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AMT v4 Changes and Impacts

National Clinical Terminology Service

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1 Context for this document

1.1 Rationale and purpose

This document presents the changes being proposed for the AMT v4 project, and details the impacts these changes will have on the terminology dataset. Benefits and risks are described to provide the audience with enough information to understand the effect these changes will have on consumers of AMT.

1.2 Overview

The Australian Medicines Terminology (AMT) model is currently undergoing changes as part of the AMTv4 project. These changes will range from minor changes to concept descriptions, to extensive modifications to concept attributes and relationships.

This work is being undertaken by the National Clinical Terminology Service (NCTS) team at CSIRO, incorporating issues and ideas raised since AMT transitioned from v2 to v3. Consultation with AMT stakeholders, users, and vendors was undertaken across several months and their feedback has also been taken into consideration.

Closer integration with SNOMED International's (SI) terminology dataset is a defining feature of the AMTv4 project. Multiple levels of integration have been considered and discussed with the wider AMT group, as the tighter the integration between AMT and SI the greater the amount of change required to support it.

1.3 Stakeholder engagement

An invitation was extended to current active AMT users to participate in co-design workshops for the new AMT model. We formed a working group of approximately 40 members who represented many organisations providing digital health solutions, ranging from clinical information systems, formulary management, message exchange, and clinical decision support. The states and territories were also involved through their use of the AMT in their clinical systems. Approximately half of the members had a clinical perspective, a third were technical, and the rest had a business, process, or product background. Some organisations declined to participate due to resourcing constraints but were happy to be kept in the loop via the broad updates about the progress of the workshops.

The working group met in 9 sessions over 4 months to discuss many aspects of the AMT model that could change. Responses were captured in the chat function in the videoconference platform and in Mentimeter. In between meetings, we invited feedback via our NCTS Office mailbox. The changes could be viewed in the Shrimp terminology browser, and members were given access to prototype files as an RF2 bundle and an AMT flat file to test in their systems.

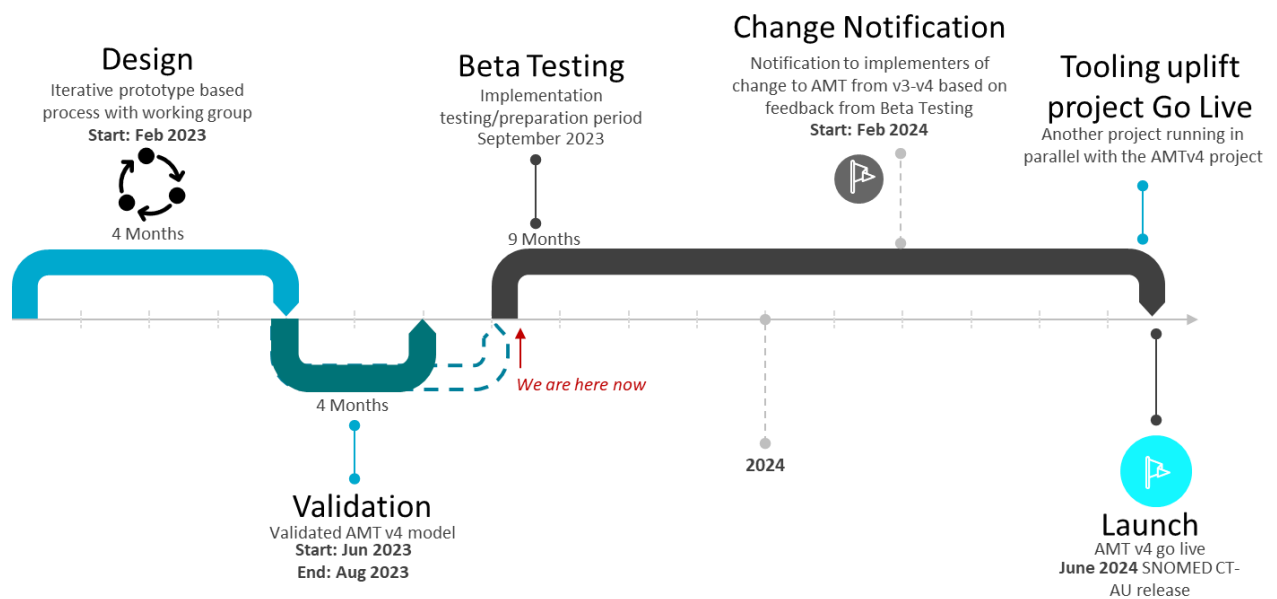
At the midway point, we created a pulse survey via Microsoft forms as an opportunity for members to give feedback about the working group and raise anything else they would like to

discuss in the remaining sessions. A feedback summary report contains more information about the outcomes of the discussion.

1.4 Timeframes and implementation support

The official change notification will be prepared for the first tandem release of AMTv3 and AMTv4. The beta testing period is the opportunity for implementers to work with the release containing AMTv4, with the NCTS providing support if needed.

AMT v4 timeline



2 General change and impact summary

Replacement of AMT concepts with equivalent SNOMED CT concepts

A substantial enhancement for AMTv4 is better integration with SNOMED CT. Where equivalent content exists in both, SI (SNOMED CT) content will take precedent over AMT, and the AMT concepts will be retired as duplicates and replaced.

The impact on the implementers will depend on how they are using the AMT:

- Native implementations, with concept identifiers (Ids) hard coded in their processes. These codes will need to be updated.
- Mapped implementations, where current AMT concept Ids in maps will need to be replaced.

This process of retiring concepts currently happens as a normal part of AMT maintenance. The AMTv4 project does so at a greater volume in a single release – which may be problematic for these vendors. A “Same as” historical association is maintained within the terminology to assist with maintenance. Additional maintenance reports (self-serve) will also be investigated.

Changes to concept model properties

Changes to the concept model involve a mixture of adding, removing, and replacing the relationships between the different concept classes.

Affected implementers will be anyone using the AMT properties. This includes:

- RF2 users who filter or transform content based on the relationship.TypeId or Concrete Domain reference sets.
- FHIR terminology server (Including Ontoserver) users who use ECL to query AMT or expand implicit FHIR value sets.

These users should review and update any such queries or assumptions.

Minimal impact to users of the AMT flat file are anticipated due to model changes. The NCTS will update internal processes to generate this file in response to AMTv4, to achieve the same content.

Changes to the RF2 distribution bundle

SNOMED CT-AU was an early adopter of RF2 and in the decade since it was first introduced, minor changes to the specification have been made. AMTv4 will realign with current international standards. This includes:

- Publishing simple reference sets together in a single file.

- Representing concrete domains (numbers and units) in a new file format¹ instead of reference sets.
- Removing a redundant “*RF2Release*” intermediate subdirectory from the zip file.

Affected implementers will be those who consume the RF2 release bundle. Import processes should be reconfigured for some of these changes.

