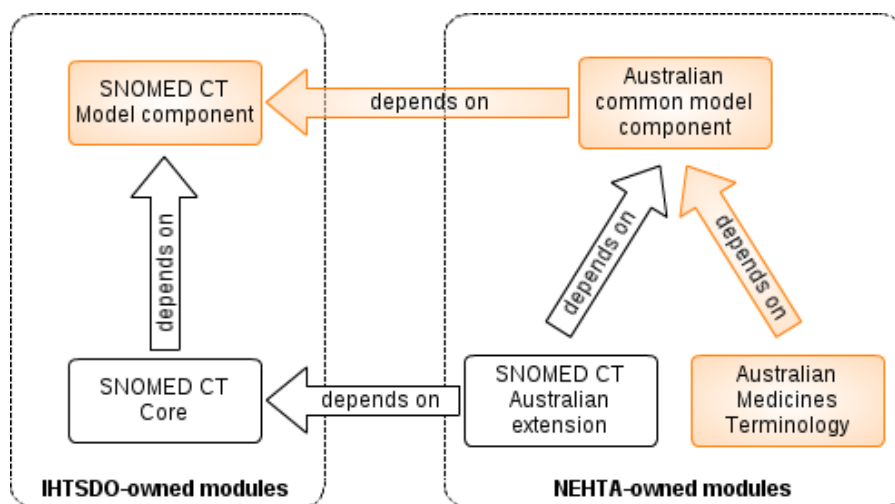


Figure 39: AMT module dependencies

3.8 Meaning of the active field

Each AMT component in RF2 has an associated active field, which can take values of true ("1") or false ("0"). The meaning of this flag is described by component type in the following table.

Table 33: Active fields in RF2

Component type	Active value	Description of behaviour when most recent row representing a component has the specified active value
Concept	true	<ul style="list-style-type: none"> The Concept is intended for active use. All active Descriptions for which the conceptId refers to this Concept are valid. Visibility of these active Descriptions depends on information contained in applicable RefsetMembers (for example, whether the Description is in a language dialect reference set that is currently enabled in the vendor's system). All active Relationships of which it is the sourceId or destinationId are applicable.
	false	<ul style="list-style-type: none"> The Concept is not intended for active use. However, it remains a valid concept for historical purposes as part of the SNOMED CT commitment to the principle of "concept permanence". Valid Descriptions of the Concept remain active allowing it to be appropriately viewed in human-readable form. An inactive Concept cannot be the sourceId, destinationId or typeId of an active Relationship.
Description	true	<ul style="list-style-type: none"> The Description contains a term that is a valid description of the Concept referred to by the conceptId. An active Description may refer to an inactive Concept, in which case the term provides a valid description of that inactive Concept. Text-based searches should (by default) include only active Descriptions that refer to active Concepts.
	false	<ul style="list-style-type: none"> The Description is not valid and the associated term should no longer be regarded as being associated with the Concept referred to by conceptId.

Component type	Active value	Description of behaviour when most recent row representing a component has the specified active value
Relationship	true	<ul style="list-style-type: none"> The Relationship represents a valid association of the type specified by the typeId, between two Concepts referred to by the sourceId and destinationId; An inactive Concept cannot be the sourceId, destinationId or typeId of an active Relationship.
	false	<ul style="list-style-type: none"> The Relationship is not valid. An inactive Relationship should be ignored as it does not apply. This does not necessarily mean that the association indicated by the Relationship does not apply. The Relationship may be inactive because it is redundant and inferable based on other active Relationships. An inactive Relationship may refer to either active or inactive components.
RefsetMember ²²	true	<ul style="list-style-type: none"> The RefsetMember contains valid information applicable to the component referred to by the referencedComponentId. The component referred to by the referencedComponentId may be active or inactive. An active RefsetMember cannot make an inactive component active but may provide related information that continues to be relevant (for example, the reason for inactivation).
	false	<ul style="list-style-type: none"> The RefsetMember is not valid. An inactive RefsetMember should be ignored. The information it contains is not applicable to the component referred to by referencedComponentId.

Note: The content of this chapter has been derived from the *SNOMED TIG* (IHTSDO, 2014), which also has further information on the RF2 specifications.

3.9 effectiveTime field

The effectiveTime of each AMT component specifies the date at which the component was first released in the terminology, or when the component's state has changed in subsequent releases.

The effectiveTime format in AMT is represented to the day of the year, using ISO 8601 basic representation of YYYYMMDD, as per RF2 specifications.

3.9.1 Using effectiveTime and active fields

If the AMT Full release files are used in an implementation, multiple versions and states of a component may exist if the component has changed over time. These will manifest as multiple rows in the release files, each with a different effectiveTime value.

To implement the latest state of each component, the latest effectiveTime value for the component should be used. In addition, only active components should be implemented (where access to historical data is not required). To achieve this, a subsequent step is to retain only the components with an active field of true ("1"). The result of these steps delivers the most recent state of each component that is deemed for active use.

²² A RefsetMember is a component that exists within a reference set. Every row of a reference set essentially is a RefsetMember.

3.9.2 Using effectiveTime for legacy data

In AMT, the effectiveTime for legacy data (that is, data brought over from AMT v2) will be true only as far back as AMT v2 release 2.0 (June 2009).

If a v2 component's effectiveTime is 20090630 or more recent, they will have the same effectiveTime in v3.

- For example, the CTPP [*Crosuva 10 mg tablet: film-coated, 30, blister pack*] was added into the AMT Jan 2014 release, and will have a v3 effectiveTime of 20140131.

If a v2 component's effectiveTime is earlier than 20090630, they will have a v3 effectiveTime of 20090630.

- For example, the CTPP [*Paclitaxel (Baxter) 30 mg/5 mL injection: concentrated, 5 mL vial*] was added into the AMT Dec 2008 release, and will have a v3 effectiveTime of 20090630.

3.10 History tracking mechanism

The history tracking mechanism used in RF2 is described in Section 5.5.1.6 "History Mechanism" of the *SNOMED TIG* (IHTSDO, 2014). The following sections provide an overview of this mechanism.

3.10.1 Append-only data model

In short, RF2 provides a "log-style" append-only data model, which provides full traceability of change. A row in any of the RF2 files represents a version of a component, and once released is never modified.

RF2 supports three types of release – Full, Snapshot, and Delta – refer to Section 3.3. The Full type provides all of the versions (rows) ever released, whereas the Snapshot type provides just the most recent versions at the point in time of the Snapshot. The Delta format provides only versions that have been created since a previous release.

Regardless of the distribution type being viewed, it must be remembered that all of these versions are still valid historical states of the components, however the Delta and Snapshot types omit some for brevity and/or convenience.

3.10.2 Modifying a component

As a version of a component cannot be modified, to modify the state of a component it is necessary to add a new version of the component with the desired change.

The new version of the component supersedes the old version of the component as the component's state from the date/time of the new version's "effectiveTime" field. Versions (rows) are therefore "effective" from the point in time specified in their "effectiveTime" field, to the point in time specified in the next chronological version's "effectiveTime".

Only one version (row) of a component is effective at any given point in time.

3.10.3 Immutable attributes

Components have mutable and immutable attributes. The mutability of an attribute is specified in Section 3.1 where the columns for each file are specified.

If an attribute is considered mutable it may appear in future versions of a component with a different value to the current and previous versions. If an attribute is considered immutable new versions are not permitted to modify the value of that attribute from the value in existing versions of the component.

That is, immutable attributes have a value set in the first version of a component and may never change for the entire life of the component. Mutable attributes may change value over time for a given component.

3.10.4 Inactive components

When a component is found to be no longer relevant, or not recommended for use, it is "inactivated" (that is, retired), but not removed. This is undertaken by creating a new version of the component and setting the "active" field of the new version to "false". This indicates that as of the "effectiveTime" value of the new version, the component is inactive.

Inactivation of a component is done for many reasons. For example:

- The component had an error in an immutable field, and the only way to correct this error is to inactivate the component and create a new one with the correct value.
- The component was a duplicate of another component, and therefore the duplicate component is inactivated.

When a component is inactivated and replaced by a new component, the component replacing it is specified in the Historical association reference sets – refer to Section 3.1.8. This is intended to aid finding replacements for inactive components.

It is important to note that once created, components are not removed from the release files, only inactivated. This is to ensure that despite being inactive, components are always available into the future in case they have been used in clinical records. It is therefore important to note that when selecting components of the terminology to use, only active components should be used.

3.10.5 Semantics of identifiers

Once created, an identifier always refers to the same component, and that component does not change meaning over its lifespan.

Regardless of whether an identifier refers to an active or inactive component, the identifier (and the thing it refers to) always means the same thing.

4 Implementation advice

This section provides general advice and topics to consider when planning an implementation of AMT. More product-specific advice can be found in Section 7.

4.1 Mapping

AMT may be integrated with an existing system by mapping either a local or “Commercial Off the Shelf” (COTS) medicines dictionary to AMT.

This approach enables systems to continue to operate without large modifications, and without a change to the current user experience, while enabling use of the AMT for information exchange and data reporting/analysis. Using COTS medicines dictionaries mapped to the AMT also introduces features provided by such medicines dictionaries not provided natively within the AMT.

However, maps can be expensive to produce and maintain over time, particularly if both the source and target of the map are living, changing products. Consideration should be given to the release and update cycles of both the COTS and AMT terminologies.

Please refer to the *AMT Mapping Guidelines* (NEHTA, 2012) if considering a mapping implementation. Additional guidance on AMT adoption via mapping can be found in the following documents:

- *Clinical Terminology - Guidance for People and Processes* (NEHTA, 2014)
- *Clinical Terminology - Guidance for Use in Healthcare Software* (NEHTA, 2014)

4.2 Native implementation

An alternative to mapping AMT to a local or COTS medicines dictionary is to directly implement AMT.

One of the first technical considerations when implementing AMT, or any SNOMED CT terminology, is how to store and retrieve the terminology as reference data²³. The aims to storing terminology as reference data are:

- to enable searching for values when entering transactional data;
- to render transactional data containing fields encoded with terminology; and
- to report across transactional data using the terminology reference data to group and filter.

There are two broad approaches that can be taken in this respect:

- custom schema and application code for the implementation; or
- use of an external terminology server.

Both have advantages and disadvantages that must be weighed when planning an implementation.

²³ Reference data is data in a system that is static (aside from occasional revisions) and non-transactional used to support the operation of the system and the transactional data.

Additional guidance on adopting AMT natively can be found in the following documents:

- *Clinical Terminology - Guidance for People and Processes* (NEHTA, 2014)
- *Clinical Terminology - Guidance for Use in Healthcare Software* (NEHTA, 2014)

4.2.1 Embedded implementation

One option to integrate AMT with an application is to embed AMT terminology data in application reference data, as illustrated in Figure 40. This may be achieved using mappings to existing application reference data sources, or manipulating AMT data to a form useful for the application.

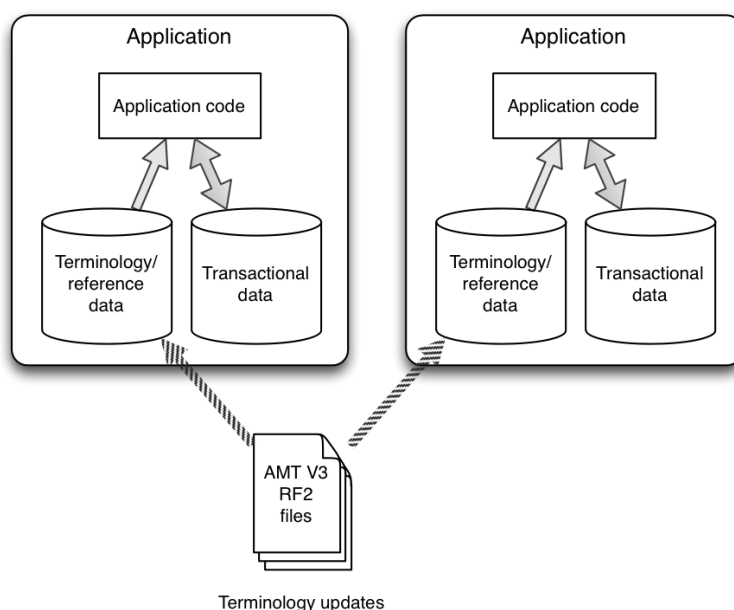


Figure 40: Example of embedding AMT reference data

RF2 is a relational representation of the terminology data used to distribute AMT, but is not intended to be an implementation format.

In order to explain and demonstrate the distribution form and AMT model, Section 5 (Sample code and scripts), is written using the release files directly translated to relational database tables. While this suits the purpose of explaining and demonstrating the distribution form, it is not likely to be the most suitable reference data schema for most applications.

Similarly, the content of the RF2 release files contains a complete tracking of all aspects of the terminology; however most implementations will only require varying subsets of this content.

Therefore identifying the subset of AMT data required for the implementation will enable designing the most appropriate and efficient data structures. In the process of designing this data structure and access methods, it is important to keep in mind the process for updating this data at regular intervals – refer to Section 4.3 Designing for data updates.

Note that the data storage technology need not necessarily be a relational schema. There are potentially non-relational storage and access options which may provide

as good or better performance in some circumstances. Other approaches include loading the entire terminology into memory for fast searching.

4.2.1.1 Reasoning

Reasoning with AMT data is also possible, and for this purpose a format such as OWL is likely more appropriate. The IHTSDO distributes an RF2 to OWL/KRSS Perl script for this purpose for SNOMED CT International. Unfortunately this script cannot be used for the AMT RF2 as the IHTSDO script has not been updated to take account of concrete domains and data type properties.

As part of the IHTSDO Representation of Numbers project, this Perl script will be updated for concrete domains and will then become useable for AMT data. This script is under development at present, however is currently sufficient to convert AMT to a useable OWL Functional Syntax format.

The script under development can be found in the IHTSDO's Subversion repositories at https://csfe.aceworkspace.net/svn/repos/perl-utilities/branches/concrete-domain/src/main/perl/tls2_StatedRelationshipsToOwlKRSS_Draft_INT.pl²⁴

4.2.1.2 Subsumption

Regardless of whether formal reasoning with the full description logic is performed, it is likely that some form of subsumption testing or subsumption-based querying may be useful and should be planned. For example, to find out if a particular AMT concept is a subtype of another AMT concept, or to find all subtypes of an AMT concept.

Techniques similar to those described in Section 3.6 are useful to achieve fast, readable queries performing subsumption testing. Section 5.3.4 demonstrates how these features can be used.

4.2.2 Terminology servers/services

Terminology servers/services may be used as an alternative to implementing storage, retrieval and maintenance of terminology within an application. Typically a terminology server is a server based application running outside a clinical application, often on a different physical machine, which manages and serves terminology to one or more applications. This is illustrated in Figure 41.

²⁴ This resource can be accessed by IHTSDO Collaborative Space account holders. Registration is free. See: <http://www.ihtsdo.org/about-ihtsdo/collaborative-space/>.

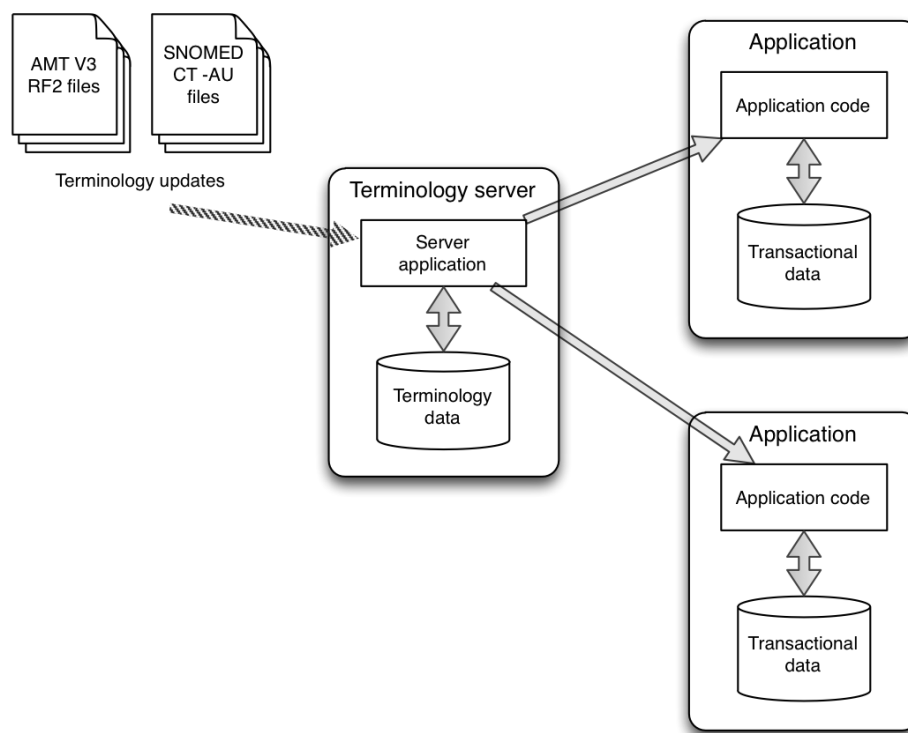


Figure 41: Example of a terminology server servicing multiple applications

One of the primary advantages of a terminology server is that they take the complexity of managing terminology out of the application itself, allowing the application developers to focus on the primary business use of the system. This can include:

- Managing multiple terminologies/code systems
- Managing multiple terminology versions
- Managing terminology updates
- Real-time searching and contextual restriction
- Embeddable widgets for streamlined clinical information capture
- Subsumption testing
- Advanced reasoning

Use of a terminology server and participating applications also allows an organisation with multiple applications and/or deployments to achieve partial or complete centralised maintenance and deployment of terminology changes.

Different terminology servers provide different arrays of functionality and interfaces which may be more or less applicable to a particular organisation or implementation. Therefore it is necessary to perform a requirements analysis prior to attempting to assess and select a terminology server supplier.

4.2.3 Terminology servers versus native implementation

Bespoke terminology data structures and implementation can provide fast functionality, well targeted to the system use cases. However this approach does have disadvantages:

- More complexity in the application which might otherwise be factored out to an external system (terminology server).
- Distraction for application developers from the main purpose of the system.
- More code to maintain and test.
- Design must take into account regular terminology updates.
- Reduced ability to centrally manage terminology for multiple systems in an organisation.
- Complex reasoning features provided by terminology servers are hard to reproduce cheaply.

Terminology servers provide an alternative which, depending upon the product chosen, can eliminate one or more of the above disadvantages. We recommend considering the following characteristics when assessing terminology servers:

Cost	Depending upon the server and the implementation, terminology server costs may exceed, or be substantially cheaper than, developing custom application functionality.
External point of failure	An external terminology server, depending upon the nature of the deployment, how it is used within an application (that is, real-time access or offline with updates), may present an additional point of failure into a deployment.
Third party component	Introduction of a terminology server will include an additional third party component, requiring the usual licence and contractual agreements.

Unless implementation of terminology within an application is trivial, a terminology server is likely to be simpler and cheaper than implementing, testing and maintaining custom functionality. However this decision must be made on a case-by-case basis.

4.3 Designing for data updates

Regardless of implementation type or technologies, terminology will have to be regularly updated within an implementation. Under the terms of the [Australian National Terminology Release Licence](https://www.nehta.gov.au/get-started-with-ehealth/what-is-ehealth/clinical-terminology/registering-for-a-license)²⁵, an implementation is required to update to a new version of AMT at minimum every 180 days, however business needs may require more frequent updates, especially for systems supporting medicinal concepts.

²⁵ <https://www.nehta.gov.au/get-started-with-ehealth/what-is-ehealth/clinical-terminology/registering-for-a-license>

4.3.1 Mapping

Updating to new data versions is a major ongoing cost of using a map between a local or COTS medicines dictionary and the AMT. Given the rate of change of medicines products and licence requirements, regular updates will be required.

When performing local mappings, it is necessary to carefully plan and design the process for:

- assessing changes in AMT;
- updating the map; and
- reviewing and testing the map.

Typically producers of COTS products will provide their own mapping, maintained and updated along with regular product updates.

4.3.2 Native implementation

When implementing custom, native data structures, it is important to consider implications of updates to ensure that they can easily be performed frequently.

There are two broad views that can be taken in storing terminology data, which relate closely to RF2's concept of distribution type (refer to Section 3.3):

- **Store and query a "snapshot".**

This approach stores only the latest state of the terminology components implemented. Queries or code written against this form are usually simpler and faster as they do not need to consider changes to terminology components over time.

However updating this form is more difficult, requiring dumping the existing snapshot and replacing it with a new snapshot, or attempting to update the snapshot with changed data. Rollback is similarly more complex, and it is only possible to operate with one version of the terminology at a time increasing change management challenges.

- **Store and query full release history.**

This approach stores all versions of terminology components implemented. Queries or code written against this form are more complex, and may be slower unless carefully planned, due to the additional time dimension.

However updating data is much simpler, as new versions of components in the terminology may simply be appended to the existing data store. Queries/code written to correctly handle change over time may be configured to retrieve data based on a given time point, representing any release point in history. Alternatively SQL views can be created that provide a Snapshot view of the Full data stored in the database based on a configured time point in order to keep queries simpler.

This enables fast and flexible rollback mechanisms and offers options to manage new terminology updates via configuration rather than physically loaded data.

Note that this approach can only be prototyped with the AMT Full release files but not with the Snapshot form.

Business processes to manage application configuration testing and deployment will also be required.

4.3.3 Historical association reference set

Regular maintenance of AMT data within an implementation also requires the use of a Historical association reference set. In AMT this file is called the *REPLACED BY association reference set*.

When a referenced component is found in an implementation, the referenced component (referencedComponentId) should be made inactive for current use and replaced by its replacement concept (targetComponentId), intended for active use. While unavailable for selection/recording, the inactive component is typically available for retrieval and reporting to support historical records and analytics. Refer to Section 2.3.5.6 for further details of this reference set.

