

The Australasian Medicines & Devices Terminology Consultation Draft

Overview and Requirements
Data definitions and structures
Technical Specification
Editorial Policies
Release 1.0 Version 0.93
2 September 2004

This work is adapted from the UK Medicine and Device Dictionary and this technical specification document is based on a document sourced from the UK National Health Information Authority (with permission,) modified and extended with input from the Australian Department of Health and Ageing, Blue Wave Informatics, members of the HL7 Australia Medicines Terminology working group

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Purpose of this document

To provide a specification which describes the structure and content of the terminology of medicines and devices for use in health computer systems used for medication management in both primary and secondary care. This combined specification is limited to medicines and devices that are prescribed, dispensed or administered within the healthcare environment of Australia and New Zealand.

Acknowledgement: HL7 Australia wishes to acknowledge the support of the National Health System Information Authority who have provided access to documentation relating to the UK Dictionary of Medicines and Devices and Julie James and Hugh Glover from Blue Wave Informatics who have greatly assisted in the development of this document.

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Document Control

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1 Foreword

This specification of the Australasian Medicines & Devices Terminology (AMDT) has been prepared by a project team from the Australian and New Zealand health informatics sector (see Appendix A) under the leadership of HL7 Australia and contracted by the Australian Government Department of Health and Ageing (HealthConnect Program).

The generous support of the National Health Service Information Authority and Blue Wave Informatics is acknowledged. This document has been based on the structure of two documents prepared as a specifications and editorial policy for the UK Dictionary of Medicines and Devices. (UK dm+d).

The basic class structure of the product terminology model is consistent with the original model accepted at the National Medicines Coding Workshop (November 1999) as proposed by Walker D. and MacIsaac P., subsequently modified by the Medicines Coding Council of Australia, and further developed at the ListerHill international workgroup on medicines terminology and dose forms (a collaboration of UK, USA and Australian government health agencies). The final version has resulted from the input of multiple individuals and organisations under the leadership of HL7 Australia, collectively known as the HL7 Australia Medicines Terminology Working Group.

While the terminology has been designed to handle the representation of medicines, it is recognised that medical devices are also managed through the same processes of ordering, supply and administration. Hence the scope of the terminology in Australia and New Zealand, as in the UK, will cover medicines as well as prescribable devices. The intention is to cover all medicines that are listed with the Australian Therapeutic Goods Administration, the devices that can be prescribed on the Australian Pharmaceutical Benefits Schedule and Repatriation Pharmaceutical Benefits Schedule and medicines and devices listed with the New Zealand MEDSAFE agency.

The product that is intended to result from the implementation of this specification is a terminology to support the clinical processes of medication and device management using computer systems in primary and secondary healthcare settings and related administrative, research and policy activities.

The medicines and devices terminology will form a component of a national **clinical terminology** program which covers:

Standardized terms and their synonyms which, when linked to their atomic concepts and core defining relationships, support the recording, processing and recall (in computer systems) of patient findings, circumstances, events, and interventions with sufficient detail to support clinical care, decision support, outcomes research, and quality improvement; and can be efficiently mapped to broader classifications for administrative, regulatory, oversight and fiscal requirements

(based on: Chute CG 2000, JAMIA 7:298-303)

This medicines and devices terminology has been designed to enable integration with a national or regional (Australia and New Zealand) integrated clinical terminology set, as this emerges through the inevitable process of health informatics standardisation. It is intended that the AMDT will be submitted through both Government (National Health Information Group) and Standards Australia processes to have this work accredited as the Australian and New Zealand Standard for Medicines and Devices terminology.

As with all terminologies and data standards the major task is not only construction, but the maintenance and support of the terminology. It is expected that an appropriate organisation will be contracted to maintain the AMDT with weekly updates, once the terminology has been

developed to cover the majority of products available. Rigorous processes to ensure quality control in the building and maintenance phase will be developed.

It is expected that this medicines and devices terminology will be used in all clinical domains. At the outset those using legacy medicines coding systems will relate to this terminology via a process of mapping their identifiers and concepts to those in the AMDT. However ongoing mapping has significant resource and safety issues and it is anticipated that, in time, this terminology and its regular updates will form the core data on which all medicines information systems are based.

There will be separate documents which describe the processes of

- Governance and management of the AMDT;
- Completing the development of this model and prototype construction;
- Editorial policy and business rules for construction of the production terminology;
- Ongoing maintenance and support;
- Implementation of the terminology and industry guide.

2 Introduction

2.1 Aim

The aim of this document is to provide a background and specification for the Australasian Medicines & Devices Terminology (AMDT) for use as a standard for the identification and description of medicines and devices.

A terminology is a method of defining, recording and retrieval of information in computerised information systems. To a large extent the terminology serves the equivalent functions of a dictionary – it defines terms and concepts in a way that they can be read and understood as well as processed by computer based information systems.

2.2 Policy Context

The need for a national standard approach to medicines identification for Australia was endorsed in November 1999 at a national conference convened by Standards Australia, the Health Insurance Commission and the Department of Health and Aged Care. Several subsequent reports have concluded that a medicines terminology has become a priority, the most recent of which was a national conference on electronic decision support (HL7 Australia November 2003). Following this meeting a group of health informatics industry vendors, users and organisations involved in governance and Quality Use of Medicines, agreed to collaborate to rapidly construct, implement and maintain a national medicines terminology. HL7 Australia approached the Department of Health and Ageing to participate in this process and provide linkages with existing work to develop a national medicines catalogue. The Department has provided significant resources and input under the *HealthConnect* program to further this work.

The *HealthConnect* trial held in Tasmania (2002-4) demonstrated the need for a standard medicines terminology to facilitate transfer of electronic medicines history between hospital and community based GP systems.

Australia and New Zealand are moving to adopt a common medicines registration process incorporating their regulatory agencies TGA and MEDSAFE, to provide a common regulatory framework by July 2005 (www.jtaproject.com). There is common use of clinical software in both countries and a tradition of collaboration on health informatics standards. Consequently the AMDT will aim to cover both jurisdictions.

Internationally, consensus is developing around the need for standard approaches to terminology in information and communication technology systems. The UK has developed a Dictionary of Medicines and Devices, and in the USA the role of a terminology standard is being shared between the National Drug Formulary – Reference Terminology (NDFRT)(US Veterans Affairs Administration) and the RXNORM system (National Library of Medicine). Australia, the UK and the USA have been participating in an international collaboration to support the development of standard medicine terminologies (known as the ListerHill group after the first meeting held at the Lister Hill campus of the US National Library of Medicine). The ISO Technical Committee 215 working group 6 is currently scoping a project to explore the business case for a national and international approach to medicines terminology.