Changes to AMT descriptions

Although a revision of the AMT naming conventions was excluded from the project, some changes will be encountered.

Fully Specified Names (FSN)

Where SNOMED CT concepts replace AMT concepts, the SNOMED CT FSN will persist. Additionally, the FSN for AMT concepts may be revised for better alignment with SNOMED Editorial Policy and most importantly, to remove existing ambiguity.

Affected systems will be mapped implementations with case-sensitive process to detect changes in terms. The meaning of the concept will not have changed, but the new FSN will be a more accurate and unambiguous label.

Preferred Terms and Synonyms

Where SNOMED CT concepts replace AMT concepts, the original AMT terms will be maintained (new description Id) unless determined to be erroneous. The only change may be the move to Sentence case formatting i.e., “*paracetamol 500 mg capsule*” changes to “*Paracetamol 500 mg capsule*”. This change will be visible to all users, whether by searching in Shrimp, or using the AMT flat file, or native implementers.

Affected implementers will be native implementations, where the new Preferred terms will be seen on user interfaces. This is consistent with best practice UI design for such content^{2,3}.

2.1 Anticipated Impact

Ideally there should be no impact to clinicians, or the end-users of the digital health solutions. AMTv4 supports the existing use cases as AMTv3, and even more. These use cases can only be satisfied if the implementing systems deliver the appropriate functionality. It is impossible to know actual impact of AMTv4 changes upon implementations, as the changes will implement every vendor differently depending. Factors influencing the impact on any given vendor include:

- Native vs mapped implementations.
- Consumption as RF2 bundle, AMT flat file or FHIR terminology services.

¹ 4.2.6 Concrete Value File Specification - Release File Specification - SNOMED Confluence (ihtsdotools.org)

² Why letter casing is important to consider during design decisions | by Quovantis | UX Planet

³ Title case vs sentence case in ui - Every Interaction

- AMT concept IDs hard coded into software, processes, triggers, or queries.
- Existing maintenance processes and use of “*Historical association reference sets*”.
- Implementation maturity, ranging from simple storage and exchange of concept IDs to leveraging the full terminology model (relationships and concrete domains) and features like Expression Constraint Language (ECL).

The changes have been broadly categorised into Low, Medium and Substantial based on the volume of content affected, likelihood of affected concept model attributes in use, and understanding that most AMT implementations are mapped and/or are reliant on the AMT flat file.

3 Low-impact changes to the AMT concept model

Background

AMT was initially developed as a standalone product with some influence from SNOMED CT design. Initial versions (2 and earlier) used the same algorithm as SNOMED CT to generate identifiers and described products using semantic triples⁴. Although there was similar content in the two products, the only identifier in common was the hierarchical 116680003 |Is a (attribute)| relationship. AMT was also published in its own unique format (not SNOMED related) based on Excel spreadsheets.

The introduction of AMT v3 saw some changes to the concept model and formalised the distribution format to the SNOMED CT RF2 specification⁵, but AMT content remained a discrete set of content. The lack of integration between the two ontologies can be summarised by:

- AMT developed its own parallel set of concepts, for substances, units of measure, dose forms and other qualifiers as it originated as a standalone product.
- To insulate AMT from problems in the SNOMED CT hierarchy, particularly the Substances, the separation was maintained for AMT v3. AMT Substances and qualifiers were modelled enough to define medicinal products but did not provide much other information about such as therapeutic categories or intended route of administration.

SI has since fixed and stabilised the substance hierarchy and overhauled much of the qualifier hierarchy as part of the SI Drug Model redesign⁶. They are now considered adequate to define AMT medicinal products.

⁴ Semantic triple - Wikipedia

⁵ SNOMED CT Release File Specifications - Release File Specification - SNOMED Confluence (ihtsdotools.org)

⁶ Drug Project - Drug Project - SNOMED Confluence (ihtsdotools.org)

3.1 Replacement of equivalent relationships

Change Summary

The following attributes (relationships) in AMT are being updated to what has been determined semantically equivalent counterparts in the SNOMED CT drug model.

AMT v3	AMT v4
700000081000036101 has intended active ingredient (attribute)	127489000 Has active ingredient (attribute)
30364011000036101 has Australian BoSS (relationship type)	732943007 Has basis of strength substance (attribute)
30523011000036108 has manufactured dose form (relationship type)	411116001 Has manufactured dose form (attribute)

Impact

- The AMT attributes will be retired because they are considered duplicates (no change in meaning), and the existing SNOMED CT attributes used in their place. Implementers will need to update the above v3 concept IDs to the v4 equivalents where hard coded into their systems. Changes will be published within the historical associations of SNOMED CT.
- It's likely the preferred terms of the SNOMED concepts will also be updated to reflect the AMT v3 preferred terms, however there are no known use cases for displaying the preferred term of these relationships to users, so this impact is negligible.

Benefits

- Some alignment to the SI Drug model and allows AMT to inherit classes such as Medicinal Product Form and Therapeutic Roles.
- Simple ECL⁷ queries using just these properties are also internationally transferable.

Example Use Case

A system may allow users to select an ingredient, and then use this filter a product list to those that have that selected (intended) active ingredient.

V3 Pseudocode:

```
Select products where attribute.ID = 700000081000036101  
and target = "Paracetamol"
```

⁷ Expression Constraint Language - Specification and Guide - Expression Constraint Language - SNOMED Confluence (ihtsdotools.org)

V4 Pseudocode:

```
Select products where attribute.ID = 127489000  
and target = "Paracetamol"
```

3.2 Replacement of Substances and Qualifiers

Change Summary

As noted above, AMT traditionally replicated parallel content for Substances and Qualifiers, that were the target for many of the relationships (including those described in 3.1).

Substances

A mapping between AMT substance and SI substance is currently maintained by NCTS as part of SNOMED CT-AU. The majority of AMT substances have equivalent concepts within SI, and a direct 1:1 replacement of these will be done in the transformation.

Where an equivalent SI substance does not exist, the AMT substance will be retained and transformed as a subtype of the existing (more general) SI substances, or modification of the substance, whichever is appropriate. The NCTS Team will monitor the release notes from the SI updates and continue replacing AMT substances as replacements become available.

The SI substances will become targets for the |Has active ingredient (attribute)| and |Has basis of strength substance (attribute)| relationships of AMT Product concepts. The existing preferred terms of the SNOMED CT substances will be used, however there are 135 SI substances that don't match AMT substance names. These will be reviewed and updated if required to align with Australian substance naming standards.

Qualifiers

Qualifiers includes all the Units of Measure, Dose Forms, Containers and other concepts (that aren't substances) that comprise the allowable range of concept attributes. Whilst the number of qualifier concepts is much smaller than substances, they are used by every concept within AMT e.g., the qualifier 99011000036109 |milligram (AU qualifier)| is used by over 900 concepts.