If an implementation has used a snapshot version of AMT and is replacing it completely with a newer snapshot version as part of the maintenance strategy, then the *REPLACED BY association reference set* is not applicable. This is because the newer snapshot already encompasses the necessary changes to each component by showing their latest state.

4.3.4 Terminology server updates

Typically terminology servers (refer to Section 4.2.2) will contain functionality to update to new terminology versions, and often enable configuration of terminology versions served to different applications. This is a considerable benefit of terminology servers, as this process is typically well defined and streamlined.

However business processes for planning, deploying and testing applications with new terminology versions will be required.

4.4 Searching and capturing input

Searching and navigating during data input is vital to an efficient and positive user experience. In order to achieve a good user experience there are some relatively simple steps that can be taken, as discussed in this section.

The NHS Connecting for Health has also produced a good deal of useful documentation on this topic in their *Common User Interface programme* (National Health Service, n.d.).

Specific to searching, the following list provides factors to consider when implementing user facing controls and backend reference data access:

- | | |
|--------------------------------|---|
| Search speed | Fast search responses are critical to a productive user experience. Use and optimisation of appropriate indexes can achieve near real-time results. |
| Dynamic search features | Dynamic features are pre-emptive suggestions made by the system before the user has completed typing their search. Their aim is to reduce the time taken for a user to complete a search. |
- **Autocomplete** – autocomplete is a common concept in modern software, and is especially pervasive in

mobile phones, where the most likely complete word for a partially typed word can be accepted by the user with a shortcut key. Care must be taken when applying these techniques to ensure safety, and it is also very easy to frustrate users with autocomplete.

- **Auto search suggestions** – auto search suggestions is a feature familiar to most through modern web browsers and search engines. Through this feature a short list of probable complete search text options are provided based on the text typed by the user to that point. Search suggestions can be based on previous searches by that user or the entire user base, or on elements of the data being searched.
- **Incremental search results** – this feature provides search results to the user based on the text they have typed so far, but prior to them completing their search. This shows users search results being refined as they type, providing feedback to the user enabling them to alter their search. It is also likely that the result the user is looking for will be present before the user completes their search text, saving considerable time.

Ranked/ordered search results

Search results need to be ordered. However search results may be ordered by many attributes. The most obvious is alphanumeric order, which will be familiar to most users. However, ordering the results by most probable match to the user's search is often much more powerful. Search engines will typically provide ranking of search results, however combining this with the most probable type of AMT concept being searched for (for example an MPUU or MPP) will achieve a better user experience.

Partial word matching

Partial word matching is implemented by most search engines, and saves users considerable time typing long words. When searching for a term containing multiple words, using multiple partial words can achieve an accurate search result with minimal typing.

Word order

Searches should be tolerant of different word orders in search text and search results. For example "codeine paracetamol" should match "paracetamol 500 mg + codeine 10 mg tablet".

Stemming

Stemming is a technique used to reduce a word to its stem, base or root form. Taking a simple English example this allows "fishing", "fish", "fished" and "fisher" to be reduced to the root word "fish". This technique is very useful when searching SNOMED CT which contains descriptions with many derivative forms of words, but it is less likely to be effective with AMT's content.

Synonyms

When searching SNOMED CT, many more relevant search results will be achieved by searching on all acceptable

Synonyms, rather than just Preferred Terms. This enables a user's search text to match potentially alternate terms for a concept that may not be the Preferred Term. While very effective in SNOMED CT, this is likely to be less effective in AMT which currently contains few alternate Synonyms for concepts.

Note that despite matching a Synonym, the Preferred Term should always be rendered to the user to select.

Structured results

When displaying search results, structuring the results as well as ordering can assist users quickly choosing their intended concept. For example grouping or flagging results to indicate what type of AMT concepts they are (for example MPUU versus MPP versus TPUU or CTPP). Results can also be further organised or categorised using the relationships within the AMT model – for example the subtype hierarchy, or using relationships to ingredients or forms.

Constraining to relevant content

One of the simplest and most effective steps in data entry for SNOMED CT and AMT is reducing the navigated/searched concepts to those relevant to the context. For example, if a user is entering data into a field intended only for trade specific concepts, returning results from other parts of the AMT model clutters search results and impedes data entry.

Similar to providing structured search results, it is possible to provide users with the ability to navigate through AMT content using concept relationships. For example it is possible for a user to specify an ingredient, or combination of ingredients, and then navigate through the generic medicines grouped by form and strength, down to trade products grouped by those generic medicines. Navigation of the subtype hierarchy for data entry is not recommended for SNOMED CT, due to its variable depth and breadth, however AMT's subtype hierarchy is much more suited to this approach.

Efficiency and usability of navigation versus searching controls will vary depending upon the setting and use case. Regardless of approach, user data entry should be limited to active AMT concepts and their current Preferred Terms at the time of entry.

When a user selects an AMT concept (either via navigation or searching), they should be presented with and select:

- the AMT Preferred Term for the concept; or
- a local/COTS medicines dictionary term in a mapped implementation (refer to Section 4.1).

Clinical users of applications **should not** be presented with Fully Specified Names or AMT Identifiers. These are part of the infrastructure of the terminology, and not intended for clinicians.

4.5 Recording and rendering recorded data

When a user's selection is recorded, two pieces of information should be persisted:

1. The identifier of the code selected.
 - If using AMT natively, this will be the AMT concept's SNOMED CT Identifier for example, |21433011000036107|.
 - If using a mapped implementation, this will be the local or COTS medicines dictionary's code for the selected item.
2. The text seen and selected by the user.
 - If using AMT natively, this will be the AMT concept's Preferred Term, for example, |paracetamol|.
 - If using a mapped implementation, this will be the local or COTS medicines dictionary's description text that was rendered to the user.

The code and text are both stored for safety, and if any doubt exists, the stored text seen by the user is the definitive record.

Additionally systems should record the version of the AMT and/or medicines dictionary being used at the time the record was made. This information is valuable as an audit trail and provides a useful tool for later diagnostics. Refer to Section 7.15 for information on how to represent AMT versions.

When rendering recorded data back to users, the original text seen by the user (recorded when the selection was made as discussed above) should be rendered. The recorded code **should not** be used to look up the latest AMT Preferred Term in the loaded reference data at the time of rendering. This avoids the risk of discrepancies between the code and description over time, which however unlikely, may occur in AMT or in its implementation.

4.6 Retrieval and analytics

Since AMT is a SNOMED CT terminology, it is able to combine encoded instance/transactional data with reference data, providing a powerful combination for data retrieval and analytics. For example these features can be used to:

- Aggregate and analyse records for research, audit and service planning.
- Identify patients with specific risk factors for preventative/investigative measures, or identification of patients for clinical trials.
- Retrieve data for an individual patient to enable summary reports or decision support protocols.

The basic principle is to determine a query on AMT which yields the list of concept identifiers encompassing the data required. This set of concepts may be joined with instance data to determine the set of instance records required.

4.6.1 Subtype hierarchy

Perhaps the simplest approach to retrieving data is to retrieve all records where a field contains a subtype of an AMT concept.

For example, to find all records where codeine is the intended active ingredient of the prescribed medication, it is possible to find all the subtypes of the AMT MP concept |codeine (medicinal product)| using a description logic classifier or transitive closure (refer to Section 3.6). This list can be joined with prescription

records and will include all prescriptions for codeine-containing prescriptions based on either their generic or trade name.

The same technique can be used anywhere the supertype/subtype hierarchy in AMT suits the required query.

Note that this technique works only with the Distribution Normal Form, as the Stated Form does not include all inferred proximal supertype relationships, and therefore not all possible subtypes can be retrieved using a transitive closure generated from AMT Stated Form.

4.6.2 Other concept attributes

Note: The scripts provided below and in other release materials are provided for educational purposes only, as noted in Section 1.5.

It is possible to query concepts from AMT using attributes other than their supertype/subtypes. For example it is possible to find AMT concepts containing more than 10 milligrams of codeine in a tablet form by creating a query looking for concepts with these characteristics.

```
select distinct
    mpuu.mpuuid,
    mpuu.mpuuterm,
    mpuu.substanceterm,
    mpuu.bossterm,
    mpuu.strengthvalue,
    mpuu.unitterm,
    toPt (hasDoseForm.destinationid)
from v3_ingredient_strength mpuu
join rf2_ss_relationships hasDoseForm
    on mpuu.mpuuid = hasDoseForm.sourceid
    and hasDoseForm.typeid = 30523011000036108 -- has manufactured dose
    form (relationship type)
    and hasDoseForm.active = 1
    and hasDoseForm.destinationid in (select distinct conceptid from
rf2_ss_descriptions where term like 'tablet%')

    and mpuu.bossterm like '%codeine%'
    and mpuu.strengthvalue > 10
    and mpuu.unitid = 700000801000036102 -- mg/each
;
```

Note that the above example assumes that the ingredients are all expressed in the same unit of measure – that is, this query would not work for a tablet expressed as “1 gram” or “0.02 gram” even though they match the specified criteria. For more on this issue refer to Section 3.2.6.

Subsumption techniques are also quite useful when looking for concepts that have a certain type of relationship to a subtype of another concept. For example where looking for an AMT concept with “dihydrocodeine” in any type of tablet dose form:

```
select
    v3_ingredient_strength.mpuuid,
    v3_ingredient_strength.mpuuterm,
    v3_ingredient_strength.bossterm,
    v3_ingredient_strength.substanceterm,
    v3_ingredient_strength.strengthvalue,
    v3_ingredient_strength.unitterm,
    toPt (hasDoseForm.destinationid)
```

```
from v3_ingredient_strength

join rf2_ss_relationships hasDoseForm
  on hasDoseForm.sourceid = v3_ingredient_strength.mpuuid
  and hasDoseForm.typeid = 30523011000036108 -- has manufactured dose
form (relationship type)
  and hasDoseForm.active = 1

where v3_ingredient_strength.substanceid = (
  select distinct conceptid
  from rf2_ss_descriptions where term = 'dihydrocodeine (AU substance)'
)
and hasDoseForm.destinationid in (
  select source from v3_tc where dest = 154011000036109 -- tablet
dose form (AU qualifier)
)
;
```

Similarly subsumption techniques also work for sub-role relationships. For example a query could be written to find all concepts with a HAS MPUU relationship to *|paracetamol 500 mg tablet|*, which will return a list of MPP concepts. If this query is expanded to return all concepts with a HAS MPUU or subtype relationship to *|paracetamol 500 mg tablet|* or its subtypes, the result will also include TPP and CTPP concepts.

```
select
  hasMpuu.sourceid as mppid,
  toPt(hasMpuu.sourceid) as mppterm,
  hasMpuu.typeid as hasmpuu_typeid,
  toPt(hasMpuu.typeid) as hasmpuu_typeterm,
  hasMpuu.destinationid as mpuuid,
  toPt(hasMpuu.destinationid) as mpuuterm,
  subRole.sourceid as sub_sourceid,
  toPt(subRole.sourceid) as sub_sourceterm,
  subRole.typeid as sub_typeid,
  toPt(subRole.typeid) as sub_typeterm,
  subRole.destinationid as sub_destinationid,
  toPt(subRole.destinationid) as sub_destinationterm
from rf2_ss_relationships hasMpuu
join rf2_ss_relationships subRole
  on hasMpuu.active = 1 and subRole.active = 1
  and hasMpuu.typeid = 30348011000036104
  and hasMpuu.destinationid = 23628011000036109
  and subRole.typeid in (select source from v3_tc where dest =
30348011000036104)
  and subRole.destinationid in (select source from v3_tc where dest =
23628011000036109)
and subRole.sourceid in (select source from v3_tc where dest =
hasMpuu.sourceid)
order by mppterm, sub_sourceterm;
```

Note that this technique is made simpler by the Distribution Normal Form, which provides all inherited relationships at each concept. However the AMT Stated Form does not provide all inherited relationships for each concept, and this means that more complex queries are required to check each concept and its ancestor concepts for relationships. Even so, not all relationships will be accessible through ancestor concepts as not all inferred supertypes are included in the Stated Form. See Section 3.6 for more details.

4.6.3 Description logic classifiers

A description logic classifier can also be used to find subtypes and supertypes of concepts within AMT. From the AMT Stated Form, use of a description logic classifier is the only reliable way to achieve this. However AMT in Distribution Normal Form allows for techniques discussed in Sections 4.6.1 and 4.6.2, which are typically simpler to set up, operate and perform.

However description logic classifiers allow for the use of “post coordinated expressions”, which are logic statements, much the same as a concept definition. A post coordinated expression effectively forms an anonymous or runtime concept, the same as the concepts distributed in AMT which are known as “pre-coordinated concepts”.

Description logic classifiers are capable of classifying a post coordinated expression to determine all of the concepts that subsume the expression, and all the concepts subsumed by the expression. This provides a very powerful and flexible alternative to the technique described in Section 4.6.2, where structural queries can become quite cumbersome when expressing a complex set of attributes.

4.6.4 Terminology servers

Terminology servers usually provide an array of services to interrogate terminology content, such as AMT, to achieve the concepts discussed in Sections 4.6.1, 4.6.2, 4.6.3, and 4.6.5. This eliminates the need to store terminology reference data structures enabling these queries, and implementation of these queries themselves.

Particularly powerful are terminology servers incorporating description logic classifiers, enabling complex and powerful queries yet hiding most of the complexity in the server.

4.6.5 Maps

Retrieval can also be performed via maps from AMT concept identifiers to other data sources, such as MIMS and ARTG ID. As more products are mapped to AMT, AMT concept identifiers can form a common reference point and bridge to map to other types of medicines information.

5 Sample code and scripts

5.1 Description

Contained within this release is a collection of SQL scripts which are intended to provide a starting point for loading and working with AMT in a relational database environment.

Note: These scripts are not a suggested implementation or a base for implementation. Their purpose is as an aid to learning AMT's release format and data structures. As such the database schema mirrors the release file structure.

Collectively, these scripts illustrate how to:

- create a MySQL database schema into which the AMT RF2 release files can be loaded;
- create a set of useful database views and procedures to simplify querying the imported AMT data; and
- write queries which utilise the AMT model to retrieve the necessary data to implement the primary AMT use cases.

The scripts referred to above are contained in the *AMT v3 TIG scripts* (NEHTA, 2013). The following table identifies each file contained in the zip file and a brief description of the purpose and content of that file.

Table 34: Contents of the AMT v3 TIG scripts

File	Description
schema/schema.sql	Contains table and view creation scripts.
schema/importTables.sql	Contains SQL statements used to load the AMT RF2 files into the created schema.
schema/createIndexes.sql	Contains SQL statements to add database indexes to the schema. These are generally added after importing the data, to maximise the performance of the import.
schema/routines.sql	Contains SQL statements to create any user-defined routines (functions and procedures). These generally consist of helper functions to shortcut repetitive coding. They will be referred to in the sample scripts.
schema/derived-model/schema.sql	Additional "derived model" tables to facilitate query simplification and performance.
schema/derived-model/importTables.sql	Population scripts for the additional derived model table.
schema/derived-model/createIndexes.sql	Index creation scripts for derived model tables.
sql/seven-notable-concepts.sql	A simple set of queries to list all concepts in each of the seven "notable" classes.

File	Description
sql/use-case.sql	A set of more complex queries which illustrate how to utilise the AMT model to satisfy prescribe and dispense use cases.

5.2 Preparation

This section assumes the reader has installed MySQL and created a database schema into which the AMT release files can be loaded. If this is not the case, <http://www.mysql.com> provides free downloads of their MySQL Community Server; installation and configuration instructions can be found on the download site.

Following this, the schema scripts should be executed in the order in which they appear in the above table. The scripts assume that the AMT bundle and the `tig_sample_code.zip` file are extracted in the following directory structure:

```
<some-root-directory>/
  release-files/
    RF2Release/
  tig/
    schema/
    sql/
```

With a current working directory of `<some-root-directory>`, open a MySQL session²⁶. The following statements will create the schema and import the RF2 release files.

```
mysql> source tig/schema/schema.sql
mysql> source tig/schema/importTables.sql
mysql> source tig/schema/createIndexes.sql
mysql> source tig/schema/routines.sql
mysql> source tig/schema/derived-model/schema.sql
mysql> source tig/schema/derived-model/importTables.sql
mysql> source tig/schema/derived-model/createIndexes.sql
```

Please note:

- The above scripts have been saved in the default MySql CLI format, using CR (carriage return) without LF (line feed). For this reason, these files will **not** display line endings correctly in some Windows (and older Mac) based programs. We specifically discourage opening these files in MS Notepad and suggest that you use an editor that honours CR line endings when displaying and writing the file content.
- The `tig/schema/importTables.sql` script contains relative paths to the RF2 files. Depending on the operating system and version of mysql, you may need to amend these and replace with the full path. For example:
 - `release-files/RF2Release/Snapshot/Terminology/sct2_Concept_Snapshot_AU1000036_20121231.txt`
 changes to

²⁶ Instructions on how to open a mysql session and how to execute commands is available on the MySQL website <http://www.mysql.com>.

```
C:/Users/nehta/Downloads/release-  
files/RF2Release/Snapshot/Terminology/sct2_Concept_Snapshot_AU1000  
036_20121231.txt
```

Once this has occurred, the release has been imported, and the imported AMT data can be queried using the sample queries contained in the sql directory.

It should be noted that the queries are provided as a starting point to demonstrate a relatively simple means of importing and querying the v3 model. It is intended to be an example only, and should not be considered fit for any other purpose.

5.3 Notable aspects of the schema creation scripts

5.3.1 Full tables

A historically complete "Full" release of AMT is loaded into the following tables:

- rf2_full_concepts
- rf2_full_descriptions
- rf2_full_relationships
- rf2_full_language_refset

The example queries are targeted at the snapshot.

5.3.2 Snapshot views

In most circumstances, a consumer of AMT will be interested in working with the "snapshot" release, which contains only the most recent version of each released component. The snapshot can be presented as a view of the full release, as shown below:

```
CREATE VIEW rf2_ss_concepts AS  
select t1.* from rf2_full_concepts t1  
where t1.effectivetime = (  
    select max(t2.effectivetime)  
    from rf2_full_concepts t2  
    where t1.id = t2.id)
```

In the statement above, the rf2_ss_concepts view (that is, snapshot concepts view) presents the most recent version of every concept in the full release. Snapshot views are also created for the descriptions, relationships and language reference set in the schema.sql file.

5.3.3 Notable concept views

It is possible to write a query which extracts every member of a notable concept class (for example, Medicinal Product Pack), and there are several valid ways to achieve this.

5.3.3.1 Using IS A relationships

One method is to find all source concepts of active relationships of type IS A which have a destination concept of "*medicinal product pack (medicinal product pack)*", as shown below:

```
select sourceid  
from rf2_ss_relationships
```

```
where typeid = 116680003 -- is a
and destinationid = 30513011000036104 -- medicinal product pack
and active = 1
```

While the above query seems correct and returns all the MPPs when querying the Stated Form it does not return the same results against the DNF which is the way AMT is released. This is because the DNF contains hierarchies with depths greater than one level (that is, this query will only return direct children of *|medicinal product pack|*, and not all descendants).

This can be addressed via the transitive closure table which returns all descendants. Since this example is seeking to **only** return MPPs it must also exclude concepts that are also descendants of *|trade product pack|* to work with the DNF. This exclusion is required due to an IS A relationship between TPP and MPP, as detailed in Section 2.3.2.6. Further explanation and exemplar of transitive closure can be found in Sections 3.6 and 5.3.4 respectively.

```
select source
from v3_tc
where dest = 30513011000036104 -- medicinal product pack
and source not in (
    select source
    from v3_tc
    where dest = 30404011000036106 -- trade product pack
)
```

Note that in the DNF, some MPPs are also subtypes of other MPPs; that is, not all MPPs are immediate subtypes of the MPP concept. Using transitive closure retrieves all subtypes of a given concept.

5.3.3.2 Using notable concept reference sets

A second method of obtaining all concepts within a notable class is to use the corresponding notable concept reference set, included as part of the AMT release file bundle. For example 929360081000036101 *|Medicinal product pack reference set|*. Refer to Sections 2.3.5.5 and 3.1.6 for further information on these reference sets.

Every child concept of a particular notable class is also given membership of its corresponding notable reference set. The component referenced by the reference set member is the child concept. This can be queried as follows:

```
select member.referencedcomponentid
from rf2_ss_refset member
where member.refsetid = (
    select conceptid from rf2_ss_descriptions
    where term = 'medicinal product pack reference set (foundation metadata concept)'
    and active = 1)
and member.active = 1
```

The above query uses the table `rf2_ss_refset`, which is effectively the union of all snapshot component reference set files contained in the release. The `refsetId` column identifies the reference set (in this case, MPP reference set), and the `referencedComponentId` identifies the child concept of the notable class.

This query is the basis of seven views contained in the `schema.sql` file, one for each of the seven notable concept classes (such as `v3_mpp`). These views provide a shortcut mechanism for quickly accessing concepts of a particular notable class, without having to explicitly query the component reference set and concepts tables. For example, using these views allows the above query to be replaced with:

```
select id from v3_mpp
```

5.3.4 Creating and using the transitive closure

A transitive closure presents an exploded view of all IS A relationships contained within the terminology. For example, if concept **α** IS A concept **β**, and concept **β** IS A concept **γ**, then it can be inferred that concept **α** IS A concept **γ**, even if that relationship is not explicitly stated. The transitive closure table (`v3_tc`) includes a row for each of these inferred relationships, as well as including all explicitly stated IS A relationships.

A procedure for creating that table is provided in `routines.sql`. The implementation of that procedure is database provider specific, and will not be explained further here²⁷. The transitive closure can be used for subsumption queries, for example, to find all descendants of `|form (AU qualifier)|`.