The AMDT provides a way of uniquely identifying packaged medicines and core components of these medicines within electronic information systems used in Australia and New Zealand. At the outset it needs to be clearly stated that the AMDT is not a medicine knowledge resource and will be limited to core medicines descriptive material.

The following broad use cases are supported:

- Electronic Health Record
- Community prescribing, dispensing and medication management and review
- Hospital prescribing, dispensing, administration and review
- Electronic transfer of prescriptions
- Electronic Decision support
- Messaging of prescription related information
- Supporting manufacturers and electronic supply chain.

2.3 The Australasian Development Process for AMDT.

Following the initial national workshop in 1999, between 2000 and 2004 a process has been underway to develop a catalogue of medicines under the then leadership of the Medicines Coding Council of Australia. This has resulted in the engagement of EAN Australia to manage the development of a national product register stored on EANnet. The pharmaceutical and complementary medicine suppliers will voluntarily enter and verify medicines data in this system and then maintain the currency of the register as product changes occur. This is seen as being the long term system for maintaining the currency of the AMDT and ensuring that pharmaceutical and complementary industries are engaged in this activity. The following diagram illustrates the relationship between the two projects:

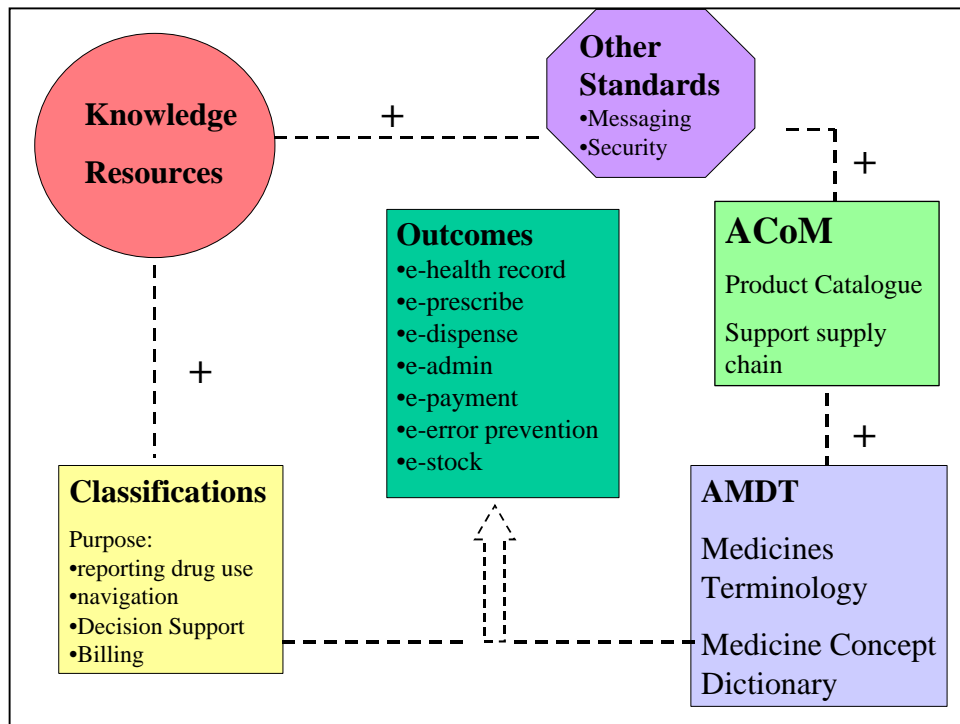


Figure One; Schematic indicating core relationship between Terminology, Classification and Knowledge to support medication management functionality

The AMDT will be constructed following an industry collaboration which has brought together medicine information providers, medication management systems, the government sector and a range of others directly requiring a national medicines terminology. This process has the support of the Australian Pharmaceutical Advisory Council (APAC) and is linked with key health standards committees, in particularly the National Health Information Group via the Health Data Standards and Health Informatics Standards Committees.

The key objectives are to ensure that the AMDT:

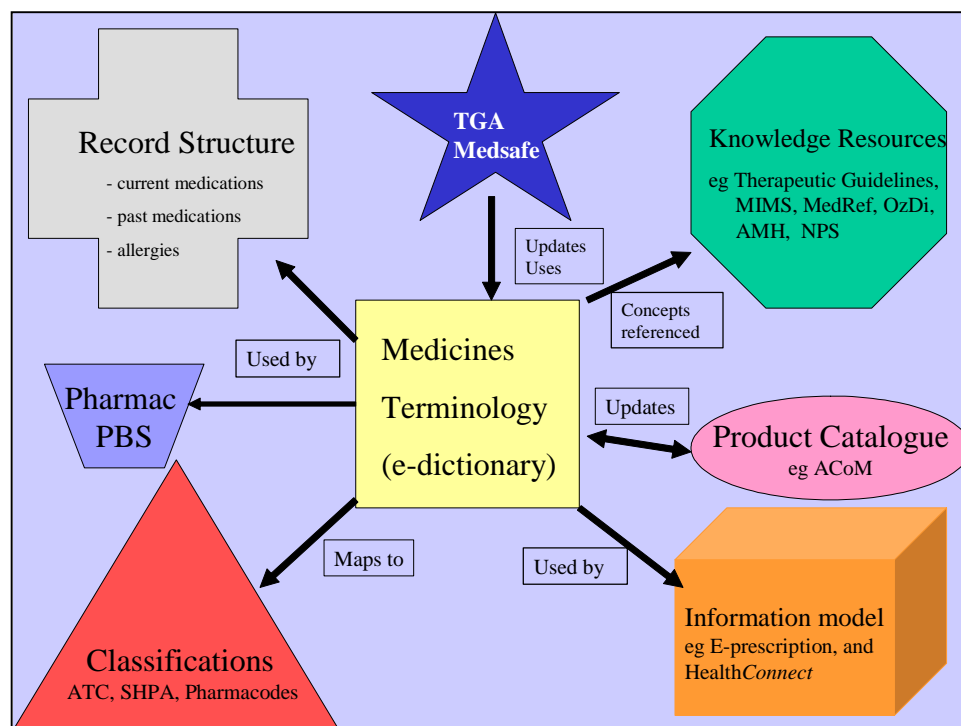
- Has sufficient breadth of information to cover the full range of user requirements;
- Includes at the outset all medications included in the medication lists of participating organisations and rapidly progresses to cover all medications listed for use in Australia and New Zealand;
- Can be delivered in a timely and quality assured manner (with a target launch at the end of 2004);
- Can be maintained into the future and distributed widely at low or zero cost to the end user.