Maps between AMT qualifiers and SNOMED CT counterparts is not maintained as part of SNOMED CT-AU, so these were developed as part of the v4 transformation process. In general, AMT concepts were replaced by SNOMED CT qualifiers if identified as equivalent. Otherwise, they were moved to become new subtypes within the relevant SNOMED CT subhierarchy.

Impact

This change is very similar to that described in 3.1 and involves updating the relevant concept identifiers. Changes will be published within the historical associations of SNOMED CT. The volume of changes is large due to the number of concepts effected and their usage.

Substances

- Implementers who are currently using AMT substances will need to update their databases to switch to the SI substance Ids. Where AMT substances are replaced by a SNOMED CT substance, this historical association will be detailed as part of the RF2 release, to assist with migration.
- Dose-based prescribing (DBP) – Where an ingredient is selected as part of a prescribing instruction, the underlying identifiers will change, but the underlying process will remain. It should not be necessary to update any queries due to a switch of substance Id. The example given in the previous section will perform the same, regardless of the identifier of *“Paracetamol”*.
- Clinical decision support (CDS) – Vendors who have built CDS systems that are triggered off substances should review how those triggers work. Where concept Ids are hard coded into CDS processes, these should be reviewed for currency.

All identifiers coded into processes should be reviewed for quality control, regardless of AMT v4 model changes. Identifiers in AMT can be inactivated and replaced as part of routine terminology maintenance.

Qualifiers

Units of Measure – These were mapped to subtypes of 767524001 | Unit of measure (qualifier value)| as per alignment with the SI drug model. Replacements were objectively non-contentious, for example the AMT concept 99011000036109 | milligram unit (AU qualifier)| is semantically equivalent to the SNOMED CT concept 258684004 | milligram (qualifier value)|.

Forms – These were mapped to subtypes of 736542009 | Pharmaceutical dose form (dose form) | as per alignment with the SI drug model. Many SNOMED CT dose forms appear more specific than the original AMT forms, however this is an artefact of the new SNOMED CT forms attempting to be absolutely unambiguous and leaning heavily into closed-world⁸ semantics and AMT being more open-world⁹.

Containers - These were mapped to subtypes of 706437002 | Container (physical object) | as per alignment with the SI drug model.

All were either determined to be equivalent and replaced by SNOMED CT concepts; or moved to within the applicable hierarchy.

The general impact is the same for all:

- Any hard coded usage of concepts in implementations needing to be replaced.
- Any mappings between local code systems and these AMT concept will need to be updated.

⁸ Closed-world assumption - Wikipedia

⁹ Open-world assumption - Wikipedia

- Search fields targeting any of these values will need to ensure the associated target range is updated. This is really an impact due to model (attribute) changes though. Changes to qualifier values, should be transparent providing the correct expansion range is coded (see 3.1)

Benefits

Adopting this change integrates AMT with SNOMED CT more effectively and enables the following:

- AMT to inherit classes such as Medicinal Product Form and Therapeutic Roles.
- Less cumbersome implementation for allergy and adverse reaction inferences. The ingredient substance 372687004 |Amoxicillin (substance)| is the same concept used to define the causative agent property of |Allergy to amoxicillin (finding). Currently the AMT substance map needs to be used to attempt such inferences.
- Leverage further properties of the SNOMED CT concept model. In particular, the SNOMED CT Pharmaceutical dose form concept model provides additional attributes that can be used for new use cases not currently supported by AMTv3.
- Reduced barrier to international vendor implementation, adoption, and interoperability.

Example Use Case

Example 1 – Prescribing alerts based on pharmaceutical ingredient.

A system has an alert such that whenever a patient prescribed a product containing “*isotretinoin*” the clinician is prompted with an alert “*Must not be prescribed during pregnancy*”.

V3 Pseudocode:

```
If PrescribedProduct.hasIngredient = 2245011000036108| isotretinoin |
Then Alert = “Must not be prescribed during pregnancy”
```

V4 Pseudocode:

```
If PrescribedProduct.hasIngredient = 387208003| isotretinoin |
Then Alert = “Must not be prescribed during pregnancy”
```

Note that the PrescribedProduct.hasIngredient property has changed, as described in 3.1.

Example 2 – Filtering medicines by target form, then specific routes of administration.

A clinician wants to prescribe paracetamol and wants to know what forms are available.

AMT v3	AMT v4
Query (<21433011000036107 Paracetamol AND ^929360031000036100 TPUU Refset) .30523011000036108 has manufactured dose form	(<90332006 Paracetamol AND ^929360031000036100 TPUU Refset) .411116001 has manufactured dose form

Result	107011000036108 capsule	420692007 Oral capsule
	257011000036100 chewable tablet	66076007 Chewable tablet
	260011000036108 effervescent tablet	764780001 Effervescent oral tablet
	129011000036109 injection	129011000036109 injection
	261011000036101 modified release tablet	385061003 Modified-release oral tablet
	139011000036106 oral liquid	139011000036106 oral liquid
	224011000036105 powder for oral liquid	224011000036105 powder for oral liquid
	264011000036103 soluble tablet	421701006 Tablet for oral solution
	152011000036100 suppository	420929008 Rectal suppository
	154011000036109 tablet	421026006 Oral tablet

This example shows that the same query produces the same results between v3 and v4, with the only difference being the change in identifiers. Note that some of the preferred terms in v4 may be revised before production.

Furthermore, AMTv4 supports additional use cases more easily. If the patient is unable to tolerate oral medicines, we can identify suitable TPUUs with a query such as

```
(<90332006|Paracetamol| AND ^929360031000036100|TPUU Refset|)
MINUS <440131009|Product manufactured as oral dose form|
```

The results include:

- Paracetamol (B Braun) 100 mg/10 mL injection, 10 mL ampoule
- Panadol 500 mg suppository
- Perfalgan 1 g/100 mL injection, 100 mL vial

3.3 Use the “Product name” qualifier to represent Trade Product

Change Summary

Trade Products in AMTv3 are associated with product concepts (TPUUs, TPPs and CTPPs) via two types of relationships. In AMTv4, all will all be associated with the TPs through the attribute 774158006|Has product name (attribute)|.

Additionally, Trade Product (TP) concepts will be made subtypes of 774167006| Product name (product name)| in the SNOMED CT Qualifier value subhierarchy.

AMT v3	AMT v4
TPUU “is a” TP	TPUU “Has product name” TP
TPUU “has TP” TP	TPP “Has product name” TP
CTPP “has TP” TP	CTPP “Has product name” TP

The Trade Product (TP) class has been marked for review following the release of AMTv4. The purpose and utility of this class is unclear and not reproducible. It generally represents the product brand name but has many challenges when authoring and using it, due to lack of standardisation between registration names, label names, and the information included (sponsor, container, strength, form, flavour etc).

Impact

- Implementers who are using the current relationships to Trade product need to update their queries.
- There will be no changes to the identifiers or preferred terms at this time.