The transitive closure table can be used to illustrate this:

```
select source, toFsn(source)
from v3_tc
where dest = (
  select distinct conceptid from rf2_ss_descriptions
  where term = 'form (AU qualifier)'
  and active = 1)
```

The above query returns all 185 descendants of `|form (AU qualifier)|` as opposed to just 73 children²⁸, had we simply looked at the destination relationships of `|form (AU qualifier)|`, shown below:

```
select sourceid, toFsn(sourceid)
from rf2_ss_relationships
where typeid = 116680003 -- is a
and destinationid = (
  select distinct conceptid from rf2_ss_descriptions
  where term = 'form (AU qualifier)'
  and active = 1
) and active = 1
```

Please note that in order to find all concepts that specifically belong to the logical grouping of the seven notable classes, the methods outlined in Section 5.3.3 are preferred. We advise using the provided reference set for the seven notable classes (Section 5.3.3.2), to avoid unexpected inclusion of concepts across multiple classes. For example:

|Miochol-E (acetylcholine chloride 20 mg) solution: powder for intraocular irrigation, vial (trade product unit of use)| -IS A→ |medicinal product|, via:

- *|Miochol-E (acetylcholine chloride 20 mg) solution: powder for intraocular irrigation, vial (trade product unit of use)| - IS A→ |acetylcholine chloride*

²⁷ Those interested in an explanation of this procedure should contact the NCTIS by emailing help@nehta.gov.au.

²⁸ Note that the number of results returned quoted in this example is based on the AMT v3 20140630 data.

20 mg solution: powder for intraocular irrigation, vial (medicinal product unit of use)|

- *|acetylcholine chloride 20 mg solution: powder for intraocular irrigation, vial (medicinal product unit of use)| – IS A→ |acetylcholine (medicinal product)|*
- *|acetylcholine (medicinal product)| – IS A→ |medicinal product|*

The above example is a correct inference of IS A relationships. Note that in this case a specific Trade Product Unit of Use concept IS A Medicinal Product, as the seven notable concept hierarchies are not disjoint.

5.3.5 Fully Specified Names

Every concept in the AMT terminology will have one active description of type *|fully specified name (core metadata concept)|*, abbreviated as FSN.

Note that FSNs represent the reference point for the meaning of the concept, however are not intended to be exposed to users of a clinical system. Refer to Section 7.12 for more details.

The following query shows how this term can be extracted for a given concept:

```
select fsn.term
from rf2_ss_descriptions fsn
where fsn.typeid = (
    select conceptid from rf2_ss_descriptions
    where term = 'fully specified name (core metadata concept)'
    and active = 1)
and fsn.active = 1
and fsn.conceptid = <id of concept>
```

The above query forms the basis of a function created in *routines.sql*, called *toFsn*, which simplifies the extraction of an FSN for a concept, as shown below:

```
select toFsn(<id of concept>)
```

5.3.6 Preferred Terms

Every concept in the AMT terminology will have one or more active descriptions of type *|synonym (core metadata concept)|*. Of the Synonyms for each concept, one must be designated as the Australian English *|preferred|* description.

This preferred description is the Synonym most suitable for use by end users of clinical systems, although other acceptable Synonyms referenced in the *Australian dialect reference set* may also be used.

The preferred Synonym for a given concept is expressed via membership of the *Australian dialect reference set*, with the *referencedComponentId* column being populated with the description id of the preferred Synonym, and the *valueId* column containing the *conceptId* of the concept *|preferred|*. The following query shows how this reference set can be used to obtain the preferred Synonym for a given concept.

```
select preferred.term
from rf2_ss_descriptions preferred

join rf2_ss_language_refset member
on member.referencedcomponentid = preferred.id
and member.active = 1
```

```
where member.valueid = (  
    select conceptid from rf2_ss_descriptions  
    where term = 'Preferred (foundation metadata concept)'  
    and active = 1)  
and preferred.conceptid = <id of concept>
```

This query forms the basis of another view defined in `schema.sql`, called `v3_ss_pts` (that is, Snapshot Preferred Terms). This view can be used to simplify the extraction of Preferred Terms, as shown below:

```
select preferred.term  
from v3_ss_pts preferred  
where preferred.active = 1  
and preferred.conceptid = <id of concept>
```

A function, `toPt` (see `routines.sql`), is also provided which further simplifies matters:

```
select toPt(<id of concept>)
```

Note: Care should be taken to avoid situations where this function is invoked in high volumes as this will negatively impact on performance. In such cases, joining to the `v3_ss_pts` table is advised.

5.4 Derived model

Queries based on the basic schema used so far tend to become verbose, repetitive and difficult to maintain when extracting anything but isolated pieces of data from the AMT model. For complex queries, it is often useful to create a customised schema to provide fast and efficient access to the specific data required for the scenario(s).

The following sections attempt to illustrate the AMT data extraction requirements required to satisfy the core prescribe and dispense use cases. In the main, these use cases are focused on searching MPs, MPPs and TPPs. Some additional derived tables have been created to demonstrate this, and are discussed before delving into the use case data queries.

5.4.1 Unit of Use

The extraction of the unit of use size and quantity for a given MPP is another good candidate for derived schema. In order to extract that data, a query would need to navigate the MPP HAS MPUU relationship, the MPUU HAS UNIT OF USE relationship, the *Unit of use size reference set* and the *Unit of use quantity reference set*. By writing this query once to populate a derived schema table, the task of creating business queries to extract unit of use data is greatly simplified. An example of this query for an MPP is shown below:

```
select  
    MPPhasMPUU.sourceId as mppid,  
    toPt(MPPhasMPUU.sourceId) as mppterm,  
    MPPhasMPUU.destinationId as mpuuid,  
    toPt(MPPhasMPUU.destinationId) as mpuuterm,  
  
    hasUnitOfUse.destinationId as unitofuseid,
```

```

toPt(hasUnitOfUse.destinationId) as unitofuseterm,

uouSize.operatorid as sizeoperatorid,
toPt(uouSize.operatorid) as sizeoperatorterm,
uouSize.value as sizevalue,
uouSize.unitid as sizeunitid,
toPt(uouSize.unitid) as sizeunitterm,

uouQty.operatorid as quantityoperatorid,
toPt(uouQty.operatorid) as quantityoperatorterm,
uouQty.value as quantityvalue,
uouQty.unitid as quantityunitid,
toPt(uouQty.unitid) as quantityunitterm
from rf2_ss_relationships MPPhasMPUU

left outer join rf2_ss_relationships hasUnitOfUse
  on MPPhasMPUU.destinationId = hasUnitOfUse.sourceId
  and MPPhasMPUU.sourceId in (select id from v3_mpp)
  and MPPhasMPUU.destinationId in (select id from v3_mpuu)
  and hasUnitOfUse.typeId = 30548011000036101 -- has unit of use
  (relationship type)
  and hasUnitOfUse.active = 1

join rf2_ss_unit_of_use_size_refset uouSize
  on hasUnitOfUse.id = uouSize.referencedcomponentid
  and uouSize.active = 1

join rf2_ss_unit_of_use_quantity_refset uouQty
  on MPPhasMPUU.id = uouQty.referencedcomponentid
  and uouQty.active = 1

where MPPhasMPUU.typeId = 30348011000036104
  and MPPhasMPUU.sourceId = 26535011000036103 -- ethinyloestradiol 35
microgram + norethisterone 1 mg tablet, 84 [4 x 21]
  and MPPhasMPUU.active = 1
;
-- ethinyloestradiol 35 microgram + norethisterone 1 mg tablet, 84 [4 x 21]

```

Examining this in a little more detail, for a known MPP concept (26535011000036103), the query:

- finds all HAS MPUU relationships for that MPP;
- for each MPUU identified, the query joins to the snapshot relationships table to find the HAS UNIT OF USE relationship for that MPUU; and finally
- the query joins to the v3_unit_of_use_size_refset table to find the reference set member which relates to the HAS UNIT OF USE relationship above.

The insert-select statement which queries the basic schema to populate the v3_unit_of_use table (schema/derived-model/importTables.sql) is based on the query structure described above, and allows that query to be rewritten as:

```
select * from v3_unit_of_use where mppid = 26535011000036103
```

5.4.2 Ingredient Strength

The extraction of the ingredients and their respective strengths for a given MPP is another good candidate for a derived schema. In order to extract that data, a query

would need to navigate the MPP HAS MPUU relationship, the MPUU HAS INTENDED ACTIVE INGREDIENT relationship, the MPUU HAS AUSTRALIAN BoSS relationship, and finally the *Strength reference set*. By writing this query once to populate a derived schema table, the task of creating business queries to extract ingredient strengths is greatly simplified. An example of this query is shown below:

```
select
  MPPhasMPUU.sourceId as mppid,
  toPt(MPPhasMPUU.sourceId) as mppterm,
  MPPhasMPUU.destinationid as mpuid,
  toPt(MPPhasMPUU.destinationid) as mpuuterm,
  hasIngredient.destinationid as substanceid,
  toPt(hasIngredient.destinationid) as substanceterm,
  hasBoSS.destinationid as bossid,
  toPt(hasBoSS.destinationid) as bossterm,
  strength.operatorid as operatorid,
  toPt(strength.operatorid) as operatorterm,
  strength.value as strengthvalue,
  strength.unitid as unitid,
  toPt(strength.unitid) as unitterm
from rf2_ss_relationships MPPhasMPUU

join rf2_ss_relationships hasIngredient
  on MPPhasMPUU.destinationId = hasIngredient.sourceId
  and MPPhasMPUU.sourceId in (select id from v3_mpp)
  and MPPhasMPUU.destinationId in (select id from v3_mpuu)
  and MPPhasMPUU.typeId = 30348011000036104 -- has MPUU (relationship
type)
  and MPPhasMPUU.active = 1
  and hasIngredient.typeId = 700000081000036101 -- has intended active
ingredient (attribute)
  and hasIngredient.active = 1

join rf2_ss_relationships hasBoSS
  on hasIngredient.sourceId = hasBoSS.sourceId and
hasIngredient.relationshipgroup = hasBoSS.relationshipgroup
  and hasBoSS.typeId = 30364011000036101 -- has Australian BoSS
(relationship type)
  and hasBoSS.active = 1

left outer join rf2_ss_strength_refset strength
  on hasBoSS.id = strength.referencedcomponentid
  and strength.active = 1
where MPPhasMPUU.sourceId = 26535011000036103 -- ethinyloestradiol 35
microgram + norethisterone 1 mg tablet, 84 [4 x 21]
```

Note that the strengths returned by this query are normalised to a denominator of one, as expressed in the *Strength reference set*. To obtain the strengths as represented in the MPUU descriptions, please refer to the technique described in Section 5.4.3.

Examining this in a little more detail, for a known MPP concept (26535011000036103), the query:

- Joins to the snapshot relationships table to find any HAS MPUU relationships for that MPP.
 - For each MPUU identified (as the destination of the HAS MPUU relationship), the query joins to the snapshot relationships table to find any HAS INTENDED ACTIVE INGREDIENT relationships for that MPUU.

- The query then joins to the snapshot relationships table to find the HAS AUSTRALIAN BoSS relationship from the same MPUU **with the same relationshipgroup** as the HAS INTENDED ACTIVE INGREDIENT relationship above.

Note: the BoSS is the substance used to express the strength of an active MPUU ingredient, which *may* differ from the active component of the substance. For example:

- HAS INTENDED ACTIVE INGREDIENT = Dexamphetamine (base)
- HAS AUSTRALIAN BoSS = Dexamphetamine sulfate (salt)
- Finally, the query joins to the `v3_strength_refset` table to find the *Strength reference set* member which relates to the HAS AUSTRALIAN BoSS relationship above.

The `insert-select` statement, which queries the basic schema to populate the `v3_ingredient_strength` table (`schema/derived-model/importTables.sql`), is based on the query structure described above, and allows that query to be rewritten as:

```
select * from v3_ingredient_strength where mppid = 26535011000036103
```

5.4.3 Combining *Strength* and *Unit of use size*

The extraction of the total quantity of each ingredient contained in an MPUU (or deriving the human friendly, denormalised strength as displayed in MPUU terms) is another query added to the derived schema.

This query combines the *Strength reference set* with the *Unit of use size reference set*, and may be used to determine:

- The total quantity of an ingredient in the MPUU – for example if the strength is “15 mg/mL” and the unit of use size is “20 mL” then the total ingredient quantity in the MPUU is 300 mg.
- The denormalised strength as represented in the MPUU descriptions, which are always based on the unit of use size. For example if the strength is “15 mg/mL” and the unit of use size is “20 mL” then the strength represented in the MPUU description will be “300 mg / 20 mL”.

In order to extract that data, a query would need to navigate:

- the MPUU HAS AUSTRALIAN BoSS relationship;
- the MPUU HAS UNIT OF USE relationship;
- the *Strength reference set*;
- the *Unit of use size reference set*; and
- the *Composite unit of measure* relationships HAS NUMERATOR UNITS and HAS DENOMINATOR UNITS.

By writing this query once to populate a derived schema table, the task of creating business queries to extract ingredient strengths is greatly simplified. An example of this query is shown below:

```
select
  strength.mpuuid as mpuuid,
  strength.mpuuterm as mpuuterm,
  strength.bossid as bossid,
  strength.bossterm as bossterm,
```

```
strength.strengthvalue as strengthvalue,  
strength.unitid as strengthunitid,  
unitterm as strengthunitterm,  
substanceid as activeingredientid,  
substanceterm as activeingredientterm,  
sizevalue as sizevalue,  
sizeunitid as sizeunitid,  
sizeunitterm as sizeunitterm,  
round(strength.strengthvalue * sizevalue, 6) as totalquantity,  
hasNumeratorUnits.destinationid as totalquantityunitid,  
toPt(hasNumeratorUnits.destinationid) as totalquantityunitterm  
from v3_ingredient_strength strength  
join v3_unit_of_use uousize  
    on strength.mpuuid = uousize.mpuuid  
  
join rf2_ss_relationships hasNumeratorUnits  
    on strength.unitid = sourceId  
    and typeid = 700000091000036104  
    and active = 1  
where strength.mpuuid = 22148011000036103;
```

Examining this in a little more detail, for a known MPUU concept (22148011000036103), the query:

1. Identifies the ingredients and strength using the derived `v3_ingredient_strength` table.
2. Joins to the snapshot derived `v3_unit_of_use` table to find the HAS UNIT OF USE relationship for that MPUU, along with the associated *Unit of use size* and *Unit of use quantity*.
3. Joins to the snapshot relationships table to find the HAS NUMERATOR UNITS relationship for the *Composite unit of measure* concept identified by the *Strength reference set* member above.
4. Multiplies the strength value by the *Unit of use size* value to compute the total ingredient quantity (rounded to six decimal places).

Both the HAS AUSTRALIAN BoSS and HAS INTENDED ACTIVE INGREDIENT relationships are required as the strength of the intended active ingredient is expressed in terms of the BoSS. That is:

- the HAS INTENDED ACTIVE INGREDIENT identifies the intended ingredient in the medication; and
- the HAS AUSTRALIAN BoSS identifies the substance that the strength of the ingredient is expressed in terms of.

Refer to Sections 2.3.5.1 and 2.3.6.9 for more details on strength representation and BoSS.

The `insert-select` statement which queries the basic schema to populate the `v3_ingredient_strength` table (schema/derived-model/importTables.sql) is based on the query structure described above, and allows that query to be rewritten as:

```
select * from v3_total_ingredient_quantity where mpuuid = 22148011000036103;
```

Note: There is some inconsistency in the AMT data with respect to the way that unit of use size has been modelled, which means that for some MPUU concepts the total ingredient quantity cannot be reliably calculated. This affects some injections and powders.

As an example, consider the MPUU 22420011000036103

- sodium bicarbonate 1.76 g + citrate sodium anhydrous 630 mg + citric acid 720 mg + tartaric acid 890 mg oral liquid: powder for, 4 g sachet

The *Unit of use size* of this example is represented as “4 g”, whereas it should be “1 sachet”. As a result, the total ingredient quantity calculated for this MPUU for ingredient citric acid is actually 2880 mg, instead of 720 mg. This issue has not been resolved at the time of writing.

5.5 Sample queries by use case

Having introduced the basic RF2 schema and the derived model tables, the following sections look at how these tables, views and procedures can be used to extract data to fulfil the core AMT use cases – prescribing and dispensing. For further details on the content of these use cases, please refer to the *AMT Survey Results and Roadmap* (NEHTA, 2012).

The queries discussed in this section are contained in `sql/use-cases.sql`.

5.5.1 Queries to support the Prescribing use case

The prescribing use case in the *AMT Survey Results and Roadmap* (NEHTA, 2012) states that in prescribing medications, *the “prescribing system software searches for products based on AMT MPUU, MPP, TPUU, TPP & CTPP”*. For simplicity, the derived model used in these samples primarily focuses on prescribing by MPP and TPP. The product pack level has been chosen as it strikes a good balance between illustrating the product components, within the context of the v3 model, and targeting a level of refinement that is most intuitively prescribable. Where prescription by CTPP, MPUU or TPUU is required, these samples can be easily adapted via the relationships from, and between, MPP, TPP and CTPP.

In the following example, the prescriber has decided to prescribe amoxycillin, and has entered the characters “a m o x” into the medications search field of their prescribing system. While this is a simplified example, a real world implementation would likely dynamically query and refine these results as the user types each character. Further consideration to performance would also be required. For the intent of this example we will illustrate a simple, transactional, text search.

The system will display a list of MPPs and TPPs for which their Preferred Term contains a word commencing with the characters “amox” or they contain a substance for which its Preferred Term commences with the characters “amox”. The majority of the task can be achieved by simply querying the derived model tables `v3_mpp_to_tpp` and `v3_ingredient_strength` as follows:

```
select
  v3_mpp_to_tpp.mppid,
  v3_mpp_to_tpp.mppterm,
  v3_mpp_to_tpp.tppid,
```

```
v3_mpp_to_tpp.tppterm
from v3_mpp_to_tpp
join v3_ingredient_strength
on v3_mpp_to_tpp.mppid = v3_ingredient_strength.mppid
where v3_ingredient_strength.substanceterm regexp (

    @search_term:='(^|^[^a-zA-Z]+)amox' collate utf8_unicode_ci

)
or v3_mpp_to_tpp.mppterm regexp @search_term
or v3_mpp_to_tpp.tppterm like @search_term
;
```

The above query makes use of the derived model mentioned above. It primarily searches the `v3_ingredient_strength` table as it is already populated with terms for the MPPs, MPUUs and substances within them. We additionally join to the `v3_mpp_to_tpp` table to provide the ability to search the Preferred Term of the TPP (in the case where the user has entered some trade/brand specific text). The query then performs the search on the relevant terms.

You will note that the query uses a regular expression for the search criteria. This has been used as a concise form of querying any term beginning with (^) or containing a word beginning with ([^a-zA-Z]+), followed by the text "amox". Additionally, a user-defined parameter "@search_term" has been used for brevity.

5.5.2 Queries to support the Dispensing use case

The dispensing use case states that in choosing medications, the product selections are "based on TPP concepts", and that the dispenser "dispenses and supplies the medication in accordance with the prescription presented by the patient".

In the following example, the prescription is for the AMT concept 12809011000036105, which is a TPP concept with the Preferred Term "Amoxil 250 mg capsule: hard, 20 capsules". The prescription indicates that a generic alternative is acceptable.

The dispensing system must find the generic form of the prescribed medication (MPP), and then find all TPPs which are associated with that MPP²⁹. Using the derived model table `v3_mpp_to_tpp`, a simple query can be written to present a list of appropriate TPPs for dispensing. The query goes further to also return all CTPPs that are associated with those TPPs.

```
select
    tpp1.tppid as originaltppid,
    tpp1.tppterm as originaltppterm,
    substitutetpp.tppid as substitutetppid,
    substitutetpp.tppterm as substitutetppterm,
    ctpps.sourceid as substitutectpp,
    toPt(ctpps.sourceid) as substitutectppterm

from v3_mpp_to_tpp tpp1
join v3_mpp_to_tpp substitutetpp
on tpp1.mppid = substitutetpp.mppid and tpp1.tppid != substitutetpp.tppid
and tpp1.tppid = 12809011000036105 -- Amoxil 250 mg capsule: hard, 20
join rf2_ss_relationships ctpps
on substitutetpp.tppid = ctpps.destinationid
```

²⁹ Note that AMT v3 does not provide bio-equivalence.

```

    and ctpps.sourceId in (select id from v3_ctpp)
order by originaltppterm, substitutetppterm
;

```

In the above query, the first join-select finds the MPP associated with the prescribed TPP, and the whole range of TPPs associated with these. The second join identifies the corresponding CTPP(s) to the dispenser from the relationships table.

5.6 Additional queries

5.6.1 Extracting dose form

An MPP forms the aggregation of one or more MPUUs, with the addition of pack quantities. Each MPUU has a *manufactured dose form* associated with it. While the extraction of dose form does not directly address the core use cases for v3, it *may* help decision support at the time of both prescribing and dispensing.

The query below seeks to extract each of the substances associated with the MPUUs contained within four sample MPPs. For each substance, the query returns its manufactured dose form for that MPUU.