While the medicines terminology is being developed as a self-sufficient structure it is intended that it link with core medicines classifications currently in use eg Society of Hospital Pharmacists codes (Aust), the ATC classification, Pharma-codes (NZ), BNF codes (NZ), and other terminologies which may become the core of a national terminology set. For example in the UK the DM&D links to the core content of SNOMED-CT to provide links with medicine concepts at the Virtual Product and Virtual Therapeutic Moiety level.

In addition to the above, associated costing information will need to be sourced to support financial aspects of medication management.

At the outset it is expected that the AMDT will map to existing proprietary systems. However, in time it is expected that the core data structures will be incorporated into the structures of medicine knowledge resources.

The following diagram illustrates the conceptual relationship between a medicines terminology and other components of the medicines information system.



2.4 The Scope of AMDT

In terms of product coverage, the scope of AMDT is to include individual medicinal products that are available in Australia and New Zealand for the treatment of human patients and will include medical devices supplied for personal use. The personal medical devices coverage is as defined by AMDT editorial board and will initially includes those devices commonly prescribed in the primary care domain, with the systematic incorporation of other groups of devices over time.

The initial scope of the AMDT will include products already listed in participating project members' software products.

A second scoping aspect of the terminology relates to the range/type of information that is associated with each entry within the terminology. Discussions with stakeholders from within various user domains across the healthcare spectrum identified a number of requirements which overlap or which at least are contiguous. The roles of the various stakeholders (actors) are listed in the table below. The requirements themselves were captured by the process of documenting storyboards and using these to validate the model developed.

Patient	Referrer
Prescriber	Dispenser
Specialist/Consultant	Medication Record
Supplier	Wholesalers
Protocol writer	Administrator
Insurer/payment agency	Validator
Buyer	Manufacturer
Waste Disposer	Recycler
Terminology Support Group	Clinical Decision support
Other Carer (PAMs, clinical support services)	Researcher

Table 1: AMDT Actors (non-exhaustive)

Product Identification	Units of weight, volume and strength
Medicinal Product Names	Ingredient substances
Strength	Pack Information
Dose form	Medicinal product sponsors

Table 2: Information elements within the scope of the AMDT

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

- Pharmaceutical Benefits Scheme and Repatriation PBS information and NZ Pharmac and Pharmacode systems.
- Standard medicines classifications [Anatomic Therapeutic Chemical Classification (WHO) and Society of Hospital Pharmacists Coding system (SHPA)]
- Existing medicine vocabularies used in Australia including those of organisations participating in the construction of the AMDT and the Therapeutic Goods Administration (TGA) Australian Register of Therapeutic Goods.
- Poisons schedule information

Examples of the knowledge based information that is not to be considered are represented in Table 3

Dose checking	Normal dose range
Indications	Contra-indications
Adverse effects	Cautions in use
Counselling instructions	Drug : drug interactions
Drug : food interactions	Cautionary label recommendations
Route of administration	Drug : Disease interactions

Table 3: Knowledge-based information elements outside the terminology scope

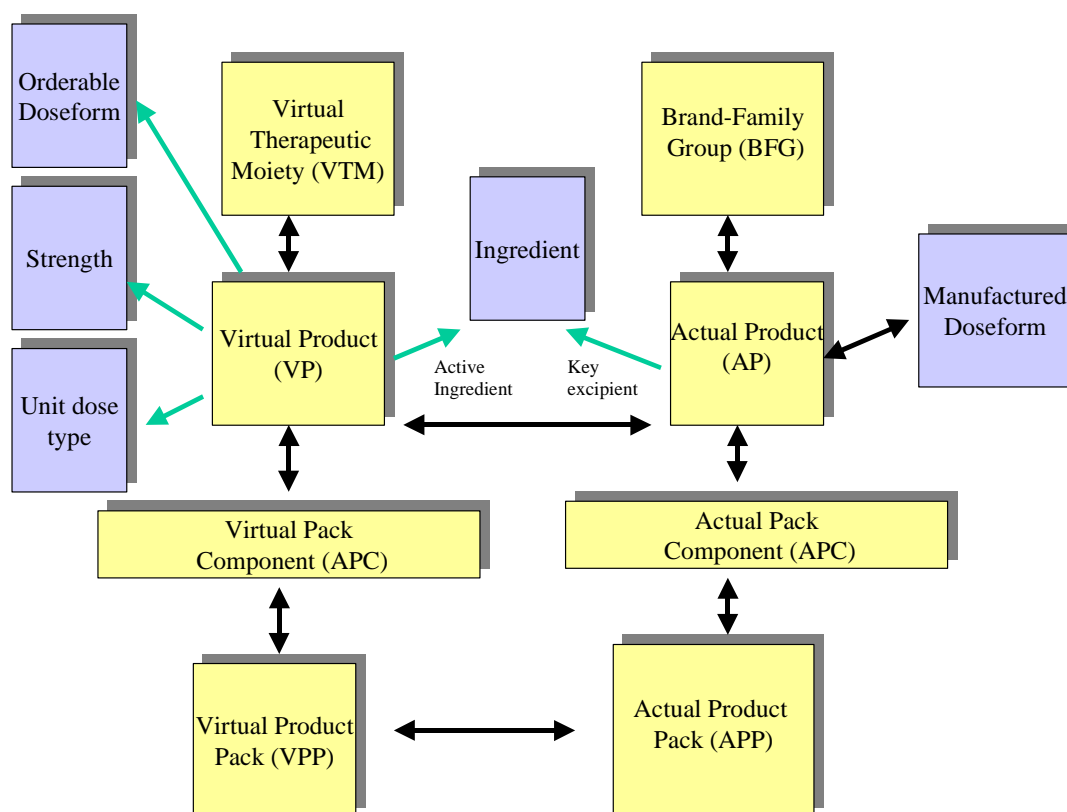
3 General Outline of Requirements and Editorial Issues

3.1 The Australasian Medicines and Devices Terminology

Section 4 of this document provides the specification for the Australasian Medicines and Devices Terminology. The terminology has six core components or classes:

Virtual Therapeutic Moiety (VTM), Brand or Family Name (BFN), Virtual Product (VP), Actual Product (AP), Virtual Product Pack (VPP) and Actual Product Pack (AMPP).

In addition to the six components described above there is an accompanying terminology or lookup tables of ingredients and reference data, examples of which are forms, routes, units of measure and suppliers.