Benefits

- A single relationship type to determine the product name (TP) of a given concept across the whole terminology makes implementation simpler.
- Closer alignment to the SI drug model.

Example Use Case

A system vendor allows users to select available products as brand names, after the user has chosen an MPUU concept.

V3 Pseudocode:

```
IF SelectedProduct = MPUU
    THEN availableProducts = (Trade subtypes of SelectedProduct)
        availableBrands = availableProducts TP supertypes
ELSE SelectedProduct = MPP
    THEN availableProducts = (Trade subtypes of SelectedProduct)
        availableBrands = availableProducts.hasTP
```

V4 Pseudocode:

```
availableProducts = ( Trade subtypes of SelectedProduct)
availableBrands = availableProducts.hasProductName
```

3.4 Remove subpack/component pack distinction for multipack products

Change Summary

Multipacks are primarily used to described:

- Products in which subpacks are intended to be used as sequentially e.g., multiphasic contraceptives
- Products in which subpacks can be reimbursed through PBS individually e.g., single blister packs of monophasic contraceptives.

Products that might come in multiple blister packs (e.g., Cold and Flu PE Day and Night tablets, 48 pack) are not modelled as multipack, even though each box may contain 4 blister packs of 12 tablets.

Currently in AMT, there is a distinction between multipacks:

- Subpack: a count of items, but can only have one type of sub item e.g., eye drops available as 3 x 3 mL bottles
- Component pack: many different items possible, but only one of each e.g., products available as an oral capsule and a cream. The count of 1 is implied but not stated in the model.

AMTv4 removes this distinction and uses the same attribute to represent the same thing.

AMT v3		AMT v4
Multipack	Component pack	
30454011000036104 has subpack	700000061000036106 has component pack	31000001108 Contains packaged clinical drug
700000121000036103 Subpack quantity reference set.value	N/A	1142142004 Has pack size

AMTv4 will also no longer state the total quantity of sub-components within the greater product.

Impact

- Implementers who are using the current relationships 'has subpack' or 'has component pack' need to update their queries.
- The total quantity of each subcomponent needs to be transitively calculated if required.

Benefits

- A single attribute is used to define multipacks, supporting simpler implementation.
- The quantity of sub-components is consistently available within the model.
- The potential ambiguity/confusion associated with restating the total subcomponent quantity is eliminated.

Example Use Case

There are limited known uses cases for querying sub-component properties. The utility is primarily in unambiguous authoring of products. Any example would be speculative. Comparative models are shown below instead.

Figure 1 : AMTv3 Multipack

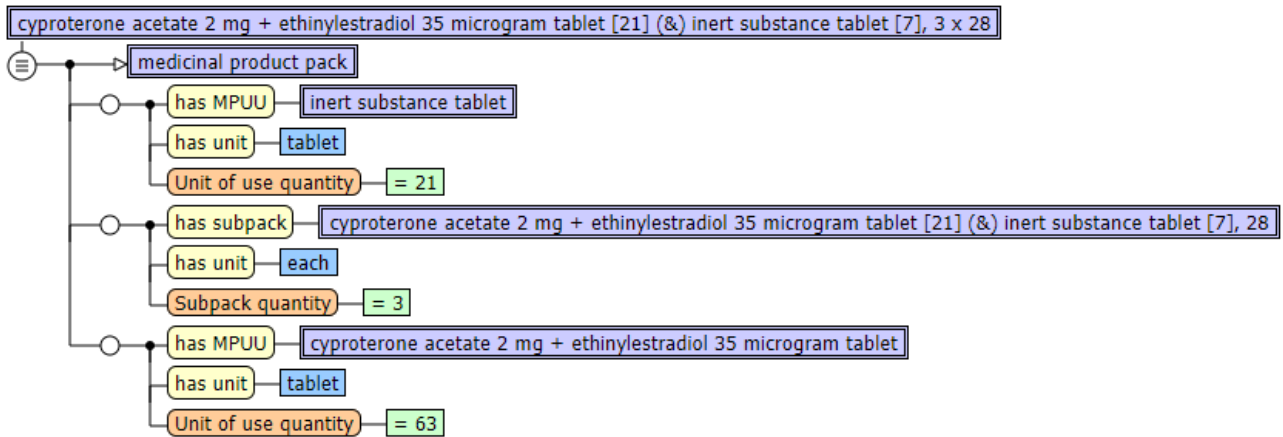


Figure 2: AMTv4 Multipack

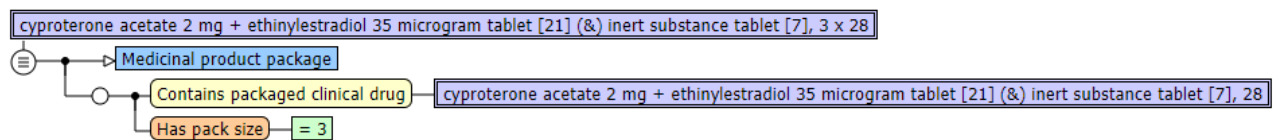


Figure 3: AMTv3 Component Pack

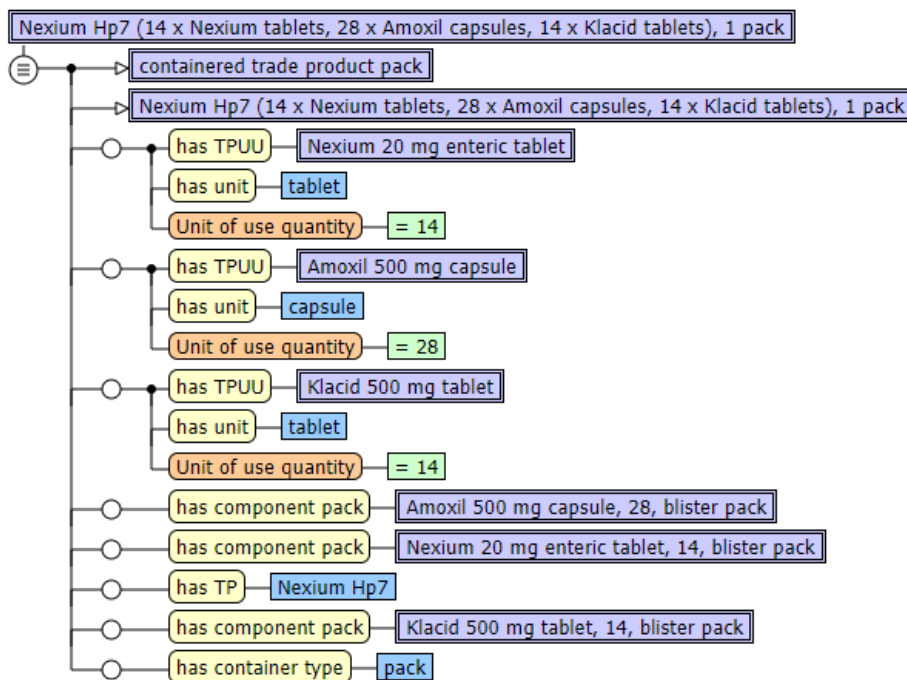
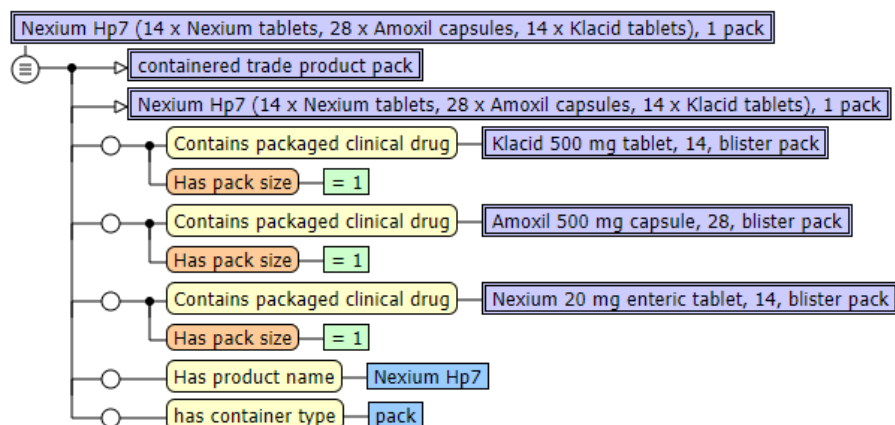