Note that for some products the TPUU *Form* is different (more specific) to the MPUU *Form*. The query below can be amended to take into account TPUU HAS MANUFACTURED DOSE FORM relationships instead.

```

select
  v3_ingredient_strength.mppid,
  v3_ingredient_strength.mppterm,
  v3_ingredient_strength.bossterm,
  toPt(hasDoseForm.destinationid)
from v3_ingredient_strength

  join rf2_ss_relationships hasDoseForm
    on hasDoseForm.sourceid = v3_ingredient_strength.mpuuid
    and hasDoseForm.typeid = 30523011000036108 -- has manufactured dose
form (relationship type)
    and hasDoseForm.active = 1

where v3_ingredient_strength.mppid in (
  26624011000036107, -- 'amoxycillin 100 mg/mL oral...'
  51572011000036101, -- 'goserelin 3.6 mg implant [...]'
  26781011000036107, -- 'peginterferon alfa-2a 135 ...'
  28051011000036109 -- 'peginterferon alfa-2b 150 ...'
)
;

```

Table 35: Results from a sample query that extracts MPP concepts and their associated dose forms

MPP ID	MPP PT	Substance	Dose Form
26624011000036107	amoxycillin 100 mg/mL oral liquid: powder for, 20 mL	amoxycillin	oral liquid: powder for
26781011000036107	goserelin 3.6 mg implant [1] (&) bicalutamide 50 mg tablet [28], 1 pack	goserelin	implant
26781011000036107	goserelin 3.6 mg implant [1] (&) bicalutamide 50 mg tablet [28], 1 pack	bicalutamide	tablet

MPP ID	MPP PT	Substance	Dose Form
28051011000 036109	peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [112], 1 pack	peginterferon alfa-2a	injection
28051011000 036109	peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [112], 1 pack	ribavirin	tablet
51572011000 036101	peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [196 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	peginterferon alfa-2b	injection
51572011000 036101	peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [196 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	ribavirin	capsule

6 Additional guidance, requirements and test cases on adopting clinical terminologies

NEHTA has published guidance material in relation to implementing the AMT and SNOMED CT-AU clinical terminologies. Some material are general in nature and covers requirements common to both terminologies, while others are specific to the AMT.

6.1 Mapping implementation

The *AMT Mapping Guidelines* (NEHTA, 2012) provides guidelines for mapping local and proprietary medicine coding systems to the AMT.

6.2 Use of terminology in healthcare software

Requirements and additional guidance for terminology use within mapping or native implementations that is common to both SNOMED CT-AU and AMT can be found at [AMT v3 - Common](#)³⁰ on the NEHTA website. Requirements may be mandatory, optional or conditional. The documents include:

- *Clinical Terminology - Guidance for People and Processes* (NEHTA, 2014):
 - Provides guidance for those involved in adopting the AMT or SNOMED CT-AU.
 - This guidance may be used to minimise clinical safety risks and maximise the benefits associated with using AMT or SNOMED CT-AU.
- *Clinical Terminology - Guidance for Use in Healthcare Software* (NEHTA, 2014):
 - Provides guidance for managing risks when implementing AMT or SNOMED CT-AU in healthcare software.
 - This guidance complements the software requirements provided by other e-health specifications.

6.3 Use of terminology in clinical information exchange

One of the AMT's intended uses is to support semantic interoperability between clinical systems. These systems can have different implementation types, be it a mapping or native adoption of the AMT and SNOMED CT-AU.

Requirements and additional guidance for use within mapping or native implementations and exchange of terminology encoded information that is common to both SNOMED CT-AU and AMT can be found at [AMT v3 - Common](#).³¹ Requirements may be mandatory, optional or conditional. The document includes:

³⁰ <http://www.nehta.gov.au/implementation-resources/ehealth-foundations/australian-medicines-terminology-common>.

³¹ See note 30.

- *Clinical Terminology - Use of Medical Nomenclatures in Information Exchange* (NEHTA, 2014):
 - Provides guidance for healthcare software systems that produce and consume clinical messages containing medical nomenclatures.
 - This guidance helps software developers to manage risks when developing healthcare software systems using medical nomenclatures for the purpose of supporting healthcare delivery through the exchange of clinical information.
 - This guidance also complements the requirements provided by other e-health specifications.

NEHTA has also developed e-health specifications for the sharing of clinical information between different healthcare domains and with the Personally Controlled Electronic Health Record (PCEHR). Some examples are eDischarge Summary, eReferral, Prescription and Dispense Records and Shared Health Summary. The [Clinical Documents](https://www.nehta.gov.au/implementation-resources/clinical-documents)³² page in the NEHTA website provides links to these e-health specifications.

6.4 Test cases

When implementing the AMT it is imperative to test whether the data implemented in the system matches the original AMT data. Typically this is achieved by running procedures suitable for your application of AMT and then checking the results for a range of AMT concepts against the original AMT source data loaded into the system.

The following test cases are available to assist implementers in checking their implementation against the requirements as identified in the Clinical Terminology guidance documents mentioned above:

- *Clinical Terminology - Tests for Use in Healthcare Software*
- *Clinical Terminology – Tests for Use of Medical Nomenclatures in Information Exchange*

These test cases are contained within the *Clinical Terminology – Test Cases for Software and Messaging* bundle (NEHTA).

A document providing supplementary information for the test cases is also included within the bundle.

³² <https://www.nehta.gov.au/implementation-resources/clinical-documents>

7 Implementation considerations

This chapter provides specific guidance on key facets for consideration when embarking on an AMT implementation.

7.1 The AMT's purpose and scope

An important consideration when implementing the AMT is to recognise the AMT's intended purpose and corresponding limitations. The AMT is a terminology, not a medicines database; therefore depending upon how the AMT is being used, it may be necessary to use the AMT in conjunction with knowledge-support and decision-support data and functionality.

If this is necessary it will involve either mapping to existing medicine data files, or creating new data files using AMT as a base, and then authoring or procuring additional medicine data to support the intended use. It is not the purpose of this guide to provide specific guidance on additional knowledge and decision support data. However some additional information can be found in the *AMT Mapping Guidelines* (NEHTA, 2012).

Examples of content not provided by AMT, but provided by other medicines data files are:

- Physiological equivalence
- Adverse effects
- Counselling instructions
- Cautionary and advisory label recommendations
- Contraindications
- Dose checking
- Drug-Drug interactions
- Drug-Allergy interactions
- Drug-Food interactions
- Indications
- Normal dose ranges
- Precautions for use
- Storage or supply chain related information

7.1.1 Medicines out of AMT's scope

The AMT is intended to cover products commonly used for human treatment in Australia. There are certain known limitations, including but not limited to:

- Clinical trial medicines
- Local specially-manufactured medicines
- Extemporaneous preparations (although the AMT currently contains the standard formula preparations, as included in the PBS)
- Medical devices (although AMT currently contains some medicated devices such as bandages, as included in the PBS)

- Blood and blood-derived products

The AMT may not include all medicines or products that are required for use across all possible local care settings. Local clinical systems will still need to be able to manage local codes and descriptions, alongside their use of the AMT. This functionality is already present in local systems and drug file management.

NEHTA welcomes requests for additions or changes to AMT content. Refer to the Request Submission process as identified on the NEHTA website³³.

7.2 Clinical safety

To support the clinically safe use of AMT in clinical information systems, system developers, vendors and healthcare organisations need to:

- Ensure that they utilise standards and industry best practice when developing and implementing their systems.
- Conduct clinical safety activities to effectively assess the clinical risks during their testing and deployment phases.
- Ensure that effective implementation of controls are in place to reduce clinical risk.

Note: If the AMT concept identifier is not available, local codes in a system should suffice to trigger any relevant decision support alerts where required.

7.3 Product availability

Initial inclusion of a medicine product in AMT is based on its registration by a sponsor with the TGA's ARTG. However this does not mean the product is available in the Australian supply chain.

Equally, when a product is removed from the supply chain and no longer available for sale, the corresponding AMT concepts are not retired or deprecated (that is, they remain as active). This is because AMT is a terminology describing known concepts, not a product database. The concepts are still needed to support existing health records (for example, past medical history) or e-health messages regardless of the current availability of the product.

Product availability information must be sourced outside of the AMT.

7.4 Synonyms

From November 2015, the AMT release includes synonyms (or alternate names) for some AMT concepts. For example, the substance concept 2153011000036108 |*frusemide (AU substance)*| will have a synonym of "furosemide" and the Medicinal Product concept 21329011000036103 |*frusemide (medicinal product)*| will have a synonym of "furosemide".

These synonyms are distinguishable from their Preferred Terms by using the *Australian dialect reference set*, whereby the synonyms are annotated with an acceptabilityId of 900000000000549004 |*Acceptable*| while the Preferred Terms are annotated with an acceptabilityId of 900000000000548007 |*Preferred*|.

³³ This can be accessed via the link <http://www.nehta.gov.au/our-work/clinical-terminology/request-submission-product-content-changes>.

Other AMT concepts that include the term “frusemide” in their descriptions have no acceptable synonyms added such as Medicinal Product Unit of Use (MPUU) and Medicinal Product Pack (MPP) concepts.

7.5 AMT and SNOMED CT Substance concepts

Substance concepts used in the AMT are unique to the AMT, and are a different set of concepts than used by the International Edition of SNOMED CT or the Australian extension SNOMED CT-AU.

This is partially due to the AMT’s parallel development to SNOMED CT, and partially due to a concern at the time of creation of the AMT that anticipated future changes to the SNOMED CT *Substance* hierarchy may destabilise the AMT.

Implementers of the AMT should note this separation, and use AMT substances for AMT-related activity. The NCTIS publishes a map between AMT substances and SNOMED CT substances. Refer to Section 2.3.5.6 for further information on this map.

Note that use of the map to integrate AMT with SNOMED CT substances may result in incorrect inferences. This is due to known modelling issues in the SNOMED CT *Substance* hierarchy which are being addressed by an IHTSDO project. However, until this work is completed and the International Edition of SNOMED CT is updated, care must be taken when using the AMT *Substance* to SNOMED CT-AU mapping.

Please also note that AMT substances do not contain non-medicinal allergens; these must be sourced from SNOMED CT-AU.

7.6 CTPP versus TPP

When choosing whether to use CTPP or TPP concepts, or both, in an implementation it is important to consider the implementation’s use cases.

Where references to trade packs are required without specifying the container type, TPP concepts should be used. For example, pack-based prescribing usually requires specifying a product pack, however it is unnecessary to specify a container. Presenting users with a variety of container-based variations of a pack (bottle, blister pack and so on.) may frustrate users with irrelevant options and slow data entry unnecessarily.

However under some circumstances, clinicians may need to specify particular containers when prescribing. Similarly the more specific CTPP concept is required when recording a specific dispensed medication, for example when recording a medication dispensed from a community pharmacy via barcode scanning.

Therefore it is necessary to analyse system requirements before choosing when CTPP concepts, TPP concepts, or both are appropriate.

7.7 Parsing descriptions

The descriptions contained in the AMT are structured according to editorial rules, as defined in the *AMT v3 Model Editorial Rules* (NEHTA, 2014).

While AMT’s descriptions are very structured, they are not intended to be parsed into smaller components. Parsing AMT descriptions presents risk and is strongly discouraged. Required atomic data should be sourced from the appropriate source

within the AMT model. For examples of extracting ingredient strengths, please refer to Section 5.4.2.

7.8 Field length

There is a maximum field length of 2,048 characters specified for the term field in AMT. However in practice the current longest AMT terms are just over 1,000 characters. Depending upon the section of AMT content being used, the longest terms actually present in AMT may be significantly shorter than this limit.

As an indication, the mean length of AMT 20140630 release active Preferred Terms is 50.46 characters, the median is 48 characters and the mode is 50 characters. Of the AMT 20140630 release active Preferred Terms, 95% are less than 93 characters.

The graph below shows the distribution of active Preferred Term lengths in the AMT June 2014 Production release.

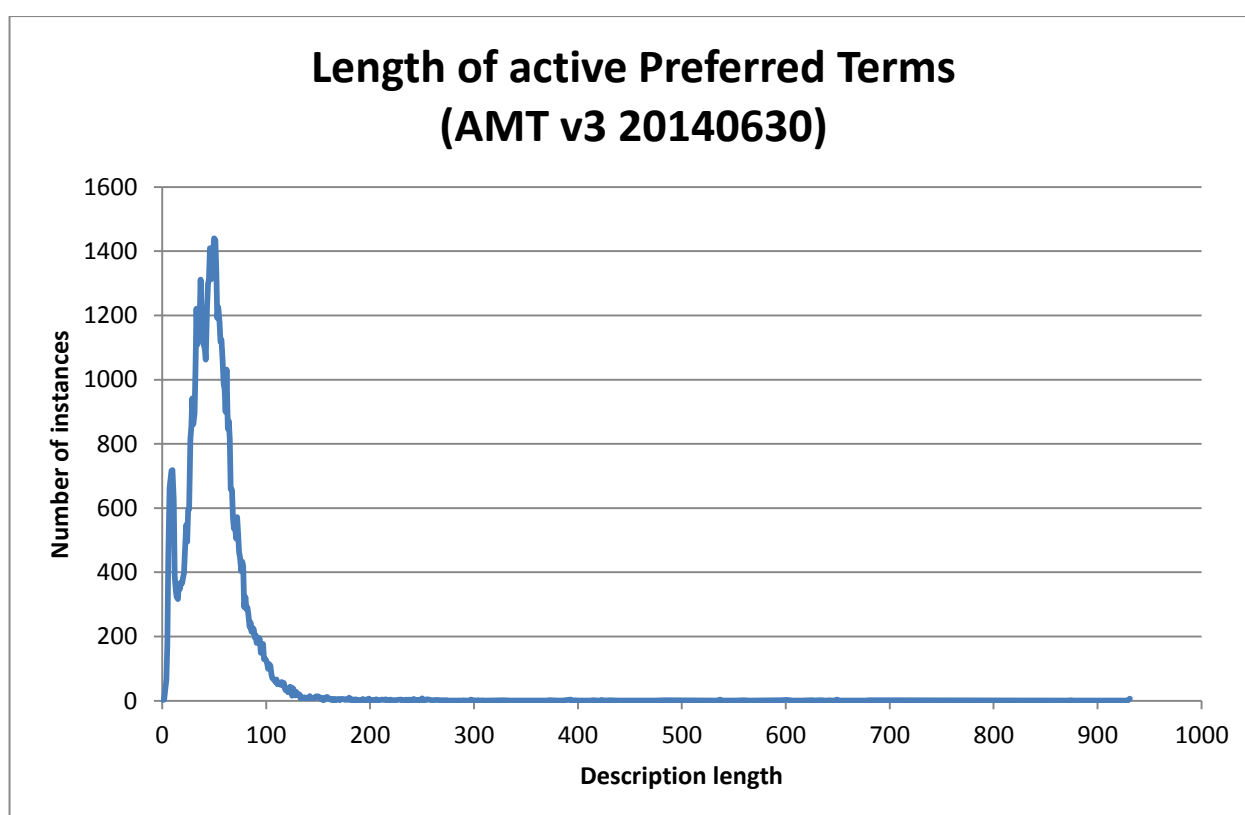


Figure 42: Active Preferred Term lengths in the AMT June 2014 Production release

System developers allocating less than 2,048 characters are advised to check the release files for the maximum description length for the AMT content they use on a per-release basis. This will help ensure that no truncation of AMT descriptions occurs, as truncation may be clinically unsafe.

Any field length restriction for an application that results in truncation of AMT descriptions should lead to a discussion with the NCTIS for implementation guidance and clinical safety considerations.

Assessment and potential development of clinical interface descriptions for AMT concepts is included in the *AMT Survey Results and Roadmap* (NEHTA, 2012), which will also consider label names, sort order and ingredient order.

7.9 Modifying or extending the AMT

7.9.1 Modifying the AMT

Similar to the use of SNOMED CT, AMT content may not be modified. This includes AMT concepts, descriptions, relationships and reference sets.

AMT's integrity must be maintained as distributed when it is implemented into local systems. That is, relationships between AMT concepts, codes and descriptions will not be edited or distorted in use.

This restriction also precludes editing any AMT description while it remains linked to its associated AMT code. If an AMT concept is not suitable for use for any reason, it should be discarded in its entirety and a local concept used in its place.

7.9.2 Extending the AMT

It is possible to extend the AMT, in much the same way that it is possible to extend SNOMED CT.

The simplest type of extension is to develop custom reference sets of AMT content for specific purposes. The AMT is published with seven reference sets, one for each of the "notable concept classes" which contains all active AMT content from these classes. These reference sets are provided as a convenience; however other more refined reference sets may be useful in specific implementations.

Adding Synonyms to AMT concepts is another simple extension, short names for example. Although use of distributed AMT descriptions should be the default approach, in some situations alternate text may be required. In this case it is possible to add new Synonyms to AMT concepts as required. Note that the *Australian dialect reference set* provided with the AMT will need to be extended if the additional Synonyms are to be considered the Preferred Term in this setting.

It is also possible to add additional concepts to AMT in an extension. This process is not trivial, however it allows implementers to add concepts required at a local level that are not applicable nationally.

Implementers may apply for a SNOMED CT namespace identifier should they wish to author and maintain their own SNOMED CT-based terminology content or extension (that is, content that is beyond the AMT and SNOMED CT-AU national terminologies). Refer to the following IHTSDO link for more details:

<http://www.ihtsdo.org/snomed-ct/change-or-add-snomed-ct>

Concepts may also be added to a local extension that are later ultimately required nationally. However it must be noted that if/when these concepts are authored in AMT, there is additional work for the local extension to identify the local and national identifiers as co-referent and cease modifications of the concept. If the final AMT modelling differs from the extension modelling, this process is further complicated. For these reasons it is usually preferable to request nationally applicable content from the NCTIS and wait for it to be present in the AMT if possible.

It is recommended that users wishing to create extensions to the AMT contact the NCTIS³⁴ for guidance and assistance.

³⁴ See Section 1.6.

7.10 ARTG identifiers

AMT v2 was distributed with ARTG Id descriptions on each CTPP concept. These descriptions provided the ARTG identifier for each CTPP concept in AMT v2.

While the ARTG Id description type has been removed in AMT v3, the same ARTG Id strings are included as an additional, non-defining Simple Map reference set. Refer to Section 2.3.5.7 for more information.

7.11 Sponsor information

AMT v2 had a series of “sponsor” concepts which represent the sponsor organisations registered with medicines products on the ARTG. These sponsor concepts were associated with the TP concepts in AMT v2, so it was possible to identify the sponsor for a trade medication using AMT v2.

Sponsors have been removed from the AMT v3 model as they were not required to support AMT use cases. Access to sponsor information for medications is available via the ARTG.

7.12 Description types

AMT contains two different types of description:

- Fully Specified Name
- Synonym

Fully Specified Names are formal descriptions of each concept and **should not** be rendered to normal clinical end users in a system. Fully Specified Names however may be used to map between local or proprietary code sets and AMT.

Synonyms are intended to be used by end users. Some Synonyms are identified in the *Australian dialect reference set* as “preferred” and others “acceptable”, which indicate their preferred use in Australia. Other language reference sets express preferences in different locations/contexts.

- “Preferred” Synonyms (also known as Preferred Terms) are intended to be rendered to end users when selecting a concept.
- “Acceptable” Synonyms are intended to be used when searching for a concept, but not used as the text presented as an option for a user to select when entering data.

Refer to Section 3.1.7 for more on Language reference sets.

7.13 AMT and PBS data

As of December 2012, PBS data includes AMT concept identifiers and Preferred Terms for MP, MPUU, MPP, TPUU and TPP. The Pharmaceutical Benefits Division is planning to increase their AMT adoption, which will eventually encompass other AMT concepts beyond those mentioned.

AMT MPUU and TPUU concepts are used to represent chemotherapy items as included in the PBS.

Where an AMT concept is not available or does not meet PBS needs, a non-AMT PBS identifier is generated. These concept identifiers include a PBS-specific SNOMED CT namespace identifier of “1000144”, as seen in the identifier

57291000144108. These concepts are published within the PBS data outputs and are maintained by the PBD.

For further information on the PBS implementation of AMT data, see the NEHTA AMT-PBS FAQs³⁵ and *Pharmaceutical Benefits Scheme (PBS)* (Pharmaceutical Benefits Scheme, 2012).

7.14 Identifiers

7.14.1 UUID

Conformant to RF2, AMT uses SNOMED CT Identifiers for identification of all components other than members of reference sets which are identified using UUIDs.

UUIDs previously used in AMT v2 as alternative identifiers for components (concepts, descriptions and relationships) have been carried forward into AMT v3 for backward compatibility. UUIDs for AMT v2 components can be found in the AMT v3 Identifiers file (refer to Section 3.1.5) traceable to the component. Components newly generated in AMT v3 do not have these additional UUIDs.

7.14.2 SNOMED CT identifier

SNOMED CT Identifiers do have a structure, built up of a namespace, sequence, partition identifier and check digit. This is explained in Section 4.3.2 "Representing SNOMED CT Identifiers" of the *SNOMED TIG* (IHTSDO, 2014).

While SNOMED CT Identifiers are constructed in this manner, the structure of SNOMED CT Identifiers should not be used to infer any meaning. Elements making up SNOMED CT Identifiers are included for infrastructural purposes, such as namespaces used to avoid collisions and to enable the decentralised allocation of SNOMED CT Identifiers. SNOMED CT Identifiers should be treated as an opaque, unique identifier.

All AMT v2 components that are included in v3 data will retain their SNOMED CT identifier, which has namespace identifier of "1000036" for example, 19838011000036104. As of the first AMT v3 release (20140630), most of the newly created components (such as new concepts, descriptions, and relationships) will have a new namespace identifier of "1000168" within their SNOMED CT identifier for example, 1532451000168124. Some new AMT v3 components will retain the original "1000036" namespace identifier.

Finally, SNOMED CT Identifiers should not be rendered to users of clinical systems. Although used in data structures and records, typical users should never see SNOMED CT Identifiers.

7.15 Identifying versions of AMT releases

When storing and using AMT v3 component identifiers (for example, in clinical documents, maps, or terminology servers) the following string should be used to identify the version of the release:

```
"http://snomed.info/sct/{moduleId}/version/{effectiveTime}"
```

³⁵ <http://www.nehta.gov.au/our-work/clinical-terminology/australian-medicines-terminology/amt-pbs-faqs>.