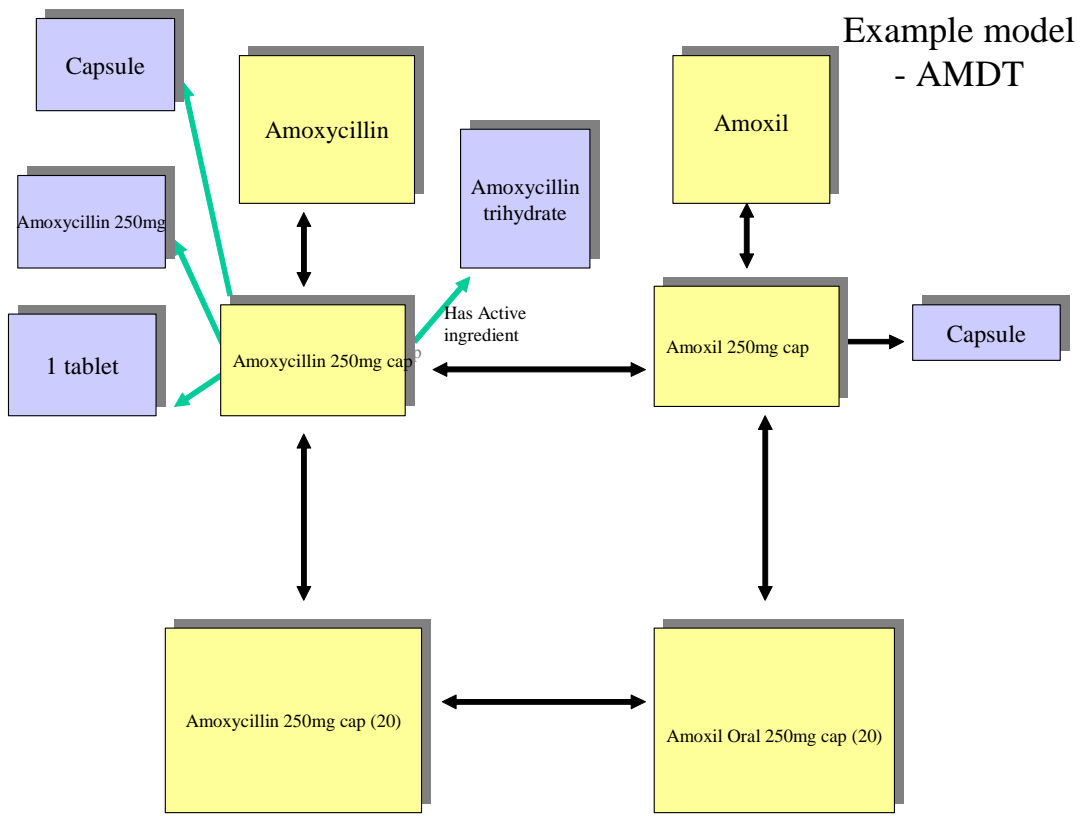
Conceptual Model - Aust. Medicines + Devices Terminology

The above diagram provides a high level overview of the terminology components:

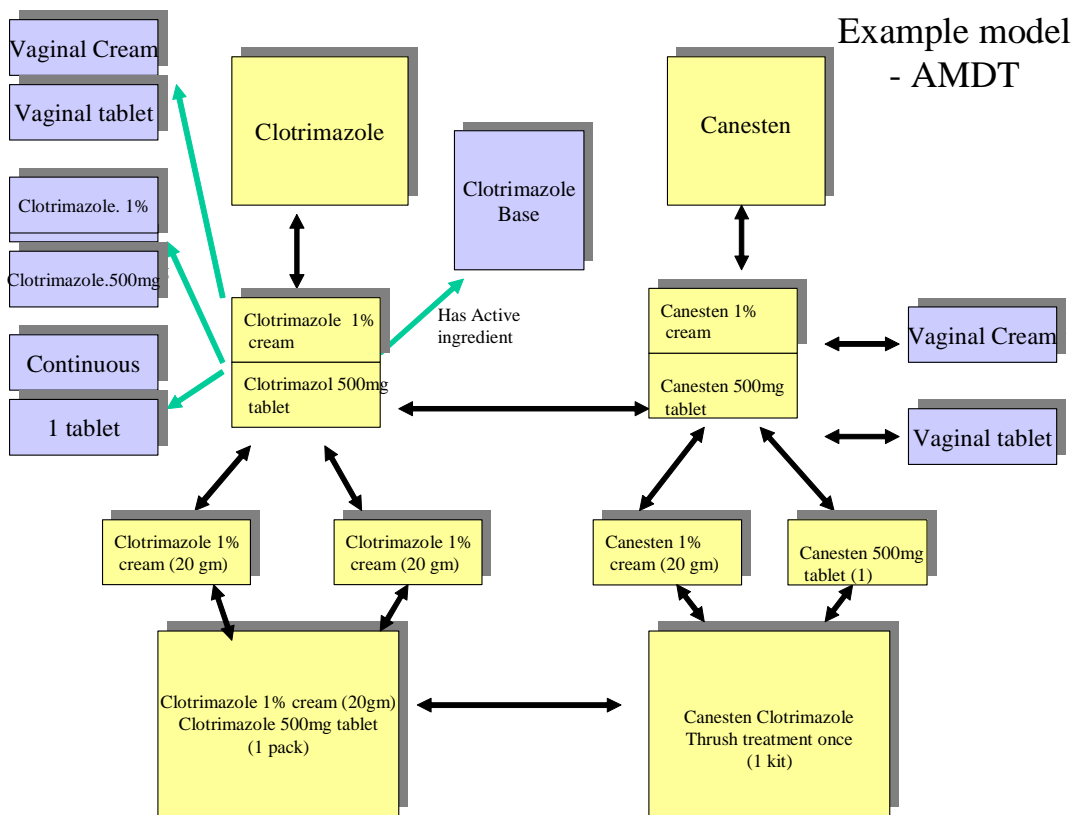
Conceptually medicines can be described or defined by their:

- Active ingredients
- Strength
- Dose form
- Administered unit dose type.

The following page contains two populated examples of the conceptual model.



1 Example of simple product format



3.2 Identifiers

Each concept, term, relationship and external map in the AMDT will be identified by a unique numeric identifier and unique text string. The identification system will use what is currently believed to be international best practice in managing this. Principles to be followed include that identifiers will be:

- Managed in a controlled process;
- Numeric;
- Contain no data or information related to the concept being identified;
- May include internal organisation relating to the structure of the identification system or terminology;
- Never be deleted, although it is permissible to mark it as no longer valid;
- Never be re-allocated to any other concept used.