Figure 4: AMTv4 Component Pack



3.5 Combine reference sets into one file per pattern

Change Summary

Each SNOMED CT-AU (including AMT) reference set is published in a discrete file, i.e. 1 file per reference set. This approach originates from the first release of AMTv3 and early RF2 specification interpretations.

Coinciding with the release of AMTv4, the NCTS will also be better aligning with international publication bundle structure. This includes publishing references sets in a “file per pattern”. For AMT and SNOMED CT-AU this means all simple type reference sets will be published in a single file.

```
der2_Refset_Simple<format>_AU1000036_YYYYMMDD.txt
```

Impact

- This change will only effect implementers who use the RF2 bundle.
- Implementers who only use a subset of the AU reference sets may choose to do some pre or post processing to minimise footprint.
- Implementers whose import routines have specific reference set file names hard coded will need to update the import routines, otherwise they will fail.
- Implementers who have more generic import routines (e.g., have wildcards in place of a hard coded name) can continue.

Benefits

- Reference set import routines are simplified, having to only import a single file.
- New reference sets are automatically imported without having to update import routines.
- File names are no longer bound to reference set preferred terms, so these names can be changed as required without breaking import processes

- Issues associated with the default windows path length of 260 characters¹⁰ are reduced (not eliminated)
- Consistent alignment to standard international distribution bundles.

Example Use Case

A vendor who implements all the following reference sets will have simplified import routines:

- Medicinal product reference set
- Medicinal product pack reference set
- Trade product unit of use reference set
- Containered trade product pack reference set
- New South Wales Reportable Schedule 4 medications reference set
- List of Medicines for Brand Consideration reference set

V3 Pseudocode:

```
IMPORT der2_Refset_MedicinalProductSnapshot_AU1000036_20230630.txt
IMPORT der2_Refset_MedicinalProductPackSnapshot_AU1000036_20230630.txt
IMPORT der2_Refset_TradeProductUnitofUseSnapshot_AU1000036_20230630.txt
IMPORT der2_Refset_ContaineredTradeProductSnapshot_AU1000036_20230630.txt
IMPORT der2_Refset_NewSouthWalesReportableSchedule4MedicationsSnapshot_AU1000036_20230630.txt
IMPORT der2_Refset_ListOfMedicinesForBrandConsiderationSnapshot_AU1000036_20230630.txt
```

V4 Pseudocode:

```
IMPORT der2_Refset_SimpleSnapshot_AU1000036_20230630.txt
```

Vendors can then choose to either implement:

- A single database table for all reference sets, filtering on the refsetId field (low maintenance); or
- Process the file such that each reference set is stored in its own file (high maintenance).

3.6 Concrete domain (strength, pack size) representation

“Concrete domains (are a feature of) of Description Logic to enable reference to concrete objects (such as numbers) and predefined predicates on these objects (such as numerical comparisons) when defining concepts.”

¹⁰ Maximum Path Length Limitation - Win32 apps | Microsoft Learn

In the context of AMT, concrete domains are how the numbers used to defined strengths and quantities of medicinal products and substances are represented. For example, the “500 mg” in “*Paracetamol 500 mg suppository*”. Treating these as numbers allows users to perform queries such as “*Products with 100 mg or less of aspirin*”.

Change Summary

The Concrete domain reference sets were created in AMT based on a proposal from SI in 2009. SI later released their Concrete Values specification¹¹ in 2020, with a significantly different format to the original proposal. AMTv4 will retire the existing Concrete Domain reference sets and migrate to the new SI specification.

In parallel to the AMTv4 project, the NCTS is migrating to the SI Managed Service (and associated tooling) in 2024. The SI Managed Service only supports the new standard specification for concrete domains.

Impact

- Many AMT implementers do not use the Concrete Domain reference sets.
- Those who do will have to change their systems to use the Concrete Values file instead. The data is very similar to the Concrete Domain reference sets, therefore the changes required to support the new file will be minimal. In addition, this file is already available in the monthly AMT releases so implementers can begin testing their changes and fully implement the Concrete Values file with AMTv3.

Benefits

- Alignment with international standards for representation of concrete domains within SNOMED CT (and AMT).
- Reduced barriers for international vendors wanting to implement AMT.
- Reduced barriers for Australian vendors wanting to implement international versions of SNOMED CT.
- Reduction on customised solutions to implement AMT. For example an international terminology server supporting ECL queries using concrete domains for SNOMED CT, will work off the shelf for AMT, without having to accommodate what is regarded as a bespoke format.

¹¹ 4.2.6 Concrete Value File Specification - Release File Specification - SNOMED Confluence (ihtsdotools.org)

Example Use Case

An international vendor has a prescribing feature that supports filtering medicines based on strength. For example, a clinician can enter “*warfarin*” in one field to filter on Medicinal Products, and then enter “2” and select “*mg*” as the strength unit. They will then be presented with a list of products containing “2 *mg of warfarin*”.

This feature will work with any SNOMED CT extension supporting the Concrete Value File specification, with minimal configuration. For it to work with the current AMTv3 concrete domain reference sets, will require significant development cost.

4 Medium-impact changes to the AMT concept model

4.1 Replacement of AMT Medicinal Products with SI Medicinal Products

Change Summary

The AMT Medicinal Product class is directly analogous to the SI drug model Medicinal Product class. AMT Medicinal Product concepts will be replaced by equivalent SI Medicinal Products where they exist. Where no SI equivalent exists, the AMT concept will be integrated into the SNOMED CT 763158003 |Medicinal product (product)| subhierarchy.