The `effectiveTime` value is derived from the `effectiveTime` of the component from the AMT release files. For example, a component released in the AMT November 2015 release will have an `effectiveTime` value of "20151130".

Before November 2015, the AMT was published as a standalone terminology and all components used the AMT module identifier of |900062011000036108|. An example of the string used to identify a component released in the AMT October 2015 release would be as follows:

```
"http://snomed.info/sct/900062011000036108/version/20151031"
```

From November 2015 the AMT will be included as a formal subset of the SNOMED CT-AU release in preparation for future integration work, and to better support of the usage of terminology within the PCEHR. The combined release will be provided in a single set of RF2 files and both terminologies will use the same SNOMED CT-AU module identifier: 32506021000036107.

The resulting string for a component released in the November 2015 release becomes "http://snomed.info/sct/32506021000036107/version/20151130"

Examples of different encodings of the version of the AMT November 2015 release are displayed below.

7.15.1 HL7 Clinical Document Architecture (CDA)

In a CDA document, the version of this release may be encoded in a Concept Descriptor field named "xyz" using the `codeSystemVersion` attribute as follows:

```
<xyz code="33256011000036105"  
codeSystem="2.16.840.1.113883.6.96"  
codeSystemName="Australian Medicines Terminology (AMT)"  
codeSystemVersion="http://snomed.info/sct/32506021000036107/version/20151130"  
displayName="Lorano 10 mg tablet: uncoated, 30"/>
```

7.15.2 HL7 Fast Healthcare Interoperability Resources (FHIR®)

In FHIR® resources, the version of this release may be encoded in a Coding field named "xyz" using the `version` element as follows:

XML example:

```
<xyz>  
  <system value="http://snomed.info/sct" />  
  <version  
value="http://snomed.info/sct/32506021000036107/version/20151130" />  
    <code value="33256011000036105" />  
    <display value="Lorano 10 mg tablet: uncoated, 30" />  
</xyz>
```

7.15.3 JSON

```
"xyz": [  
  {  
    "system": "http://snomed.info/sct",
```

```

    "version":
    "http://snomed.info/sct/32506021000036107/version/20151130",
    "code": "33256011000036105",
    "display": "Lorano 10 mg tablet: uncoated, 30"
  }
]

```

For further information on the URI standard that governs the application of this versioning, see the *SNOMED CT URI Standard* (IHTSDO, 2014).

7.16 Strength reference set considerations

7.16.1 Sufficiency of floating point strength accuracy

When normalising values to populate the value field of the *Strength reference set* (Section 2.3.5.1), the result includes some real numbers that forever repeat after the decimal point (for example, 0.33333333...). It was determined that up to 13 significant figures are required to arrive at a sufficiently accurate strength value when calculating the non-normalised strength attribute, such as 16666.66666667, 33333.33333333 and 149.25373134.

For example the strength value of the MPUU “epoetin beta 5000 international units/0.3 mL injection, syringe” is “16666.66666667”. This product has a Unit of use size of “0.3 mL”, thus recalculating non-normalised (human readable) strength results in “5000.000000001 international units/0.3 mL” which affords sufficient accuracy.

Note that if arithmetic is performed using AMT floating point strengths, issues relating to rounding of recurring numbers may be encountered and should be taken into account. The following table of MPUUs provides examples which can be used for testing.

MPUU ID	MPUU Preferred BoSS Term	Strength Value	Strength Unit
21995011000036101	epoetin beta 4000 international units/0.3 mL injection, syringe	13333.33333333	international unit/mL
21996011000036108	epoetin beta 5000 international units/0.3 mL injection, syringe	16666.66666667	international unit/mL
22082011000036102	follitropin beta 900 international units/1.08 mL injection, cartridge	833.33333333	international unit/mL

MPUU ID	MPUU Preferred Term	BoSS	Strength Value	Strength Unit
23132011000036108	follitropin beta 300 international units/0.36 mL injection, cartridge	follitropin beta	833.33333333	international unit/mL
23133011000036101	follitropin beta 600 international units/0.72 mL injection, cartridge	follitropin beta	833.33333333	international unit/mL
23315011000036101	anakinra 100 mg/0.67 mL injection, syringe	anakinra	149.25373134	mg/mL
82931011000036102	epoetin beta 200 microgram/0.3 mL injection, syringe	epoetin beta	666.66666667	microgram/mL
82932011000036108	epoetin beta 100 microgram/0.3 mL injection, syringe	epoetin beta	333.33333333	microgram/mL
82935011000036100	epoetin beta 50 microgram/0.3 mL injection, syringe	epoetin beta	166.66666667	microgram/mL
933220001000036107	benzathine benzylpenicillin 1.2 million units/2.3 mL (900 mg/2.3 mL) injection, syringe	benzathine benzylpenicillin	391.30434783	mg/mL
23019011000036103	oestradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hour patch	norethisterone acetate	10.41666667	microgram/hour
45136011000036102	lignocaine hydrochloride anhydrous 2% (36 mg/1.8 mL) + adrenaline 1 in 80 000 (27.5 microgram/1.8 mL) injection, cartridge	adrenaline	15.27777778	microgram/mL

7.16.2 Unit conversion

Unit conversion occurs in the *Strength reference set* when different MPUU concepts share the same BoSS (that is, have the same destination *Substance* for the HAS AUSTRALIAN BoSS relationship), and different strength units are used (for example, “microgram/mL” and “mg/mL”). A single unit of measure is chosen to represent the strength for this set of MPUUs (for example, only to “mg/mL”). This is to allow easier automated strength comparisons across similar products in the absence of machine-computable unit conversion factors.

This normalisation of units of measure does not affect MPUU (and other) descriptions, where they may represent the strength in the most useful form to humans that is equivalent to the machine representation in the *Strength reference set*.

The table below describes an example of unit conversion in the AMT v3 *Strength reference set*.

MPUU Preferred Term	BoSS	Denormalised/ human readable strength (in MPUU Preferred Term)	Normalised strength (in Strength reference set)	Units converted
metformin hydrochloride 500 mg tablet	metformin hydrochloride	500 mg	500 mg/each	No
metformin hydrochloride 850 mg tablet	metformin hydrochloride	850 mg	850 mg/each	No
metformin hydrochloride 1 g tablet	metformin hydrochloride	1 g	1000 mg/each	Yes

The last row in the table shows a unit conversion (that is, from “g” to “mg”) along with an equivalent strength value conversion.

Implementers who are interested in using the atomically accessible strength details (calculated from the *Strength* and *Unit of use size reference sets*) should consider if the calculated strength is appropriate for use when unit conversion has occurred. While the calculated strength is equivalent to the human readable strength in the MPUU description, it may not appear in identical characters (that is, not a lexical match).

Using the same example as above, the MPUU description’s human readable strength is “1 g” while the calculated strength is “1000 mg”. Unit conversion factors are not currently included in AMT data.

7.16.3 Normalised strength for patches

Certain products with a *Form* of “patch” have the strength value and unit representing a release rate in the *Strength reference set*, as this is considered more clinically relevant than the total amount of an active substance. The release rate representation is not calculated to a denominator of one, which is typical for the strength value field.

For example, the MPUU *|testosterone 5 mg/24 hours patch|* has a strength value of "5" and a *Composite unit of measure* of *|mg/24 hours|*.

7.17 Terminology browser

Terminology browsers are available to review the AMT content. Some example browsers include the following:

- CSIRO Shrimp browser, which is accessible via <http://ontoserver.csiro.au/shrimp/>
- CSIRO Minnow browser, which is accessible via <https://aeherc.com/research/software/minnow/>

7.18 Non-breaking spaces in descriptions

Space characters between strength values and units in AMT descriptions are intended to be non-breaking spaces.

This has not yet been implemented in AMT. In a future AMT release these characters will be replaced by non-breaking whitespace characters (UTF-8 0xC2 0xA0), which it will be necessary to honour in rendering these descriptions.

7.19 Duplicate metadata concepts

The AMT v3 releases share the same metadata content as SNOMED CT-AU releases. These are concepts found within the 900000000000441003 *|SNOMED CT Model Component|* hierarchy.

Any of the following criteria identifies if a component is a metadata concept:

- The concept has a supertype (parent or ancestor) concept of 900000000000441003 *|SNOMED CT Model Component|*; or
- A moduleId value of 90000000000012004 refers to the *SNOMED CT Model Component module* concept, which belongs to the international SNOMED CT release's metadata hierarchy.

Prior to November 2015, AMT and SNOMED CT-AU releases were published separately. Therefore users who were implementing both AMT and SNOMED CT-AU data would have encountered duplicate metadata concepts.

From November 2015 onwards, there is a combined release bundle that includes both AMT and SNOMED CT-AU. This release bundle contains only one metadata hierarchy and therefore no duplicate metadata concepts.

7.20 SNOMED CT-AU and AMT integration

SNOMED CT-AU and the AMT contain some equivalent concepts i.e. different concepts with unique identifiers that have the same meaning. Some concepts from the following AMT hierarchies have equivalent concepts in SNOMED CT-AU:

- *Substance*
- *Medicinal Product*
- *Medicinal Product Unit of Use*
- *Form*

- *Container Type*
- *Unit of Use*
- *Unit of Measure*

The following table lists some examples of equivalent concepts.

Table 36: Equivalent AMT and SNOMED CT-AU concepts

AMT concept (Fully Specified Name)	SNOMED CT-AU concept (Fully Specified Name)
2442011000036104 paracetamol (AU substance)	387517004 Acetaminophen (substance)
21433011000036107 paracetamol (medicinal product)	90332006 Acetaminophen (product)
22974011000036109 codeine phosphate 15 mg + paracetamol 500 mg tablet (medicinal product unit of use)	407853009 Paracetamol+codeine phosphate 500mg/15mg tablet (product)
259011000036107 tablet: dispersible dose form (AU qualifier)	385036001 Dispersible tablet (qualifier value)
99011000036109 milligram unit (AU qualifier)	258684004 milligram (qualifier value)

Full integration of AMT and SNOMED CT-AU has not occurred yet. This is an area of future product development that is included in the AMT roadmap. Full integration would mean whenever AMT and SNOMED CT-AU components are equivalent, only the SNOMED CT or SNOMED CT-AU component is retained for active use. The AMT Identifier file will include the original AMT component identifiers to provide backward compatibility.

When implementing AMT and SNOMED CT-AU together within a system, care should be taken to include only one set of concepts where equivalence is found. In this case, the SNOMED CT-AU concept should be retained and AMT concept deprecated.

Contact the NCTIS³⁶ for further guidance on identifying equivalent concepts between the AMT and SNOMED CT-AU.

³⁶ See Section 1.6.

Appendix A Subpacks and combination packs

A product pack (MPP or TPP) always contains components (MPUUs or TPUUs) in a primary container. The primary container is the lowest-level container (non-ingestible) that immediately surrounds the medicinal product. Examples of a primary container are: *blister pack*, *bottle*, *vial* and *cartridge*.

Some products may also have a secondary container that envelops the components contained within one or more primary containers. An example of a secondary container is "carton". AMT does not include specific information on secondary containers but uses the container type "pack" for all CTPP representing secondary containers.

The component(s) within a secondary container may:

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

A.1 Subpacks

When there are multiple identical representations of the same component(s) within the same type of primary container, the product pack is said to have subpacks.

Subpacks are only represented for specific product categories in AMT. The categories currently include some oral contraceptives, hormone replacement therapy products and any other multi-pack products that are presented in multiple subpacks. Only the primary container immediately enveloping the unit of use is modelled for these products (for example, blister pack). Secondary containers are not modelled.

Subpacks will be added when they are deemed to be required:

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

The number of subpacks contained within a pack containing subpacks is included in the *Subpack quantity reference set* for example, "4 each".

The following is an example of a CTPP pack containing subpacks and its subpack CTPP respectively:

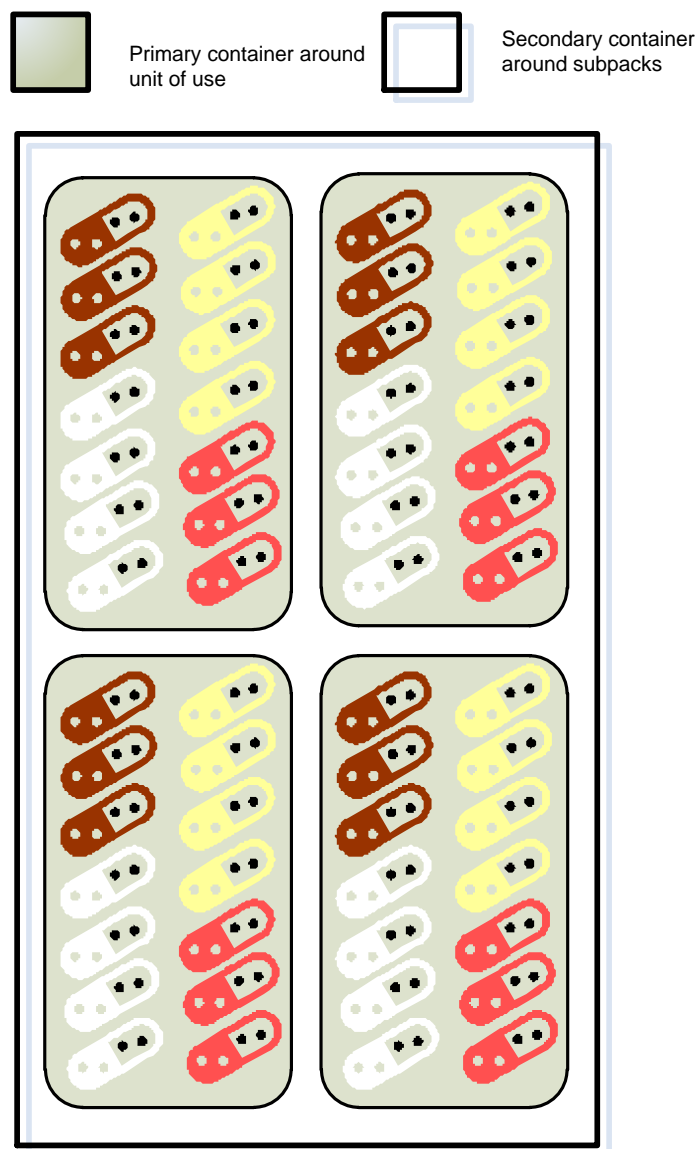
- |*Microgynon 50 ED, 112 [4 x 28], blister pack*|
- |*Microgynon 50 ED, 28, blister pack*|.

Using the same example, the related MPP pack containing subpacks and its subpack MPP respectively are:

- |*ethinylloestradiol 50 microgram + levonorgestrel 125 microgram tablet [84] (&) inert substance tablet [28], 112 [4 x 28]*|
- |*ethinylloestradiol 50 microgram + levonorgestrel 125 microgram tablet [21] (&) inert substance tablet [7], 28*|

A.1.1 Example product

The following figure depicts an example of a pack containing subpacks and its four identical subpacks.



A.2 Combination packs

If a product pack contains multiple units of use, with each unit of use contained in a separate primary container, then the product pack is deemed to have component packs. The component packs within a combination product pack typically have different active ingredients. They may have the same form or have different forms.

The CTPP representing the combination product pack (that is, containing all the component packs) will have an associated generic container type of "pack". The CTPP representing a component pack will have an associated specific container type such as *blister pack*, *bottle*, and *ampoule*. Only the primary container immediately enveloping the unit of use is modelled for these products (for example, *blister pack*). Secondary and tertiary containers are not modelled.

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

Nexium Hp7's component pack CTPPs are as follows:

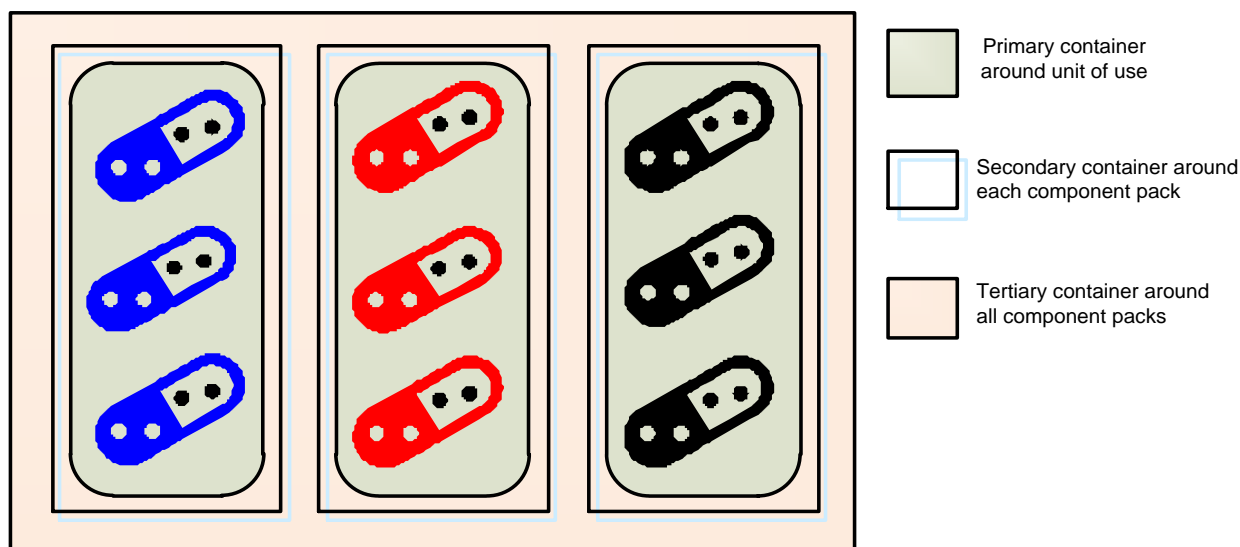
- |Amoxil 500 mg capsule: hard, 28, blister pack|
- |Klacid 500 mg tablet: film-coated, 14, blister pack|
- |Nexium 20 mg tablet, 14, blister pack|

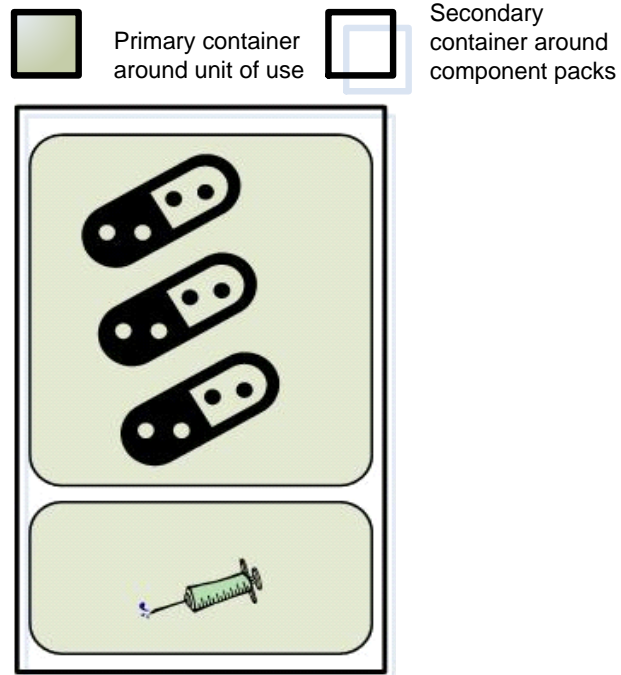
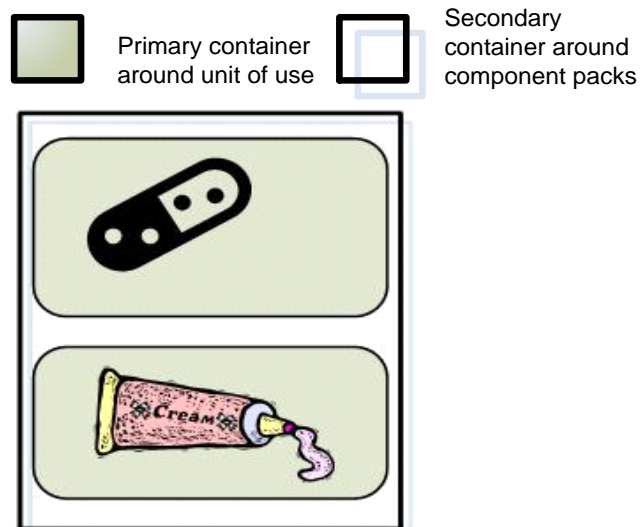
And its combination pack CTPP is |Nexium Hp7 (14 x 20 mg enteric tablets, 14 x 500 mg tablets, 28 x 500 mg capsules), 1 pack|. That is, this is the overall product, the "combination pack" CTPP.

The following figures depict examples of component packs for three products.

A.2.1 Example products

A.2.1.1 Nexium Hp7 (14 x 20 mg enteric tablets, 14 x 500 mg tablets, 28 x 500 mg capsules), 1 pack



A.2.1.2 ZolaCos CP (1 x 3.6 mg implant, 28 x 50 mg tablets), 1 pack**A.2.1.3 Canesoral Duo (1 x 150 mg capsule, 1 x 10 g cream), 1 pack**

Appendix B AMT Reference Set Descriptor

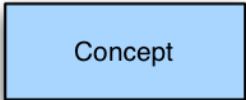
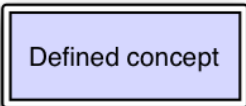
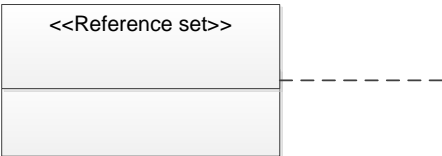
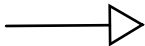
The table below shows an excerpt of the reference set descriptor (described in Section 3.1.12.3) delivered in the AMT data. For readability, concept identifiers have been converted to Preferred Terms, and some columns have been omitted for brevity.