It is not expected that end users will ever see an identifier as these are used within applications. Users will see concept descriptors in the English language and the AMDT will allow for the use of recognised synonyms.

Unique identifiers are provided for each concept which can be referenced externally e.g. BFN, VTM, VP, AP, VPP, APP and some supporting tables such as Ingredient Substances. These will be Concept Unique Identifiers based on the Object identification system (OID).

The International Standards Organisation has created a system for unique identification of objects, known as the Object IDentification (OID) system. Through a controlled process an OID root number is allocated to the terminology itself and registered with HL7 internationally. Further information on OIDs is available at www.hl7.org.au (members only section).

HL7 Australia has reserved the following root OID for the AMDT - (2.16.840.1.113883.2.3.4.1).

The options for the AMDT are to:

1. Allocate a unique reference number within the AMDT structures which is appended to the AMDT OID root;
2. Use the internal system for identification developed by SNOMED-CT. This would have the advantage of facilitating linkages with this system should it become a national standard core terminology.

To avoid ambiguity the identifiers used for each category of medicinal product and packs shall be unique and non-overlapping, e.g. an identifier for a VTM should not also be an identifier for a VP, AP, VPP, APP, or Ingredient Substance.

The terminology will provide a mapping between its entries and other medicinal product coding schemes such as the EAN numbers, now officially described as Global Trade Identification Numbers (GTIN), ATC codes, SHPA codes, and the ARTG numbers and NZ Pharmacodes.

During the construction phase maps will be created to the identifiers of participating organisations.

There is a need to track changes in terminology entries over time. This will occur in the terminology management environment. A process for managing changes to the AMDT will have to be developed. The UK model provides for at least the last change to be stored within the UK DM&D, however for quality control and audit purposes all changes will need to be stored. It is proposed that changes will not be stored in the core terminology structure, however a complete

audit trail will be maintained within the AMDT production system. These changes may be made available to end users, if required, to facilitate end user systems providing access to, and tracking of, previous values of attributes over time - for audit purposes.

In order to support the distribution of terminology updates which contain products which are not yet available, however which will become available prior to the next update, a product availability or start date is provided.

Periodically, entries in the terminology will be found to be no longer relevant or valid. These entries will then be marked as invalid, and an effective date for this occurrence will be entered, however the entry will remain in place within the terminology.

3.3 Naming conventions

The TGA produces a reference list of approved names based on the recommended international non-proprietary name (rINN). In the AMDT this will act as a guide to the naming of Virtual Therapeutic Moiety and Ingredients.

The TGA lists of approved names are not terminologies and in themselves cannot fulfil this function.

Consistent systems have to be developed for the naming of each class within the AMDT. Each instance of every class will have a unique name which fully describes the concept. These names represent the Semantic Normal Form of the name. Editorial policy for each name is dealt with in the appropriate part of the specification.

For example the Virtual Product will have a structured name consisting of:

Products:

Active ingredient (base); Strength; Modification; Form; Unit dose; additional information.

Virtual Ingredient	Dose form	Strength		unit dose type (“the each”)	Pack size	Pack Ty
		Weight active ingredient	Unit dose type (each)			
Atenolol	Tablet	50mg	Per 1 tablet	1 tablet	50 tablets	bottle
Frusemide	Solution	20mg	per 2mL	2mL ampoule	10 ampoules	box
Hydrocortisone 1%	Cream	1g	per 100g	continuous	15g	tube
Colifoam	Enema	90mg	per applicator	1 applicator	14applications	Pressure
Metronidazole	Oral suspension	200mg	per 5mL	teaspoon (5mL measure)	100mL	bottle
Salbutamol	Aerosol	100 microgram	per actuation	1 actuation (puff)	200 actuations	Aerosol o
Crepe bandage 10cm	Not Applicable	Not Applicable	Not Applicable	Not Applicable	1	Shrink w

The unit dose type is often omitted in descriptions to avoid redundancy of information and is represented by the lighter text in the above table of examples

3.4 Strength

The “strength” is the representation of the amount of active ingredient present in a single dose unit of a medicinal product or concentration for products which do not have a defined administerable unit (known as “continuous”).

VP will usually have a strength for all active ingredients There are various patterns of strength expression.

3.4.1 Solid dose forms

- Weight eg mg
- Ratio 800mg/125mg (for combination products which have a generic name eg. co-trimoxazole)
- Percentage
- A volume (eg liquid filled capsule)
- Activity eg units
- Other eg mmol.

3.4.2 Liquid injections and infusions

Expressed as a total amount of active in the administered unit dose volume (eg 100mg/5mL vial)

- Weight eg mg
- Number of units eg units, million units
- No strength (eg water for injection).

Alternative ways of representing strength will be used where this is the commonly used and recognised format. These are:

1. Unit strength where the intention is to draw from a multi-dose container and the strength is recorded as mg per 1 mL (mg/mL). Eg Insulin 100units/mL solution for injection in 10mL vial (alt strength method 1);
2. Dual representation of unit strength and a ratio or percentage eg. Adrenaline (1in1000) 500microgram/0.5mL solution for injection ampoule (alt strength method 2);
3. Percentage for large volume infusions eg Sodium Chloride 0.9% solution 1 litre bags.

3.4.3 Liquids (other) expressed

- Weight / unit volume
- No. of units / unit volume
- Percentage.

3.4.4 Continuous semi-solid preparations

Eg cream, gel, ointment. Strength usually expressed as a percentage depending on product this may be:

- Weight/weight (w/w)
- Weight/volume (w/v)
- Volume/weight (v/w)
- Volume/volume (v/v).

Strength may be expressed as an amount per gram eg weight (eg mg) or activity (eg units).

Some products do not need a strength e.g. aqueous cream.

3.4.5 Continuous liquid preparations

Eg oral solutions, paints, eye drops.

Liquids intended for oral administration will usually express the strength per volume representing the usual administered dose type (a 5mL measure or teaspoon).

Usually specified as amount per administrable dose unit (eg 250mg/5mL) or may be expressed as amount per unit dose. Some products may not specify a strength.

3.4.6 Continuous solid preparations

Eg granules, powders. May be expressed as a percentage or weight per weight or weight per volume.

3.4.7 Miscellaneous

- Patches - strength usually expressed as amount per time period of release. Hyoscine 1mg/72 hour patches;
- Inhalers and sprays; strength expressed as amount per actuation;
- Implants and devices; strength are expressed as amount per device;
- Dry powder injections will have strength expressed as amount (weight or units) per vial.