Impact

- This change is technically identical to that described in 3.2, however as it affects one of the notable concept classes, most implementers will be affected, including those who only consume the AMT Flat File.
- Most consumers of AMT are mapping concepts into their local code systems. Implementers will need to update their product maps to reference the new MP identifiers.
- A mapping of AMT MPs to SI MPs would be provided to the consumers so they may adjust their internal systems accordingly. This mapping will be available in the historical association reference sets (der2_cRefset_AssociationSnapshot_AU1000036_YYYYMMDD.txt).
- The Australian preferred terms will be used for on SI MPs but the SI Fully Specified Names will persist.
- AMT MPs that do not have an equivalent SI MP may will revise their fully specified name to align with SNOMED CT editorial rules, which has a different syntax e.g. ‘elasomeran (medicinal product)’ in AMT will change to ‘Product containing elasomeran (medicinal product)’. FSNs are not used on clinical interfaces but the backend to facilitate mapping, and no risks have been raised by the working group. The NCTS will monitor for feedback when AMTv4 goes live.

Benefits

- The SI Medicinal Product hierarchy is a key integration point for knowledge provider systems for an array of decision support features. After aligning substances, at least 50% of AMT MPs can be replaced by SI MPs.
- Alignment with the SI Medicinal Product concept model provides access to different aggregation classes, properties such as therapeutic roles, general dose forms, routes of administration, and chemical structures. These are inherited automatically as part of the classification process.
- Reduces general duplication across the terminology if a separate Australian Medicinal Product hierarchy were maintenance.

Example Use Cases

Example 1 – Dispensing against MP prescription.

A pharmacist receives an Active Ingredient Prescribing prescription from a patient that includes the Medicinal Product (“*amoxicillin*”) and a strength (“*250 mg*”) specified as free text. The dispensing system finds the associated TPUUs and returns the same list.

Prescription

	AMT v3	AMT v4
	@MP@ = 21415011000036100 amoxicillin @Strength@ = “250 mg”	@MP@ = 27658006 Amoxicillin @Strength@ = “250 mg”
Query	<!(<@MP@ {{ term = @Strength@}})) <!(<21415011000036100 {{ term = “250 mg”}}))	<!(<@MP@ {{ term = @Strength@}})) <!(<27658006 {{ term = “250 mg”}}))
Result	Alphamox 250 mg capsule Alphamox 250 mg/5 mL powder for oral liquid, 5 mL Amiloxyn 250 mg capsule Amohexal 250 mg capsule Amohexal 250 mg/5 mL powder for oral liquid, 5 mL Xycilan 250 mg capsule Yomax 250 mg capsule	Alphamox 250 mg capsule Alphamox 250 mg/5 mL powder for oral liquid, 5 mL Amiloxyn 250 mg capsule Amohexal 250 mg capsule Amohexal 250 mg/5 mL powder for oral liquid, 5 mL Xycilan 250 mg capsule Yomax 250 mg capsule

Caution: This example required no change. Other factors could affect the outcomes of the query including:

- Combinations with other ingredients (e.g. Amoxicillin 250 mg with clavulanic acid)
- Other intermediate concepts between the selected MP and TPUUs.

These factors apply in both v3 and v4, and all assumptions and queries should be thoroughly tested always.

Example 2 – Identify ACE inhibitors

It's currently not possible to identify products in anything but their active ingredients in AMTv3. AMTv4 introduces additional concepts and classes that can be used for new use cases. For example, a clinician wants to identify all patients who have been prescribed an ACE Inhibitor.

The set of MPs can be identified using this ECL:

```
<41549009|ACE Inhibitor| AND ^929360061000036106|MP refset|
```

This can also be extended to identify the TPUUs and return over 600 results.

```
<41549009|ACE Inhibitor| AND ^929360031000036100|TPUU refset|
```

Caution: There's currently no assurance from SNOMED International that the inferences from these groupers are complete. There is a possibility of errors of omission, and these should not be relied on when there is a direct risk to patient safety.

Possible uses might include:

- Secondary use of data, such as analytics or reporting.
- Aids for user interface navigation aids, e.g. 1145021005|Vitamin-containing product (product)|
- As an aid (but on its own) to building clinical decision support.

4.2 Changes to descriptions (primarily FSNs)

Change Summary

Although a revision of the AMT naming conventions was excluded from the project, some changes will be encountered. Aside from correcting erroneous descriptions, this includes:

Fully Specified Names (FSN)

- Where SNOMED CT concepts replace AMT concepts, the SNOMED CT FSN will persist.
- Additionally, the FSN and semantic tags for AMT concepts may be revised for better alignment with SNOMED Editorial Policy and most importantly, to remove existing ambiguity.

Preferred Terms and Synonyms

- Where SNOMED CT concepts replace AMT concepts, it is intended the original AMT terms will be maintained (with a new description Id) unless determined to be erroneous.

- It's proposed that Sentence case formatting is adopted for AMT concepts i.e. "*paracetamol 500 mg capsule*" to "*Paracetamol 500 mg capsule*".

Impact

The impact of this change should technically be low, however it is known that some existing implementation approaches will be impacted.

Mapped implementations

- Where case-sensitive processes are in place to detect changes in terms, these may produce unnecessary noise in change management. Alternative string comparison methods could be used to mitigate this.
- The gold standard for mapping is to use the FSN. The changes to FSNs may trigger maintenance alerts for systems using string comparisons to detect maintenance. The changes of FSN will not be suggestive of a change in meaning (will only be a more accurate and unambiguous label). Existing maps to concepts that remain active may be reviewed for assurance should be sufficient.
- FSN should always in be US English¹².

Native implementations

- Where preferred terms are seen on user interfaces, the adoption of sentence case will be evident to end users. However, this is consistent with best practice UI design for such content^{13,14} and should be seen as an improvement.
- FSNs are intended to provide an unambiguous label for back-end users to manage the terminology and should not affect clinical (front-end) users.

Benefits

- Any revisions to FSNs are aimed at reducing ambiguity, either real, perceived or potential.
- Sentence case preferred terms will provide better consistency with the rest of the terminology¹⁵, and general User Interface styleguides. The tradition for AMT to use all lowercase terms is believed to be an artefact of historical processes where AMT was originally maintained in spreadsheets and product names were a series of concatenations of different cells. (The most notable use of lowercase text in a commercial user interface is Windows Phone 7 and 8 ¹⁶).