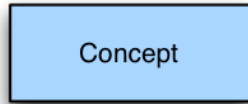
Module name	Referenced component name	Attribute description	Attribute type	Attribute order
Australian Medicines Terminology module	<i>Containerised trade product pack reference set</i>	Referenced component	Concept type component	0
Australian Medicines Terminology module	<i>Medicinal product pack reference set</i>	Referenced component	Concept type component	0
Australian Medicines Terminology module	<i>Medicinal product reference set</i>	Referenced component	Concept type component	0
Australian Medicines Terminology module	<i>Medicinal product unit of use reference set</i>	Referenced component	Concept type component	0
Australian Medicines Terminology module	<i>REPLACED BY association reference set</i>	Association source component	Component type	0
Australian Medicines Terminology module	<i>REPLACED BY association reference set</i>	Association target component	Component type	1
Australian Medicines Terminology module	<i>Strength reference set</i>	Referenced component	Component type	0
Australian Medicines Terminology module	<i>Strength reference set</i>	Unit Id	Concept type component	1
Australian Medicines Terminology module	<i>Strength reference set</i>	Operator id	Concept type component	2
Australian Medicines Terminology module	<i>Strength reference set</i>	Value	Floating point	3
Australian Medicines Terminology module	<i>Subpack quantity reference set</i>	Referenced component	Component type	0
Australian Medicines Terminology module	<i>Subpack quantity reference set</i>	Unit Id	Concept type component	1
Australian Medicines Terminology module	<i>Subpack quantity reference set</i>	Operator id	Concept type component	2
Australian Medicines Terminology module	<i>Subpack quantity reference set</i>	Value	Unsigned integer	3
Australian Medicines Terminology module	<i>Trade product pack reference set</i>	Referenced component	Concept type component	0
Australian Medicines Terminology module	<i>Trade product reference set</i>	Referenced component	Concept type component	0
Australian Medicines Terminology module	<i>Trade product unit of use reference set</i>	Referenced component	Concept type component	0

Module name	Referenced component name	Attribute description	Attribute type	Attribute order
Australian Medicines Terminology module	<i>Unit of use quantity reference set</i>	Referenced component	Component type	0
Australian Medicines Terminology module	<i>Unit of use quantity reference set</i>	Unit Id	Concept type component	1
Australian Medicines Terminology module	<i>Unit of use quantity reference set</i>	Operator id	Concept type component	2
Australian Medicines Terminology module	<i>Unit of use quantity reference set</i>	Value	Floating point	3
Australian Medicines Terminology module	<i>Unit of use size reference set</i>	Referenced component	Component type	0
Australian Medicines Terminology module	<i>Unit of use size reference set</i>	Unit Id	Concept type component	1
Australian Medicines Terminology module	<i>Unit of use size reference set</i>	Operator id	Concept type component	2
Australian Medicines Terminology module	<i>Unit of use size reference set</i>	Value	Floating point	3
SNOMED CT core	<i>Description format</i>	Description type component	Concept type component	0
SNOMED CT core	<i>Description format</i>	Description format	Concept type component	1
SNOMED CT core	<i>Description format</i>	Description length	Unsigned integer	2
SNOMED CT core	<i>Module dependency</i>	Dependency target	Concept type component	0
SNOMED CT core	<i>Module dependency</i>	Source effective time	Time	1
SNOMED CT core	<i>Module dependency</i>	Target effective time	Time	2
SNOMED CT core	<i>Reference set descriptor</i>	Referenced component	Concept type component	0
SNOMED CT core	<i>Reference set descriptor</i>	Attribute description	Concept type component	1
SNOMED CT core	<i>Reference set descriptor</i>	Attribute type	Concept type component	2
SNOMED CT core	<i>Reference set descriptor</i>	Attribute order	Unsigned integer	3

Appendix C AMT v3 model diagram conventions

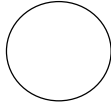
The AMT v3 model diagram (Figure 1, p.19) reflects the Stated Form of AMT. It has been created using a combination of UML syntax and the *SNOMED CT Diagramming Guideline* (IHTSDO, 2013). The non-UML elements used in this diagram are summarised below.

Primitive concept		<p>This diagram element represents a primitive concept.</p> <p>A primitive concept is a concept that does not have sufficient defining relationships to computably distinguish them from more general concepts (supertypes).</p>
Defined concept		<p>This diagram element represents a defined concept.</p> <p>A defined concept is a concept that has sufficient defining relationships to computably distinguish it from other concepts.</p>
Reference set		<p>This diagram element represents a reference set member. The target of the dotted line represents the AMT component (such as a concept, description, or relationship) that is being referenced by this reference set member.</p> <p>A reference set member is a uniquely identified reference (a row) within a reference set.</p> <p>A reference set is a set of references to AMT components that may represent additional properties of the components, associations between members of the set with content of another nomenclature, classification or knowledge structure. A reference set may also be a logical subset of AMT components grouped for a particular purpose or those that belong to the same concept class.</p> <p>Each reference set is distributed as a distinct text file separate to the RF2 core files.</p>
IS A relationship		<p>This diagram element represents an "IS A" relationship.</p> <p>A relationship is an association between a source concept and a destination concept. An "IS A" relationship specifies the supertype (or parent) concept for a given subtype (or child) concept. The child concept shares all the definitional attributes of the parent concept, with optional, additional defining characteristics. The arrow head always points to the parent (supertype) concept.</p>

**Primitive
concept**

This diagram element represents a primitive concept.

A primitive concept is a concept that does not have sufficient defining relationships to computably distinguish them from more general concepts (supertypes).

**Attribute
group**

This diagram element represents an attribute group.

An attribute is a relationship that represents a characteristic of the meaning of a concept or the nature of a refinement. An attribute group is a collection of attributes that are logically put together to allow correct interpretation of the meaning of a concept.

Appendix D AMT product model diagrams

This section includes model diagrams for twelve AMT products. Different products have been deliberately chosen to illustrate specific parts of the AMT model and data. **Note:** the diagrams are illustrative only and do not conform strictly to the *SNOMED CT Diagramming Guideline* (IHTSDO, 2013).

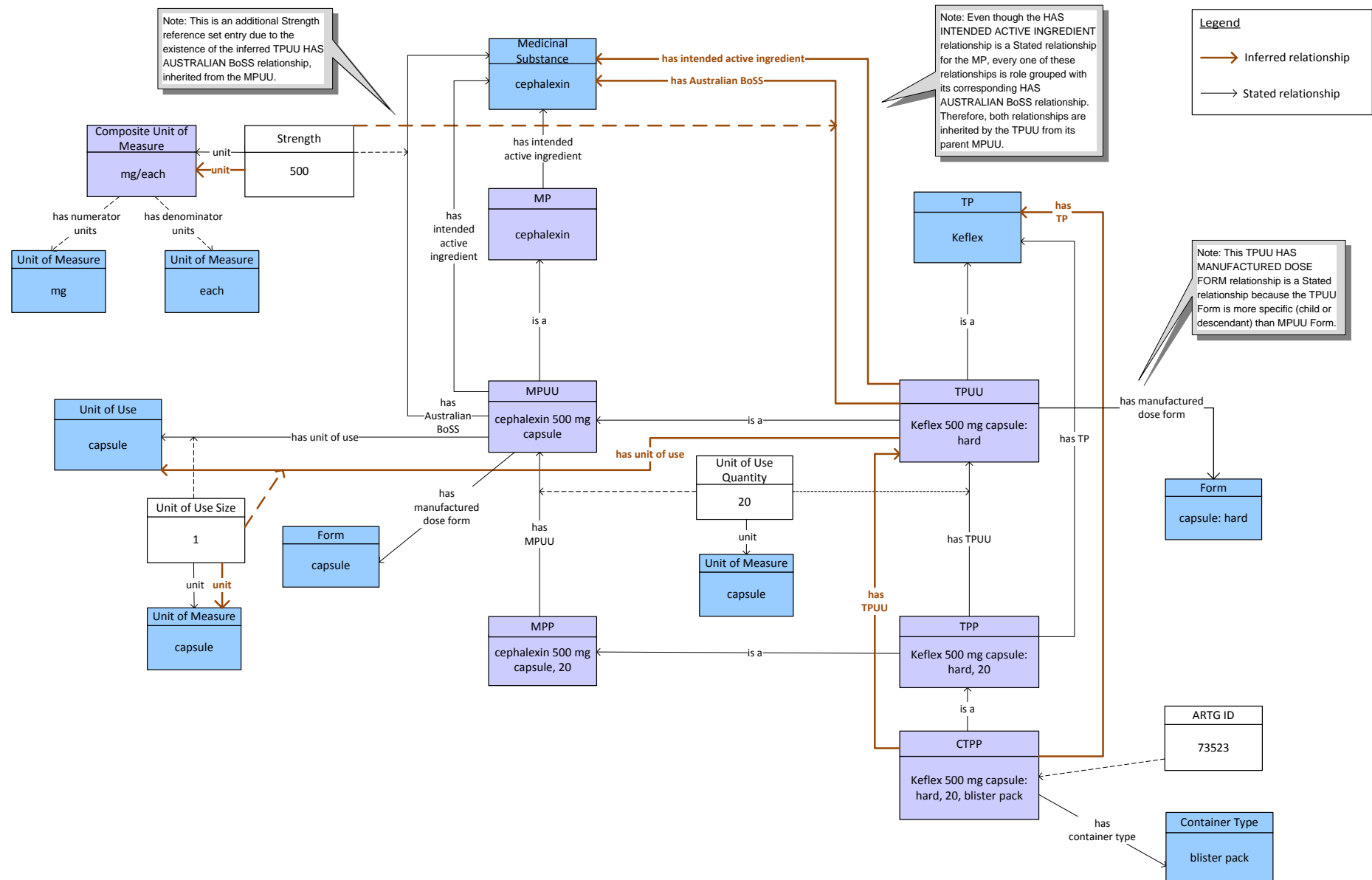
For brevity the model diagrams depict the Preferred Terms and main attributes of each concept class but may not include a full representation of every attribute.

The diagrams include both stated and inferred relationships. Stated relationships are released in AMT's Stated Form (not published in AMT at the time of writing). AMT is currently released in Distribution Normal Form (DNF); the AMT Relationship file includes all relationships as inferred relationships. Inferred relationships are coloured brown.

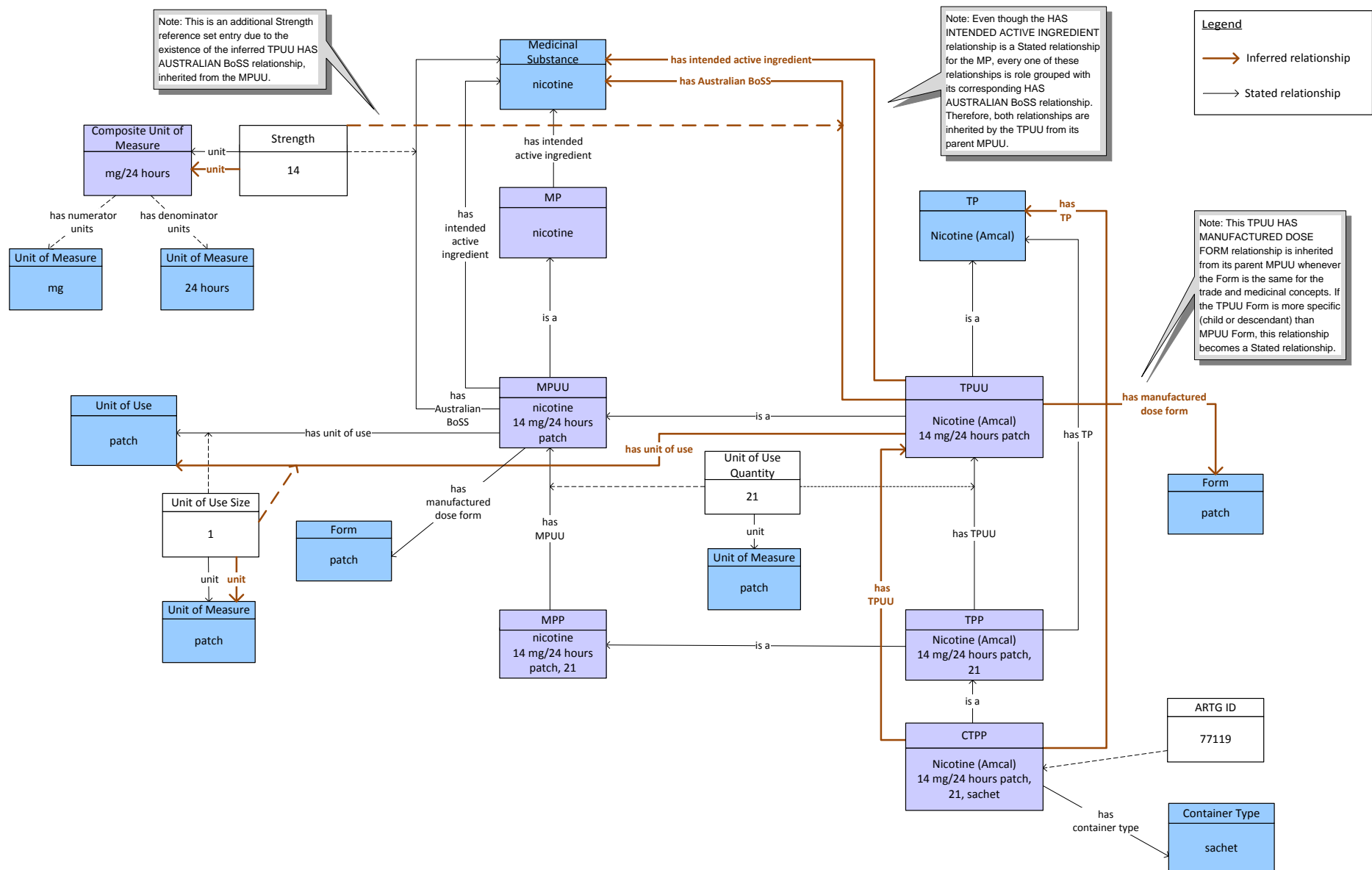
Appendix	Product name (CTPP Preferred Term)	Type of product
D.1	Keflex 500 mg capsule: hard, 20, blister pack	<ul style="list-style-type: none"> Single ingredient Single component
D.2	Canesten Clotrimazole 1% (10 mg/g) cream, 20 g, tube	<ul style="list-style-type: none"> Single ingredient Single component Form of cream
D.3	Nicotine (Amcal) 14 mg/24 hours patch, 21, sachet	<ul style="list-style-type: none"> Single ingredient Single component Form of patch Has a generic name TP
D.4	Nexium 10 mg granules: enteric-coated, 30 sachets	<ul style="list-style-type: none"> Single ingredient Single component Form of granules: enteric-coated
D.5	Panadeine Forte tablet: uncoated, 20, blister pack	<ul style="list-style-type: none"> Multi-ingredient Single component Has a new TP
D.6	Influvac Junior 2013 injection: suspension, 1 x 0.25 mL syringe	<ul style="list-style-type: none"> Multi-ingredient Simplified ingredient in Preferred Terms Single component
D.7	Rivotril (5 x 1 mg/mL (1 mL) ampoules, 5 x 1 mL diluent ampoules), 1 pack	<ul style="list-style-type: none"> Multi-component Form of injection/diluent Strength displayed in descriptions; Strength reference set is different
D.8	Nexium Hp7 (14 x 20 mg enteric tablets, 14 x 500 mg tablets, 28 x 500 mg capsules), 1 pack	<ul style="list-style-type: none"> Multi-component Has component packs

Appendix	Product name (CTPP Preferred Term)	Type of product
D.9	Triphasil, 112 [4 x 28], blister pack	<ul style="list-style-type: none"> • Multi-component • Has subpacks
D.10	Codral Day and Night Cold and Flu (36 x day tablets , 12 x night tablets), 48, blister pack	<ul style="list-style-type: none"> • Multi-component, non-subpack product • Strength displayed in descriptions; Strength reference set is different
D.11	Trizivir tablet: film-coated, 60, bottle	<ul style="list-style-type: none"> • Multi-ingredient • Single component
D.12	Actonel EC Once-a-Week 35 mg tablet: enteric, 4, blister pack	<ul style="list-style-type: none"> • Single ingredient • Single component • Shows the result of proximal supertype rule (DNF) for MPUU

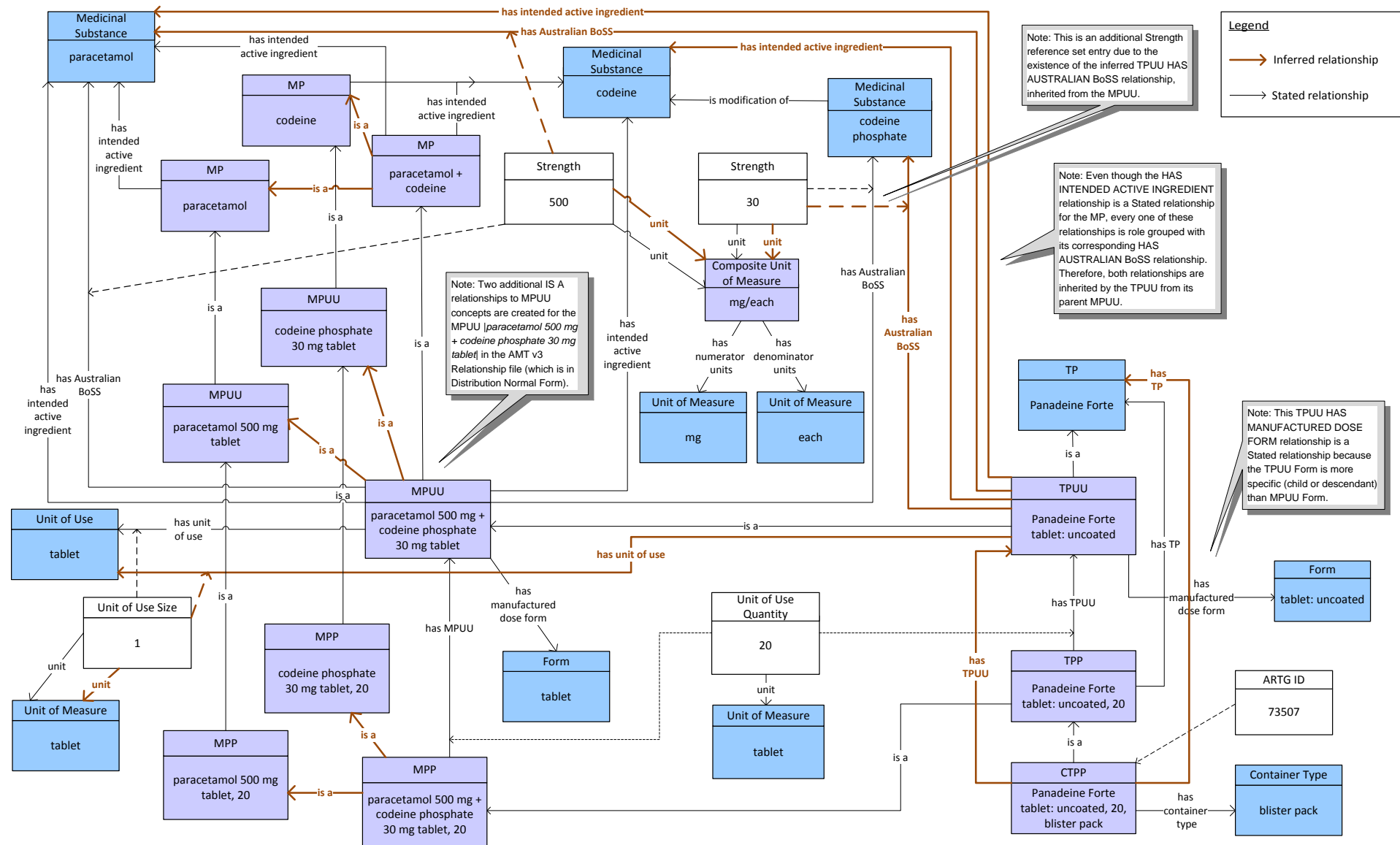
D.1 Keflex 500 mg capsule: hard, 20, blister pack