3.5 Ancillary Reference Terminologies

In addition to the main terminology classes there is a requirement to supply and support a number of additional reference terminologies which supply 'look-up' files whose coded entries are used by the terminology. In particular files are required for the concepts described below.

Although there are some standards governing the naming of medicine components and concepts held by the TGA, these systems have been developed for regulatory purposes and may not meet the needs of users of terminologies and clinical information systems.

It is likely that until local and international standards emerge for the following ancillary medicines terminology that these terminologies will have to be maintained as part of the AMDT. Once other options become available then a migration strategy to using these options will become necessary.

As these reference terminologies are essential for the definition of medicines these need to be defined and finalised prior to the construction of the AMDT.

3.5.1 Dose Form

Each entry in this code list will contain a unique code taken from a controlled vocabulary, and a textual description representing a dose form. There are two types of dose form described in the AMDT.

1. Orderable dose form which describes the form usually encountered in the ordering of medications (hence suitable for dispensing and administration).
2. Manufactured dose form. The dose form created by the manufacturer will also be recorded. (eg powder for reconstitution as suspension)

3.5.2 Ingredient

Each entry in the code list/ingredient file will contain a unique code taken from a reference terminology and a textual description representing any of the following:

- a substance which acts as an actual ingredient substance within medicinal products (e.g. amoxicillin sodium, erythromycin stearate);
- a substance which is the base ingredient where a specific salt is not recognised or where the base is the commonly regarded active ingredients (eg amoxicillin). Amoxicillin sodium “is a kind of” Amoxicillin (base).

NOTE: excipient ingredients (non actives) are currently outside the scope of the AMDT, except for a small number which are defined by editorial policy to be potentially clinically significant. The TGA has defined a list of excipient ingredients which are potentially clinically important

The names used to describe substances shall be taken from the TGA list of approved names where possible.

In the AMDT ingredient is used in a range of contexts:

Active ingredient is the representation of the substance (chemical or biological) intended to achieve the pharmacological effect in an medicinal product. Active ingredients may be grouped under a “base ingredient” which may represent several equivalent ingredient salts.

A Basis of Strength Ingredient or Substance (BOSS) is the representation of the ingredient for which the strength is specified regardless of what ingredient is defined as the component of the medication. Eg all erythromycin products have strength of erythromycin base described rather than the individual salt.

3.5.3 Unit of Measurement

Each entry in this code list will contain a unique code and a description or other generally recognisable representation of a unit of measurement with use within the medicines terminology.

3.5.4 Administerable unit dose type

This concept describes the administerable dose type eg. 1 tablet, 2mL vial or continuous (for creams, solutions). This concept defines the “each” that is the unit of administration. This is usually the denominator of the strength field.

3.5.5 Medicinal product suppliers/sponsor

This information will not be held in a terminology, but in an ancillary data table. The supplier will be regarded as the organisation listed on the product package.

Each entry in this code list will contain a unique code and a textual description of a supplier of one or more medicinal products. The supplier is the organisation cited on the product package and may or may not be the manufacturer of a medicinal product. Suppliers may change over time.

NOTE: A supplier may have an invalidity flag indicating that this entry was invalid. The entry needs to be retained in case it was used prior to the detection of the error(s) which caused its invalidation.

3.6 Medical Devices

Prescribable medical devices will be included in the AMDT. Based on the UK DM&D it is feasible to manage the data for prescribable devices within the same data structure as used for medicines. However the use case is limited to the ordering and supply of devices hence the only mandatory components of the model for devices will be the Actual Product and Actual Product Pack classes. All other cardinalities will be able to be “relaxed” indicating that data is not required in these fields eg virtual product.

3.7 Multi-component and multi - ingredient medicinal products

Medicinal products vary enormously in the complexity of their packaging and internal structures. The AMDT is required to represent this complexity in order to support the whole range of user requirements.

Actual medicinal products may consist of single or multiple ingredients in a single administerable dose form e.g. Paracetamol 500mg + Codeine 30mg tablets (Panadeine forte).

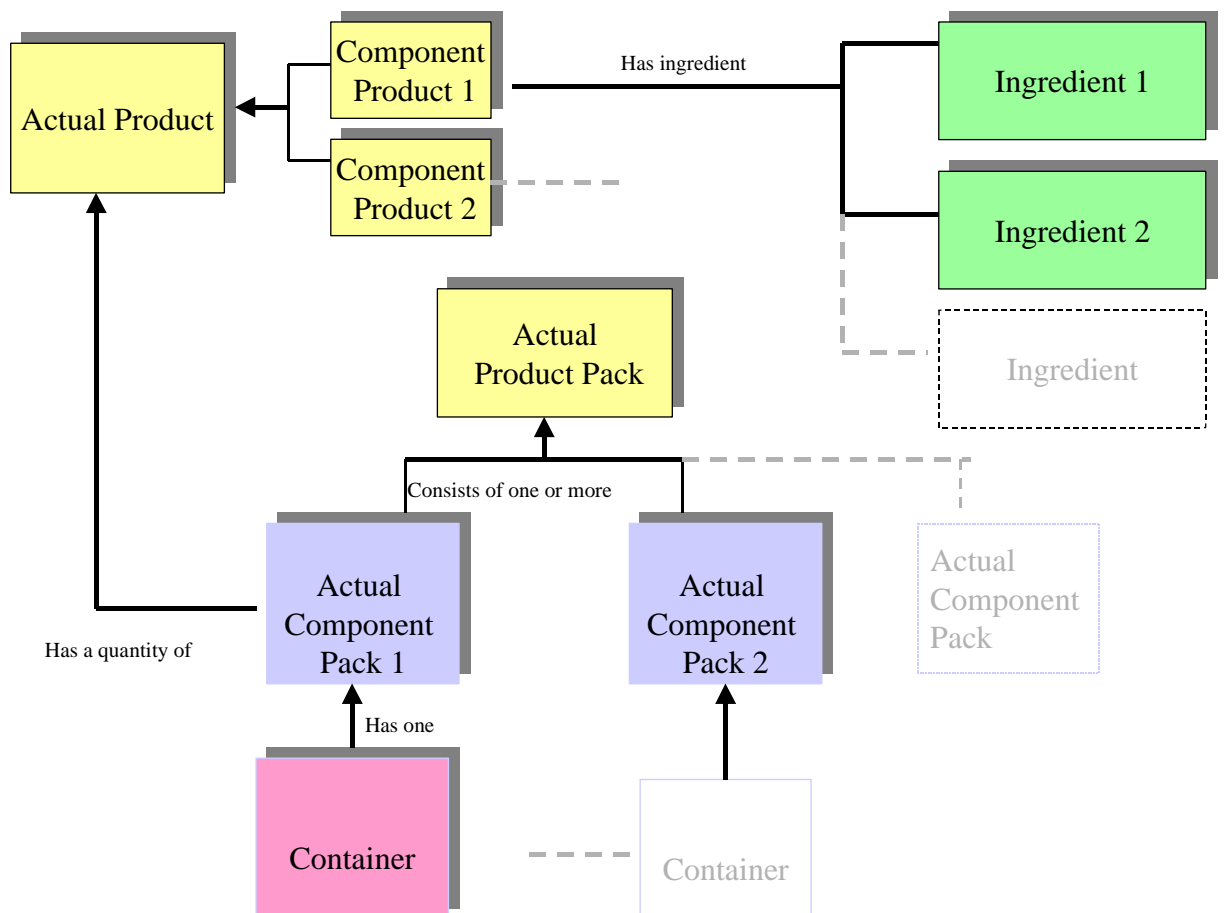
Actual medicinal product packs may consist of a variable number of component packs, which themselves may be present in quantities of one or more. Each component pack ultimately delivers to the patient a fixed quality of Actual Product.