¹² US vs. GB English - SNOMED CT Editorial Guide - SNOMED Confluence (ihtsdotools.org)

¹³ Why letter casing is important to consider during design decisions | by Quovantis | UX Planet

¹⁴ Title case vs sentence case in ui - Every Interaction

¹⁵ Case Significance - SNOMED CT Editorial Guide - SNOMED Confluence (ihtsdotools.org)

¹⁶ Text Guidelines for Windows Phone 7 | Rhymed Code

Examples

Fully Specified Names (FSN)

AMT v3	AMT v4
paracetamol (medicinal product)	Product containing paracetamol (medicinal product)
suppository dose form (AU qualifier)	Conventional release rectal suppository (dose form)
litre unit (AU qualifier)	Liter (qualifier value)

Preferred Terms and Synonyms

AMT v3	AMT v4
paracetamol	Paracetamol
suppository	Suppository
L	L

Note: The terms in the current prototype may not currently reflect those in the final production AMTv4. The above examples are demonstrative only.

5 Substantial changes to the AMT concept model

5.1 Move bandages, dressings etc to the “Physical object” hierarchy in SNOMED CT

Change Summary

Non-medicinal products such as bandages and dressings are available in the AMT to support PBS/RPBS requirements. They are currently included in AMT under the standard 7-box model, e.g. there is an MP for “*bandage absorbent wool*” which has an intended active ingredient of “*bandage absorbent wool*”. This modelling is not relevant to these products and add unnecessary complexity.

To avoid noise in the medicinal portion of the dataset, these products will be relocated in a separate hierarchy to the “*Physical object*” hierarchy and will no longer have “*has active ingredient*” or “*has manufactured dose form*” attributes to define them.

Impact

- Implementers who are identifying these products by ingredient or dose forms need to update their queries.
- The affected concepts will no longer have a relationship to MP.

- They will still be included in the AMT reference sets and flat file.

Benefits

- These products can be more easily identified and excluded from medicine lists.

Example Use Case

A system may constrain a data entry field to brands of non-medicinal products. In v3, all dose forms had to be specified in the query and have to be maintained to include new dose forms. In v4, the query is much simpler.

V3 Pseudocode:

```
Select products where refset.ID = 929360031000036100 |TPUU refset|
and doseform.ID IN (48077011000036102 |bandage| ... 48087011000036105
|XX/large size bandage|)
```

V4 Pseudocode:

```
Select products where refset.ID = 929360031000036100 |TPUU refset|
and parent.ID = 49062001 |Device (physical object)|
```

5.2 Removal of the “Unit of Use” role group

Change Summary

The unit of use concepts (MPUU, TPUU) have unnecessarily complex modelling that can be simplified. Analysis of the unit of use role group revealed that it is the source of multiple issues:

- Different purposes for different types of products.
- Inconsistently populated/modelled.
- Predominately redundant information.

The exact purpose or intention of the Unit of Use is unclear and therefore was concluded to fail the URU criteria¹⁷ of “*Understandable, Reproducible, Useful*”.

As a result, there are various AMTv4 changes associated with resolving the issue including:

- The unit of use role group (and properties) will be removed.
- Where it describes a container type or device, this will be modelled more appropriately.
- Where it describes a quantity of medicine (in a container), this will be modelled more appropriately.

¹⁷ URU - SNOMED CT Editorial Guide - SNOMED Confluence (ihtsdotools.org)

- Where it describes an arbitrary value for term generation e.g., “/5 mL measure”, this will be replaced by editorial procedures.

Impact

- Implementers who are using the unit of use role group properties will have to update their queries to find the same information.
- However, there is not believed to be significant use of these properties (presumably due to unclear purpose and consistency).