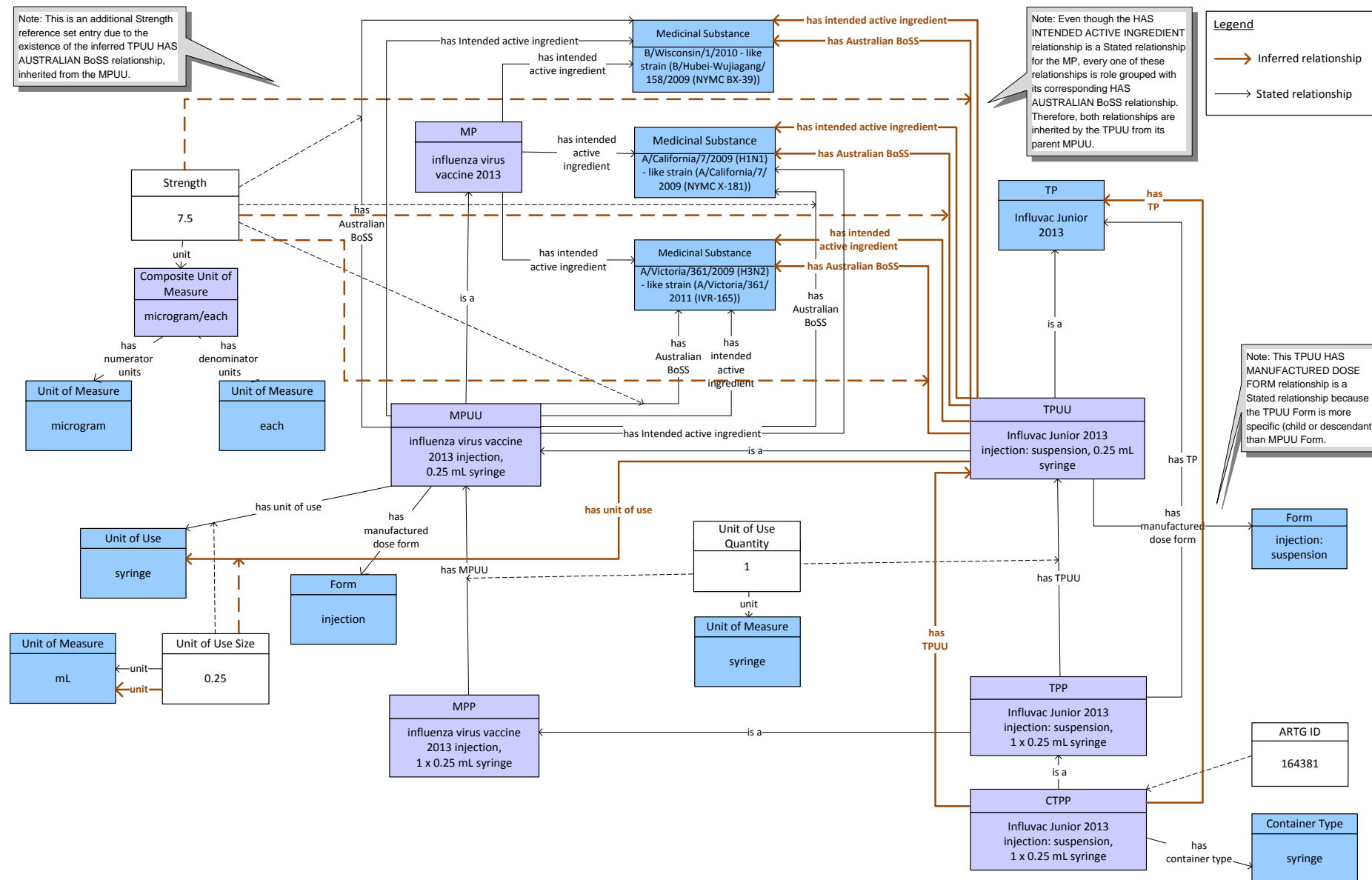
D.3 Nicotine (Amcal) 14 mg/24 hours patch, 21, sachet



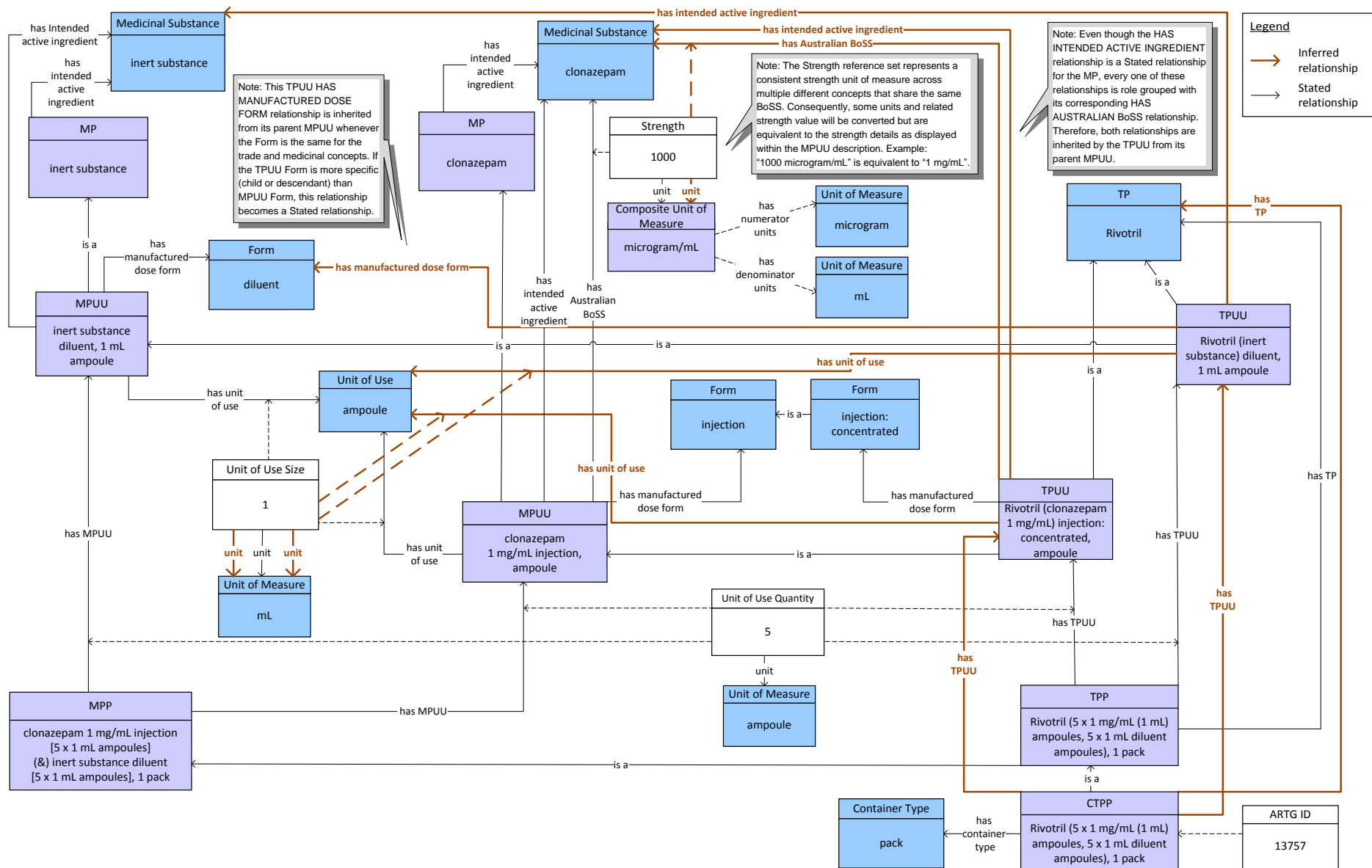
D.5 Panadeine Forte tablet: uncoated, 20, blister pack



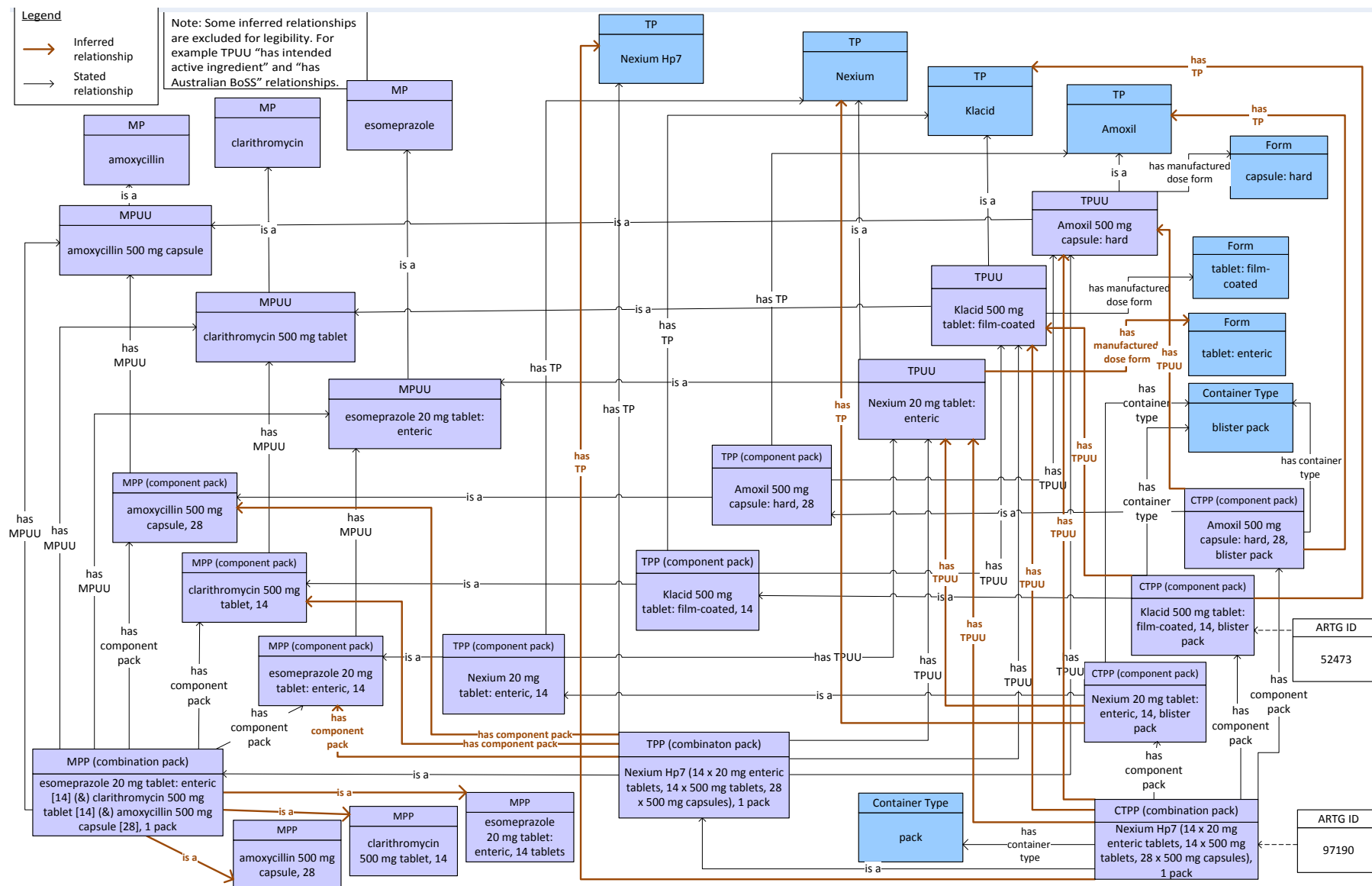
D.6 Influvac Junior 2013 injection: suspension, 1 x 0.25 mL syringe



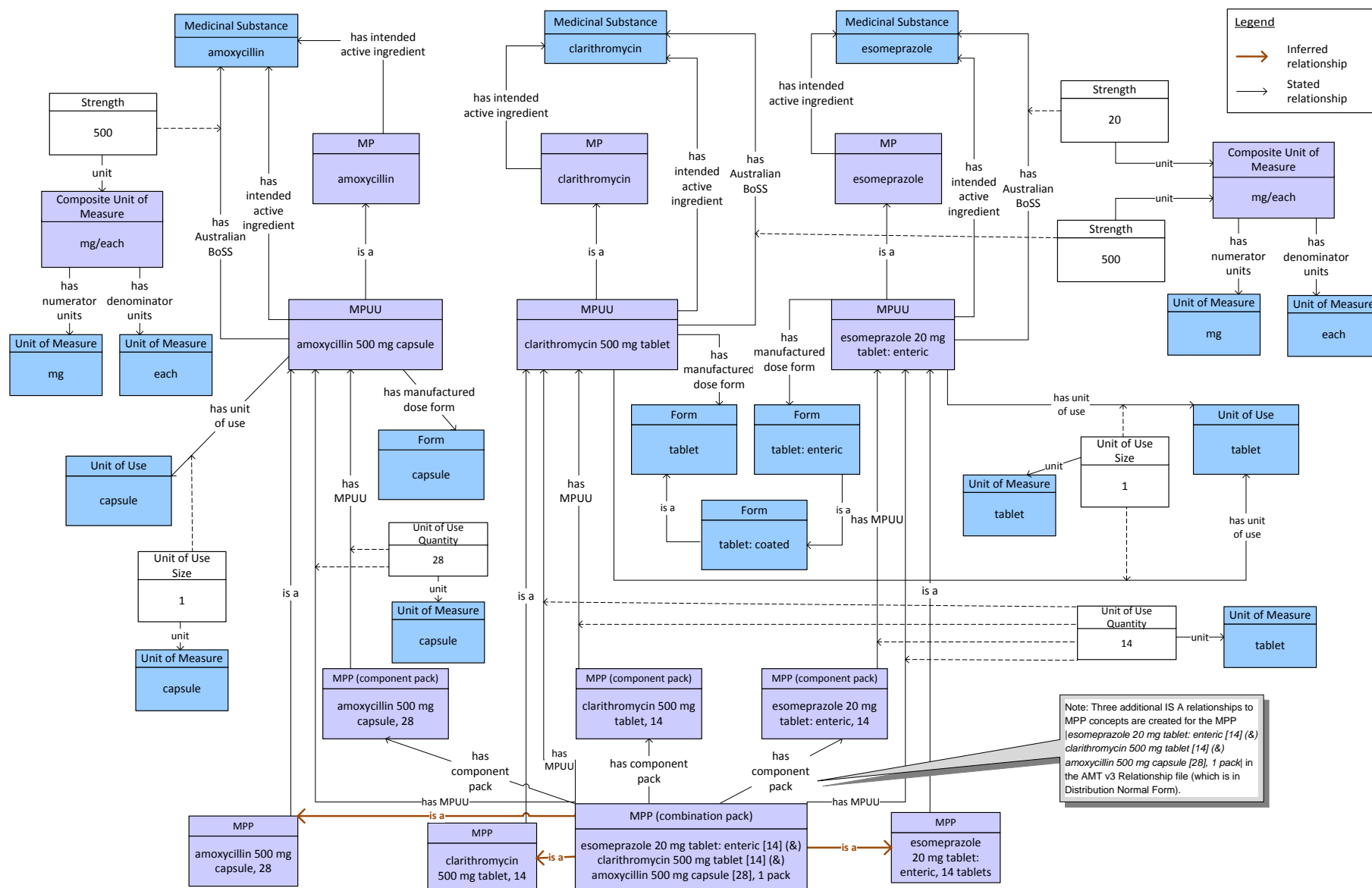
D.7 Rivotril (5 x 1 mg/mL (1 mL) ampoules, 5 x 1 mL diluent ampoules), 1 pack



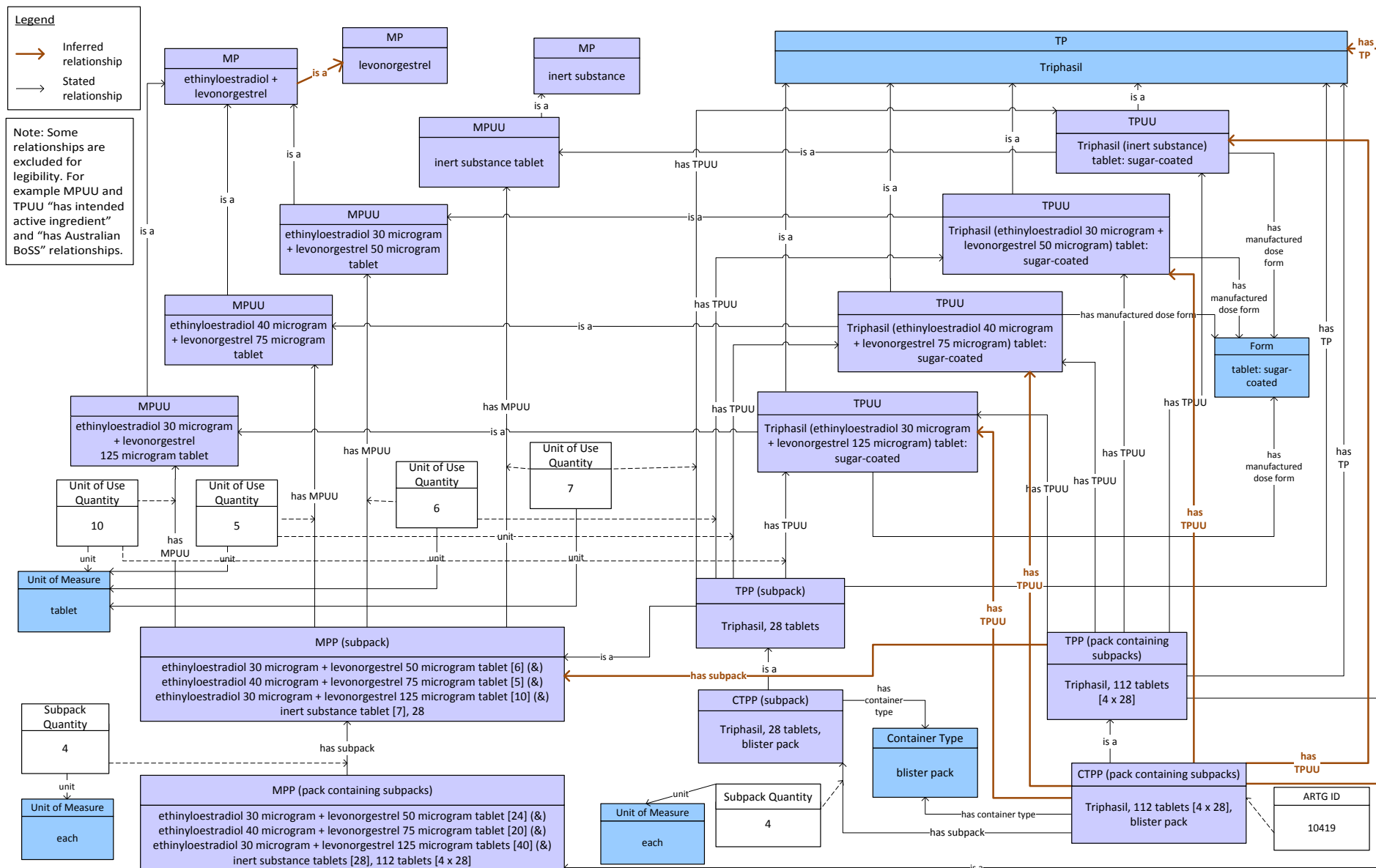
D.8 Nexium Hp7 (14 x 20 mg enteric tablets, 14 x 500 mg tablets, 28 x 500 mg capsules), 1 pack



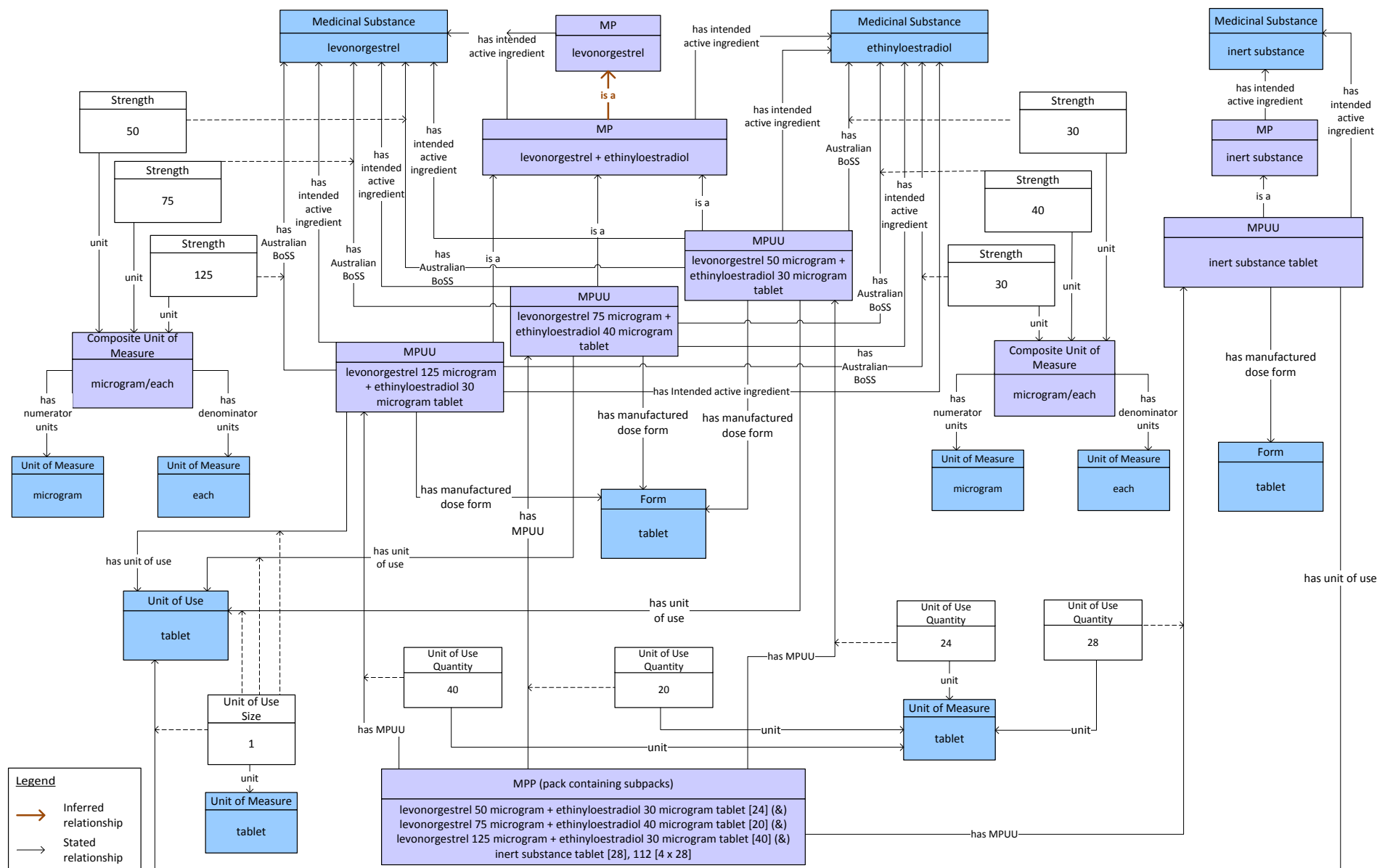
D.8.1 Nexium Hp7 (14 x 20 mg enteric tablets, 14 x 500 mg tablets, 28 x 500 mg capsules), 1 pack (MPUU modelling)