The user requirements for dealing with multiple component and ingredient products mandate that every actual product must be able to be prescribed and supplied as a whole entity, however the individual components have to be able to be identified for purposes of supply and administration.

Multi-ingredient products are relatively straight forward as they are represented in the same way as single ingredient products, however the multiple ingredients and their corresponding strength are included in the VP name (up to 3 in total). Where more than 3 active ingredients are present the name will follow the style (generic + AP name). The VP however has links with every active ingredient. .

Multi-component products are more complex as they are represented at the VP, AP, VPP and APP levels as both a single instance and also as instances of the constituent components. While component products are conceptually considered as a separate class, there may be more than one level of component product and this may differ for different products. This is managed by using a “recursive” relationship where a component product pack is a product pack (flagged as a component pack which may or may not be prescribable in its own right) which is a part of another product pack, and so on until eventually the content of the product pack is the actual medicinal product.

The following diagram represents schematically combination and multi-ingredient product packs.



3.8 Editorial Policy

Current editorial policy is detailed in this document. In future, a separate editorial policy document could be created to record decisions made during the population and maintenance of the terminology, where issues are not documented in this specification. Reference material for editorial policy could be informed by the UK DM&D editorial policy, editorial policy for the secondary care medicine dictionary prototype of the UKCPRS, the Guide to RX Norm and the policy decisions of the former Medicines Coding Council of Australia.

4 Model and description of the Australasian Medicines Terminology

4.1 Introduction

In this design, the terminology consists of six distinct sub-sections each section containing a set of entries. These sub-sections are:

- Brand or Family Name (BFN)
- Virtual Therapeutic Moiety (VTM)
- Virtual Product (VP)
- Actual Product (AP)
- Virtual Product Pack (VPP)
- Actual Product Pack (APP).

These core concepts are defined below. Definitions of attributes are given in the text of the document.

4.1.1 Brand or Family Name (BFN)

A Brand or Family Name (BFN) represents the product brand name or the grouping of products in “family”. In general these products represent the same therapeutic agents eg Amoxil contains the prescribable VTM amoxicillin, however this may not always be so eg. Canesten which can represent both an antifungal cream and a urinary alkaliniser. This class will allow the recording of medications where incomplete information is available and the grouping of products for analysis. For example a patient may be aware that they were previously prescribed “amoxil” but can not be more specific about the form and strength.

Examples of Brand or Family Names:

- Aspirin (Bayer)¹
- Amoxil
- Canesten
- Zoloft.

4.1.2 Virtual Therapeutic Moiety (VTM)

A Virtual Therapeutic Moiety (VTM) is the abstract representation of the active ingredient(s) or substance(s), which when formulated as a medicinal product, is intended by an authorising health care professional for use in the treatment of the patient. The VTM is derived from the active ingredient base concept with the following knowledge or rules incorporated:

- Up to 3 ingredients are specified for multiple component medications
- The precise ingredient (salt) is specified where this is therapeutically necessary
- Some medications are not recommended to be prescribed generically eg. Warfarin.

The VTM defines a group of Virtual Products which contain the intended therapeutic substance.

Examples of Virtual Therapeutic Moieties:

- Atenolol
- Sulfamethoxazole + Trimethoprim (synonym Co-trimoxazole)
- Doxorubicin
- Fluorouracil

¹ Note where the brand family name is a VTM the name of the sponsor will be appended to allow the name to be unique.

Paracetamol + Codeine
Hyoscine hydrobromide.

The VTM list of therapeutic intents is designed to be used to support “generic prescribing” in a secondary care setting. Note that it is not sensible or possible to prescribe all products generically, hence VTMs may not exist for multi-ingredient products (number of active ingredients > 3). For multi-ingredient products the VTM will contain the individual therapeutic intent agents joined by a “plus” (+) sign. Since the purpose of the VTM is not to aggregate products, link with decision support or evaluate prescribing trends, multi-ingredient products will only be linked to the combined entry and not to sub-components of the VTM. For example Panadeine will link through to VTM (Paracetamol + Codeine) and not to VTM (Paracetamol) and VTM (Codeine) individually.

4.1.3 Virtual Product (VP)

A Virtual Product (VP) is an abstract concept representing the properties of one or more clinically equivalent Actual Products, where clinical is defined as having the same active ingredients, strength, dose form, and administrable unit type, and where the Actual Products are considered as clinically equivalent.

Although Virtual Product entries within the terminology are expected to equate to prescribable products there will be a number of entries which are related to entities which cannot normally be prescribed or which cannot be represented in a way suitable for use in prescribing. For example, Norgestrel 150 microgram tablets are only encountered as a part of a combination pack and are not prescribable in any pack size in their own right. Another example is the generic representation of products containing more than two active ingredients such as “Generic Intralipid 30%”, which is not a suitable term for use in prescribing. Each Virtual Product is therefore accompanied by a status flag which indicates its prescribing status. The information relating to Virtual Products (dose form, active ingredient(s) and strength(s),) is also intended to support aspects of decision support and general prescribing scenarios.

Examples of Virtual Products:

- Atenolol 100 mg tablets
- Generic Estracombi patches
- Amoxicillin 500mg + Clavulanic Acid 125mg tablet
- Doxorubicin 10mg/5mL injection 5mL vial
- Fluorouracil 5% cream
- Hydrocolloid Dressing 10cm x 10 cm.