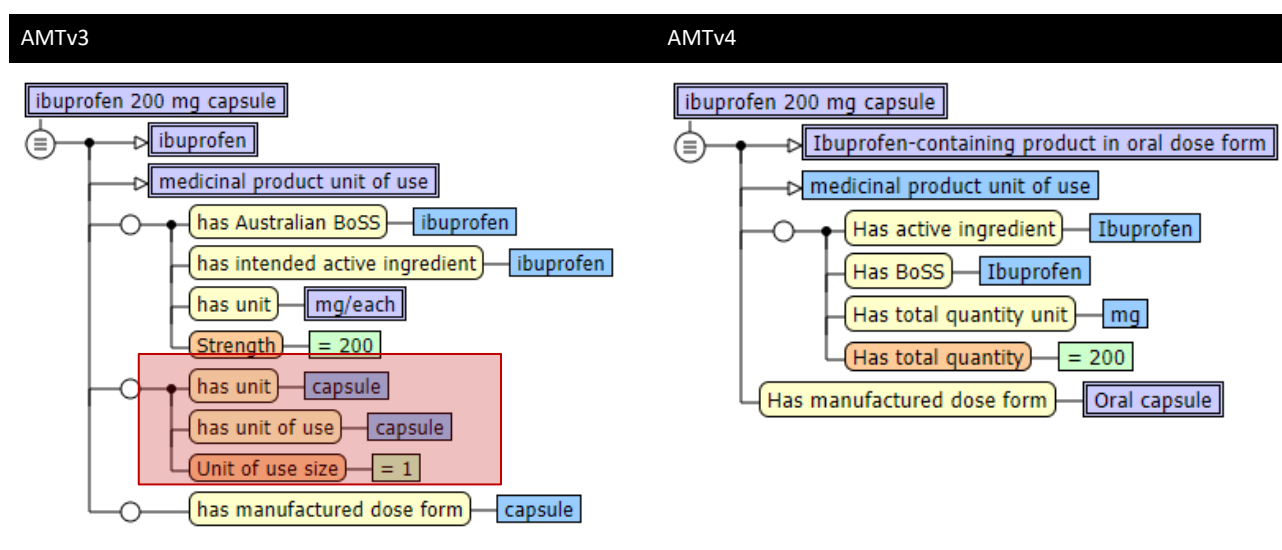
Benefits

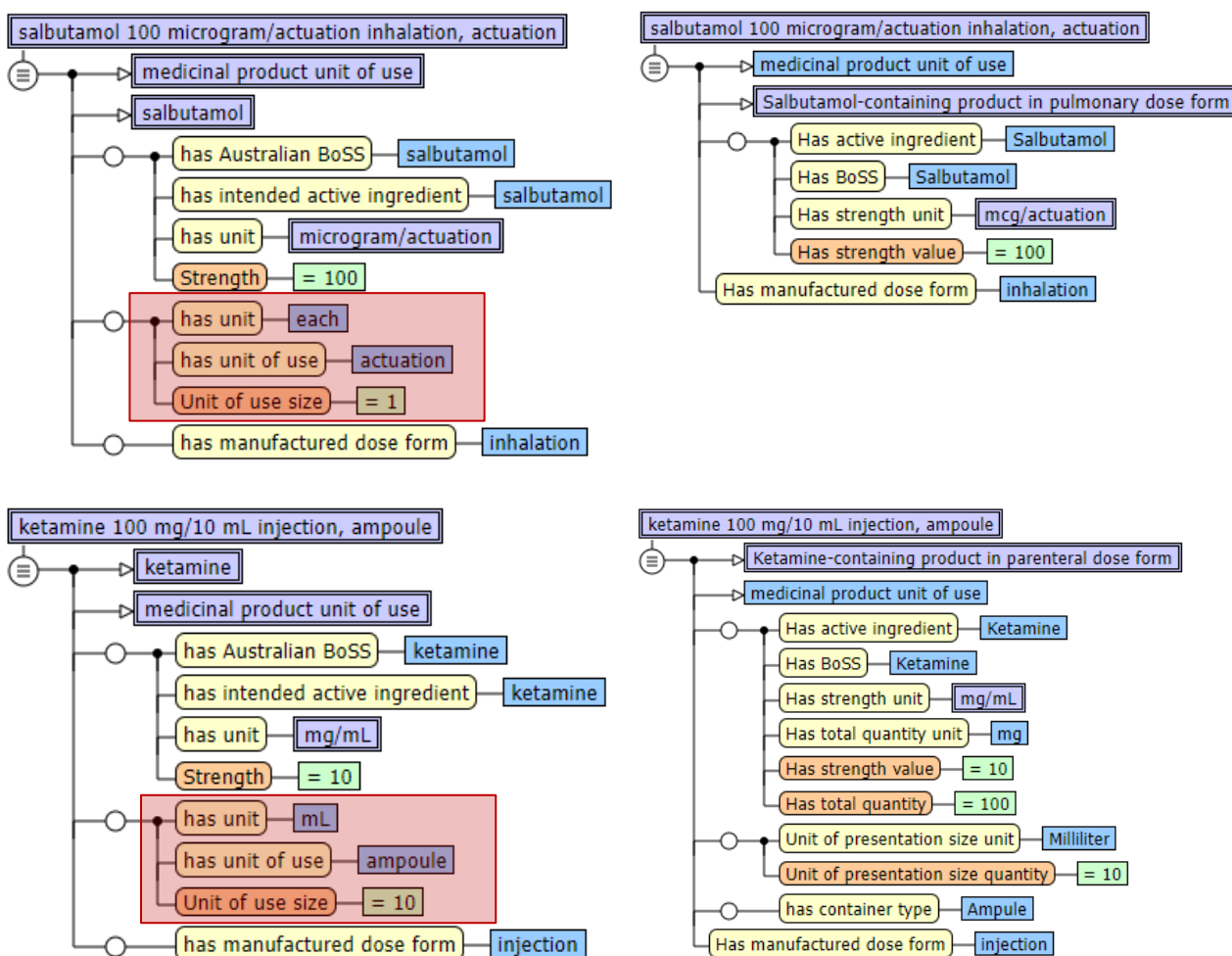
- A simplified model that has fewer moving parts and is easier to maintain and implement.
- A simplified model is safer implement, as implementers are less likely to make incorrect assumptions.
- Removal of redundant and inconsistent properties is a substantial quality improvement.
- Introduction of more explicit properties to describe the contained units and devices is less ambiguous.
- Supports better grouping of products that contain the same total dose and/or concentration.

Example Use Cases

The current clinical use cases for Unit of Use are unknown, or speculative at best.

Examples of the model change are provided. For the majority of products, the unit of use role group (highlighted) contains redundant information and adds complexity without value. In some products, such as the ketamine example, the unit of use describes a pack size. These have been remodelled as a “*presentation size*” role group in AMTv4.





5.3 Represent “total quantity” of an ingredient in discrete products, and represent a “concentration strength” where available

Change Summary

AMTv4 will introduce a new pair of properties on unit of use concepts:

- Has total quantity (attribute)
- Has total quantity unit (attribute)

Total quantity is always grouped with, and relative to, a Has basis of strength substance (BoSS).

For discrete dose forms (e.g., tablets) these properties replace the strength, which was represented using a composite unit “Unit/each”.

For continuous products (e.g., solutions) that contain a size, the total quantity will describe the total quantity of BoSS in the MPUU. The products will continue to have a “has Strength” property, that describes the concentration of BoSS in the product.

Some continuous products are modelled as either discrete or continuants, depending on the information available in the TGA registration. This primarily affects injection solutions.

Impact

- Two possible variations in modelling unit of use products.
- Discrete products will now have strength represented using a new property.
- What was viewed as “*has Strength*” in AMTv3 will be modelled two different ways in AMTv4 depending on the product. Either a “*concentration of BoSS*” or “*total quantity of BoSS*” in a given MPUU. Some products may have both.

Benefits

- Prescriptions and medication instructions etc. using “dose size” are more easily parsed to AMT.
- Similar products are still able to be identified within the terminology, despite the unavoidable variations in modelling (that exists in v3, and will continue in v4)

Example Use Cases

A clinician wants gives an instruction to administer a “100 mg remdesivir”

In AMTv3, the only way to identify possible MPUUs is a simple text search for this string.

In AMTv4, the matching products can be found using ECL or text search.

```
^929360071000036103|MPUU| :  
{732943007|hasBoSS|=1480731000168109|remdesivir|,  
91000001109|Has total quantity|=#100,  
121000001103|Has total quantity unit|=258684004|mg|}
```

5.4 Introduce attributes for other identifying information, and counts of ingredients or components

Change Summary

Removing the unit of use role group led to unexpected results, such as

- Unwanted subsumption between some products that contain identical defining attributes but differences in brand name, e.g. products with flavours
- Removal of components of multicomponent products that are considered redundant by the classifier, e.g. products with a single ingredient tablet and a multi-ingredient tablet of the same ingredient and size

To correct these, AMTv4 introduces

- an ingredient role group count to TPUUs to correct subsumption at that level
- an ingredient count to each role group adding MPUUs to MPPs and TPUUs to TPPs to correct subsumption issues at MPP caused by MPUUs subsume

- a package type count to MPP/TPP/CTPP to avoid subsumption between products available as single and multiple packs

Impact

These new attributes will be visible in the model diagram in Shrimp but do not affect existing relationships.

Benefits

These attributes were included to correct some modelling issues so there are no immediate benefits. However, the counts may be able to help implementers determine branded products with a specific number of ingredients or components.

Example Use Cases

A system wants to find MPPs that have more than 1 component.

```
^929360081000036101|MPP| :  
1142143009|Count of clinical drug type|>#1
```

6 Out of scope

The following items were considered out of scope for the delivery of the AMTv4 model project. However they will be considered as part of a roadmap:

- A full revision of the AMT naming conventions.
- Trade product modelling (potential for MP + brand and MPF + brand) and alignment with registration/label naming.
- Adding missing continuants.
- Removing duplicate TPP/CTPPs
- Standardising container information at MPUU/TPUU vs CTPP.
- Adding missing Medicinal Product Form concepts.
- Adding missing therapeutic roles.
- Removing overly specific MP/MPUUs, and including more OTC products.

The following items were considered out of scope of the AMT:

- A single concept representing multicomponent MPs.
- Subsuming SNOMED clinical drug concepts.



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