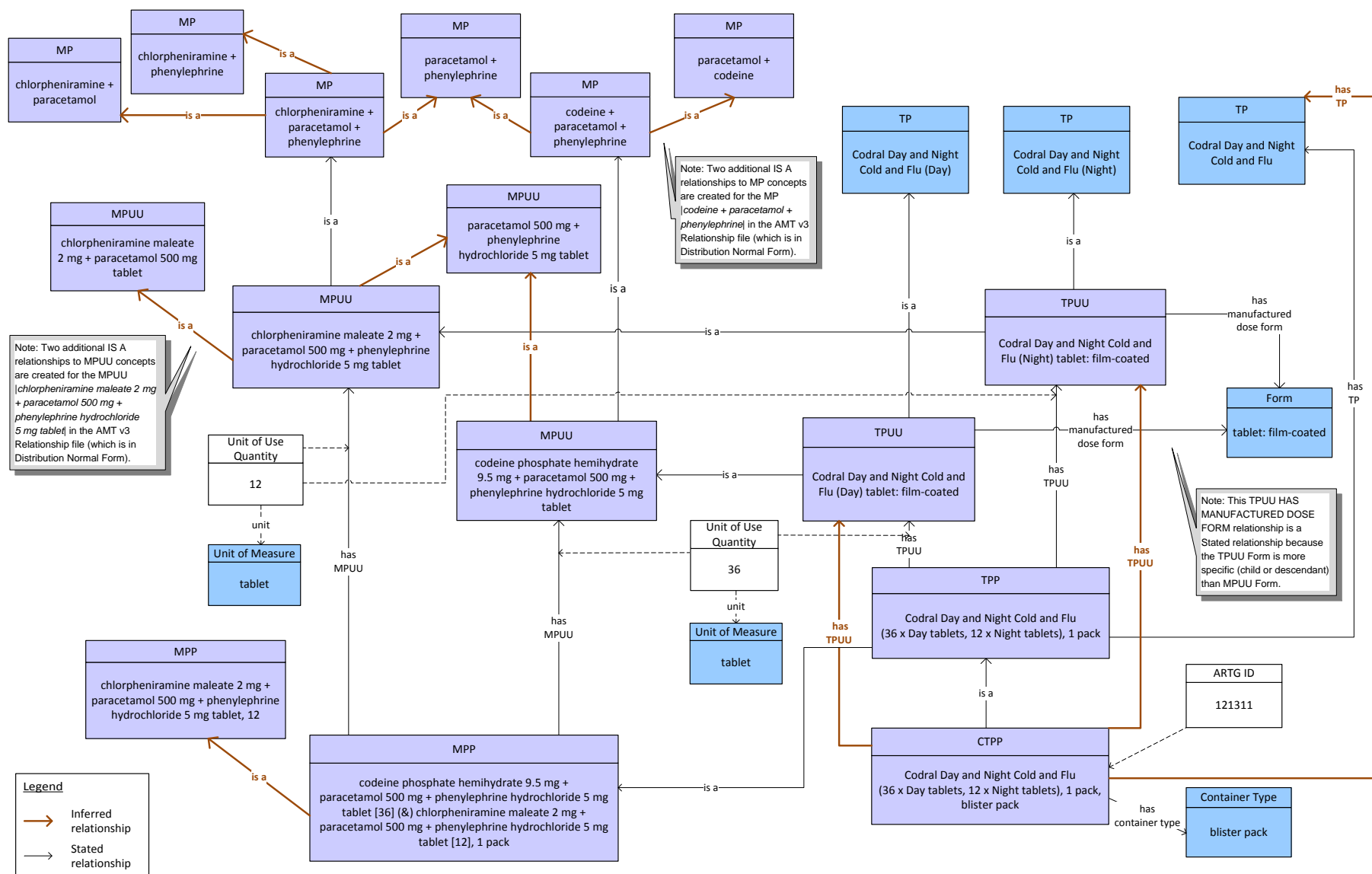
D.9 Triphasil, 112 [4 x 28], blister pack



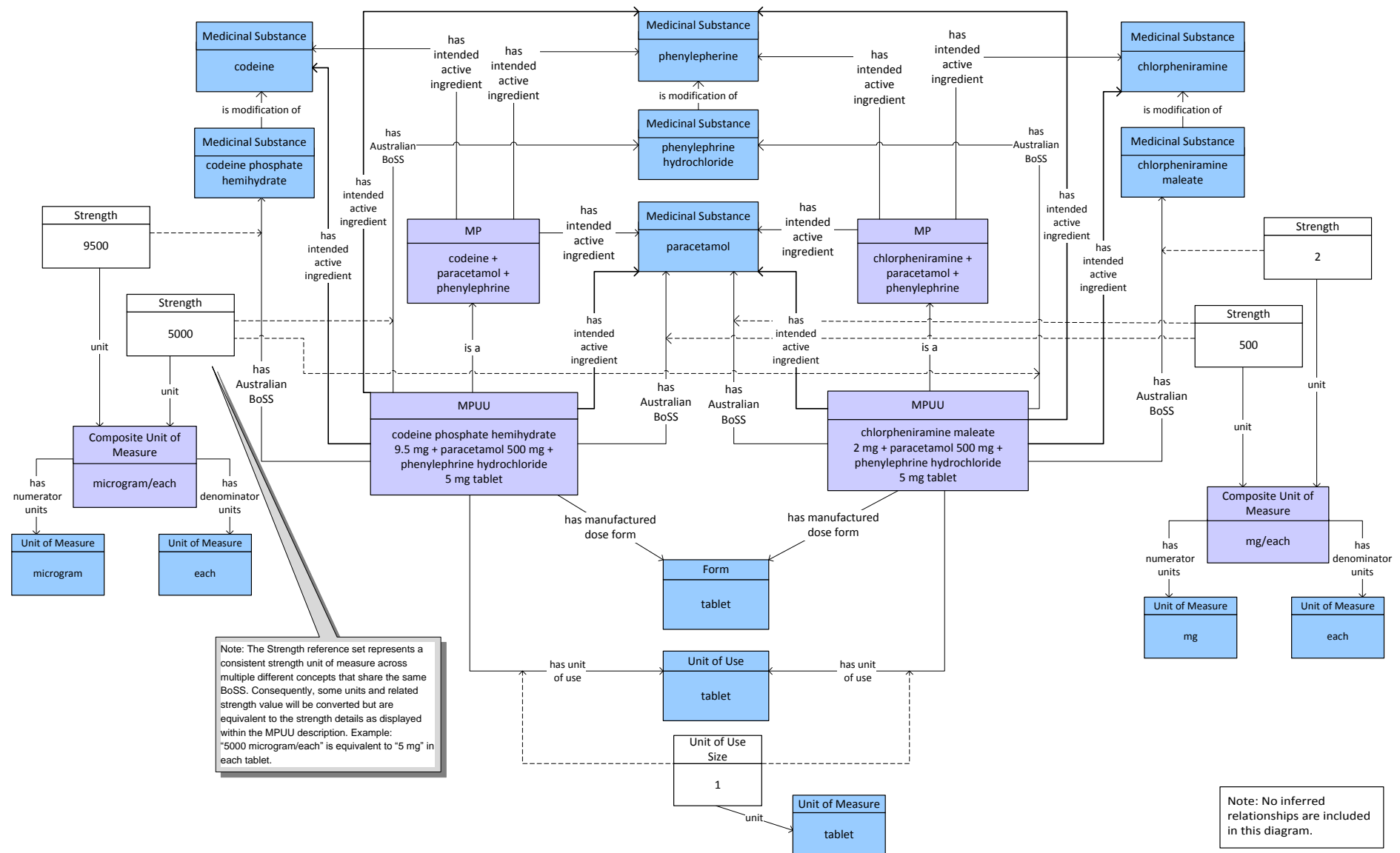
D.9.1 Triphasil, 112 [4 x 28], blister pack (MPUU modelling)

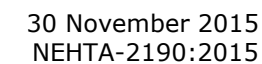


D.10 Codral Day and Night Cold and Flu (36 x day tablets , 12 x night tablets), 48, blister pack

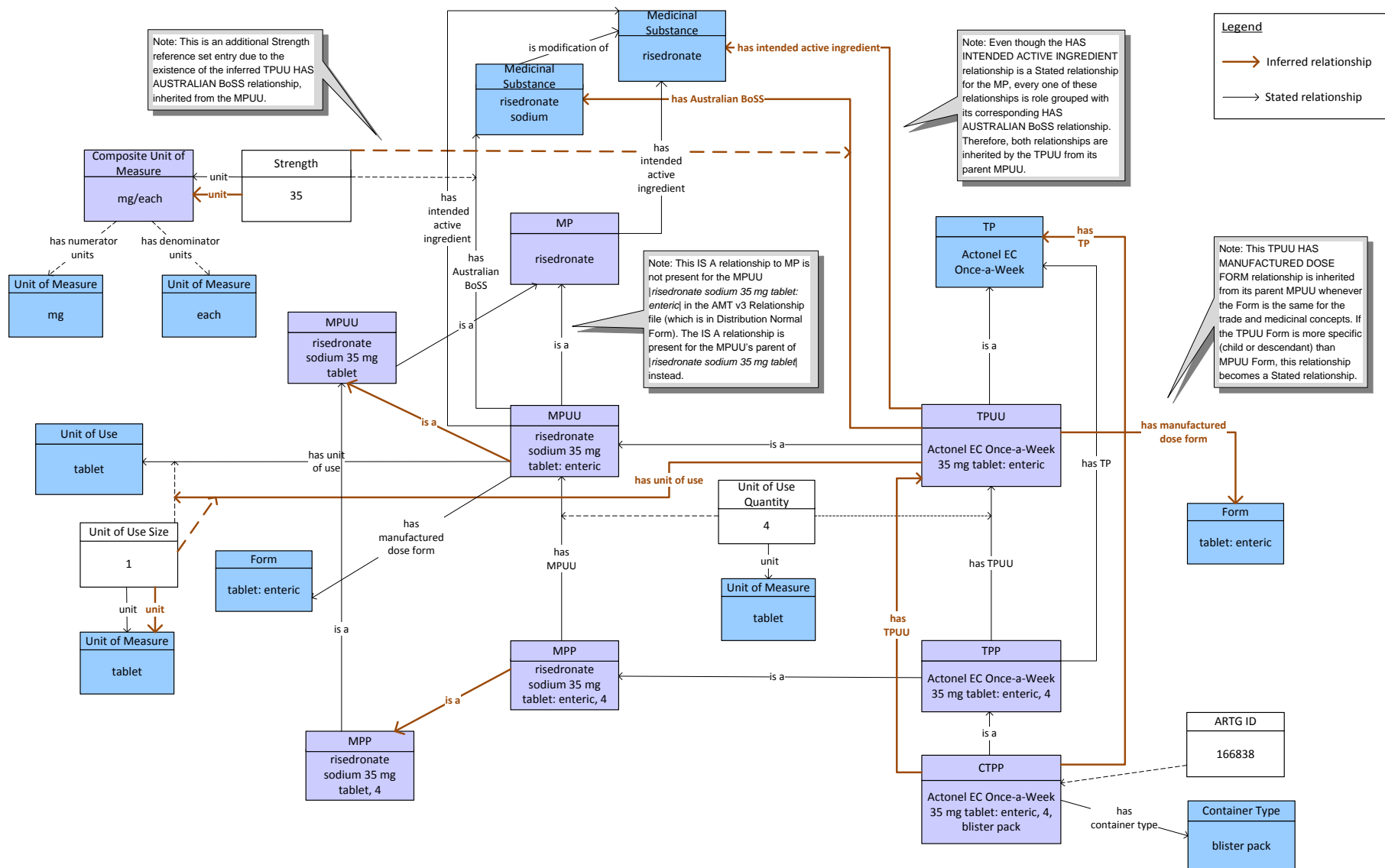


D.10.1 Codral Day and Night Cold and Flu (36 x day tablets , 12 x night tablets), 48, blister pack (MPUU modelling)





D.12 Actonel EC Once-a-Week 35 mg tablet: enteric, 4, blister pack



Acronyms

Acronym	Description
AMT	Australian Medicines Terminology
AMT v3	Australian Medicines Terminology, version 3 model
ARTG	Australian Register of Therapeutic Goods
ARTG ID	Australian Register of Therapeutic Goods Identifier
BoSS	Basis of Strength Substance
CCA	Compliance, Conformance and Accreditation
COTS	Commercial of the Shelf
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CTPP	Containerised Trade Product Pack
DL	Description Logic
DNF	Distribution Normal Form
DOS	Disk Operating System
FSN	Fully Specified Name
IHTSDO	International Health Terminology Standards Development Organisation
ISO	International Organization for Standardization
KRSS	Knowledge Representation System Specification
MP	Medicinal Product
MPP	Medicinal Product Pack
MPUU	Medicinal Product Unit of Use
NCTIS	National Clinical Terminology and Information Service
NHS	National Health Service
OWL	Web Ontology Language
PBS	Pharmaceutical Benefits Scheme
PCEHR	Personally Controlled Electronic Health Record
PT	Preferred Term
RF1	SNOMED CT Release Format 1
RF2	SNOMED CT Release Format 2
RPBS	Repatriation Pharmaceutical Benefits Scheme
SCTID	SNOMED CT Identifier
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
SQL	Structured Query Language

Acronym	Description
TGA	Therapeutic Goods Administration
TP	Trade Product
TPP	Trade Product Pack
TPUU	Trade Product Unit of Use
UCS	Universal Character Set
UCUM	Unified Code for Units of Measure
UML	Unified Modelling Language
URI	Uniform Resource Identifier
UTF-8	UCS Transform Format – 8-bit
UUID	Universally Unique Identifier

Glossary

Term	Meaning
AUSTL	Type of ARTG ID assigned to “listed” items on the Australian Register of Therapeutic Goods. Listed medicines are much lower risk self-medication products than those listed as AUSTR medicines. Listed medicines include sunscreens over SPF4 and many vitamin, mineral, herbal and homoeopathic products.
AUSTR	Type of ARTG ID assigned to “registered” items on the Australian Register of Therapeutic Goods. Registered medicines include all prescription only medicines and many over-the-counter products such as pain relief, coughs and colds and antiseptic creams.
Australian Medicines Terminology	National terminology that identifies medicines used in Australia, using unique codes to deliver unambiguous, accurate and standardised names for both branded (trade) and generic (medicinal) products.
Australian Medicines Terminology Version 3	Latest version of the AMT product, consisting of a series of model and editorial rule changes from the previous versions – AMT v2.x.
Australian Register of Therapeutic Goods	Australian register on which all therapeutic goods must be registered before they can be lawfully supplied in Australia. Managed by the Therapeutic Goods Administration.
Basis of Strength Substance	Ingredient strengths are always represented in terms of a Basis of Strength Substance (BoSS). The BoSS may be a base, salt or modified salt, and may be the same or different to the actual ingredient being measured.
Classifier/reasoner	A piece of software used to perform automated classification of, or reasoning about, description logic rich data such as SNOMED CT or AMT.
Commercial of the Shelf	Type of product acquisition where the supplied product is commercially sold and can be procured and used for its intended purpose without need for modification or customisation.
Compliance, Conformance and Accreditation	NEHTA programme responsible for developing a national framework assuring systems comply with Australian specifications and demonstrate appropriate standards of interoperability, security and clinical safety in the way they handle and exchange information.
Containerised Trade Product Pack	A category of AMT concepts representing marketable medical entities available for patient use, with details of container type. Refer to Section 2.3.2.6.
Description Logic	Family of formal knowledge representation languages used in artificial intelligence for formal reasoning with concepts from a domain. Description logic is the formalism that underpins SNOMED CT’s and AMT’s machine readable definition of the concepts they contain.
Disk Operating System	Name used to identify several closely related operating systems used in the IBM compatible PC market through the 1980s and 1990s, particularly Microsoft DOS.

Term	Meaning
Distribution Normal Form	A normalised inferred form specified by the IHTSDO as the mandatory distribution form for SNOMED CT and extensions. This form specifies that only proximal supertype and non-redundant inherited relationships will be included from the full set of inferred supertypes and relationships.
Fully Specified Name	Type of description (human readable name) given to a concept in SNOMED CT and AMT that is used as the definitive meaning of the concept.
International Health Terminology Standards Development Organisation	International not for profit organisation which owns and administers the rights to SNOMED CT and related terminology standards.
International Organization for Standardization	International standards development organisation
Knowledge Representation System Specification	Knowledge representation language with a Lisp-like syntax that may be used as an input format to a classifier. SNOMED CT RF1 and RF2 may be transformed into KRSS format
Language reference set	A reference set pattern specified in the SNOMED CT RF2 specification used to indicate language preferences for SNOMED CT Synonyms in specific contexts, such as dialectic language preferences. Language reference sets are used to express which Synonyms are preferred, acceptable and unacceptable from the set of Synonyms distributed in the Descriptions file.
Medicinal Product	Category of AMT concepts representing abstract formulated representations of therapeutic active ingredients used in treatment of human patients in Australia. Refer to Section 2.3.2.1.
Medicinal Product Pack	Category of AMT concepts representing the abstract concept of marketable medicinal entities available for patient use, devoid of brand and container type. Refer to Section 2.3.2.3.
Medicinal Product Unit of Use	Category of AMT concepts representing abstract formulations containing active ingredient, strength and form in a single dose form or unit of use component of a multi-component formulation, devoid of brand. Refer to Section 2.3.2.2.
National Clinical Terminology and Information Service	Group within NEHTA responsible for development, publication and maintenance of clinical terminology and information products for Australia.
National Health Service	Government organisation responsible for funding and administering publically funded healthcare in the United Kingdom.
Notable concepts	A collective term for the following concepts: <ul style="list-style-type: none"> • Medicinal Product (MP) • Medicinal Product Unit of Use (MPUU) • Medicinal Product Pack (MPP) • Trade Product (TP) • Trade Product Unit of Use (TPUU) • Trade Product Pack (TPP) • Containered Trade Product Pack (CTPP)
Personally Controlled Electronic Health Record	Australia's national electronic health record system.

Term	Meaning
Pharmaceutical Benefits Scheme	Australian government subsidy system for medicines and a supporting regulatory body.
Preferred Term	A Synonym for a concept designated within a given context as the preferred way of representing or referring to that concept. In AMT this refers to the Synonym for a concept referenced by the <i>Australian dialect reference set</i> as the preferred way of referring to that concept. Each concept has one and only one active Preferred Term at one time point in any given language reference set. Refer to Section 3.1.7.
Seven notable concepts	See <i>Notable concepts</i> .
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms. Parent terminology of AMT and SNOMED CT-AU.
SNOMED CT Identifier	Identifier scheme defined for distributed components (concepts, descriptions, relationships) of a SNOMED CT or extension release.
SNOMED CT Release Format 1	Original SNOMED CT release file format used to since 2002 and actively being replaced by RF2.
SNOMED CT Release Format 2	New SNOMED CT release file format replacing RF1.
Sponsor	<p>The TGA describes a sponsor as a person or company who does one or more of the following:</p> <ul style="list-style-type: none"> • exports therapeutic goods from Australia • imports therapeutic goods into Australia • manufactures therapeutic goods for supply in Australia or elsewhere • arranges for another party to import, export or manufacture therapeutic goods.³⁷ <p>AMT v2 included a “Sponsor” field to record this information, but this was not retained in AMT v3.</p>
Stated Form	The form of AMT or SNOMED CT directly stated by the authors, containing no machine inferred statements.
Structured Query Language	Programming language originally based on relational algebra and tuple relational calculus, designed to manage data in relational databases.
Synonym	Type of description comfortable and natural for use by clinicians and end users. This differs from the Fully Specified Name, which by contrast is intended as the formal, definitive and unambiguous definition of a concept not intended for everyday use.
Systematized Nomenclature of Medicine – Clinical Terms	A systematically organised, computer processable collection of medical terms, providing codes, terms, synonyms and definitions. SNOMED CT is designed to underpin clinical data recording and meaning-based retrieval and use.
Therapeutic Goods Administration	Australia’s regulatory authority for therapeutic goods, which among other duties, maintains the Australian Register of Therapeutic Goods.
Trade Product	Category of AMT concepts representing product brand names. Refer to Section 2.3.2.4.

³⁷ <http://www.tga.gov.au/industry/basics-role-of-sponsor.htm>

Term	Meaning
Trade Product Pack	Category of AMT concepts representing marketable medicinal entities available for patient use devoid of container type. Refer to Section 2.3.2.6.
Trade Product Unit of Use	Category of AMT concepts representing marketable formulations containing active ingredient, strength and form in a single dose form or unit of use component of a multi-combination pack. Refer to Section 2.3.2.5.
UCS Transform Format – 8-bit	Variable width encoding format that can represent all Unicode characters.
Unified Code for Units of Measure	Coding system for units of measure which includes a grammar for coordinating codes into complex unit expressions and conversion factors for units.
Unified Modelling Language	Standardised general purpose modelling language aimed at object-orientated software engineering.
Unit of use	The <i>Unit of use</i> describes a discrete unit dose form (such as tablet or capsule) or a continuous substance where a consistent physically measurable unit or sub-unit cannot be identified (such as cream or eye drops).
Universal Character Set	Standardised set of characters defined by ISO/IEC 10646. Used as a basis for many character encodings.
Universally Unique Identifier	An identifier scheme used for distributed allocation of identifiers.
Web Ontology Language	Family of knowledge representation languages for authoring ontologies. SNOMED CT RF1 and RF2 formats may be transformed to OWL Functional or OWL XML formats for consumption by description logic reasoners.

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