4.1.4 Actual Product (AP)

An Actual Product (AP) is a single dose unit of a finished dose form (unless the product is presented as a continuous dosage form eg liquid or cream), attributable to an identified supplier that contains a specified amount of an ingredient substance. This is the medicines object or “each” that is taken or held by the patient. The Actual Product may contain key non active ingredients (excipients) which may be of clinical significance.

Examples of Actual Products:

- Aspirin 300mg tablets (Bayer)
- Tenormin 100 mg tablets
- Estracombi patches
- Augmentin Duo tablets
- Doxorubicin 10mg/5mL injection 5mL vial
- Efudix cream 5%
- Restore Plus 9956.

4.1.5 Actual Product Pack (APP)

An Actual Product Pack (APP) is the packaged product that is supplied for direct patient use. An APP may contain multiple components flagged as Actual Pack Components (APC) each of which may or may not be available for supply as an independent prescribable product. Within each pack (APP) or component (APC) there may be specific containers eg bottle, tube, blister pack etc. These sub-packs are supported by a recursive relationship between pack components and packs. This approach allows description in the model of packs at multiple levels. For example for Oral Contraceptives, the top level APP will be a box which contains an APC consisting of 3 blister packs each of which contains 21 (or 28) tablets (7 tablets of three different hormone combinations). Thus users and software can identify the components of the pack at a level of detail required by the application.

Examples of Actual Product Packs:

- Aspirin (Bayer) 300mg tablets (20 tablets)
- Tenormin 100 mg tablets [30 tablets]
- Estracombi patches (4 patches)
- Augmentin Duo tablets (10 tablets)
- Doxorubicin 10mg/5mL injection 5mL vial (4 vials)
- Efudix cream (20g tube)
- Restore Plus 9956 (5 dressings).

4.1.6 Virtual Product Pack (VPP)

A Virtual Medicinal Product Pack (VPP) is an abstract concept representing the properties of one or more quantitatively equivalent APPs.

For every Actual Product Pack (APP) there will exist a corresponding VPP which will have one or many APPs linked to it.

Examples of Virtual Product Packs:

- Atenolol 100 mg tablets (30 tablets)
- Generic Estracombi patches (4 patches)
- Amoxicillin 500mg + Clavulanic Acid 125mg tablet (10 tablets)
- Doxorubicin 10mg/5mL injection 5mL vial (4 vials)
- Fluorouracil 5% cream (20 g tube)
- Hydrocolloid Dressing 10cm x 10 cm (5 dressings).

Not all of the above eg generic estracombi are suitable concepts for prescribing at the generic level.

5. UML Model of the AMDT

The diagram (to be included in next phase of the project) in this section will provide a UML class diagram of the major information classes that constitute the terminology and the relationships between these classes. This is supported by the textual description of each of the classes (Section 4) and the data table descriptions (Section 7).

Further information on UML can be found at www.omg.org

Model to be inserted when complete

6 Description of the AMDT from a terminological perspective

Primary Author: Don Walker

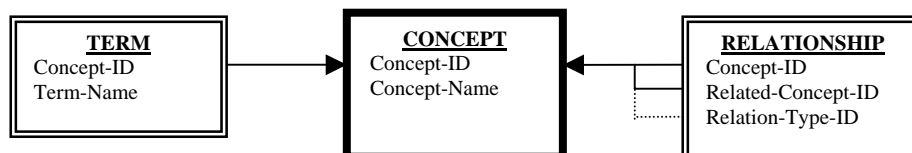
The UK DM&D is constructed and published using a database paradigm, whereas other terminologies such as SNOMED-CT and the RX-NORM are published in “terminological” format which then requires translation into standard data table formats suitable for the intended application.

There are several advantages to using a terminological structure, not the least is the ability to coordinate the medicines terminology with other terminology components and to support the use sophisticated generic terminology development and maintenance software. The terminological format is very flexible and is a standard for the publication of terminologies.

It is recommended that in the development and prototyping stages of the AMDT that both a standard normalised database approach and terminological approach are adopted.

The following material refers to software called the Poly-browser and Authoring Tool. A licence for the use of this product is held by the National Centre for Classification in Health and the Department of Health and Ageing. It is proprietary software owned by Dr Donald Walker and the University of Adelaide.

A data structure that may be of interest when building a Medicines-Terminology, is that contained in the Poly-browser and Authoring Tool (PAT) used by NCCH. It is very similar to the basic structure employed by SNOMED and RxNorm. It involves three core tables:



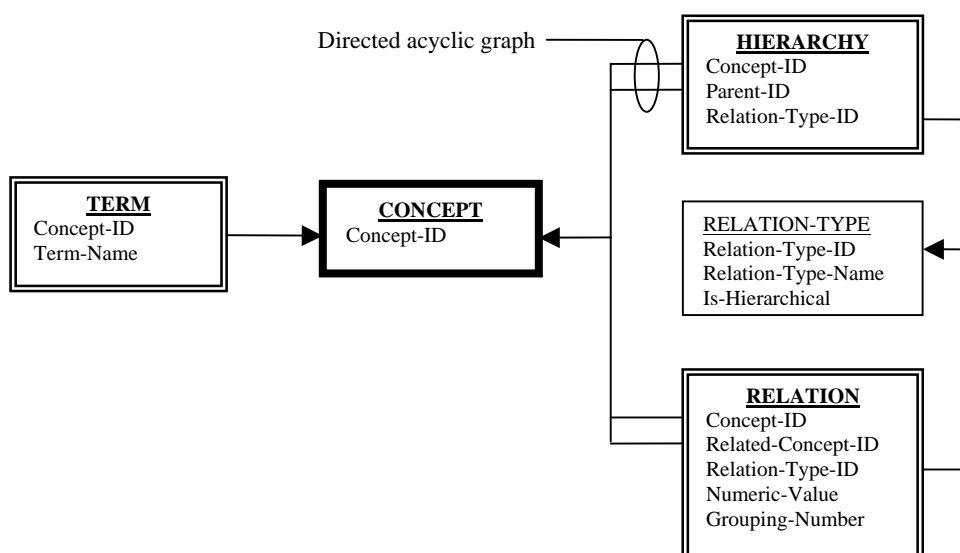
The CONCEPT table contains the unique concept identifier (a number) and the Concept-Name (i.e. its “preferred” or “fully-specified term”) is included.

The TERM table has a many-to-one relationship with the CONCEPT table via the Concept-ID. In it, various descriptions of the concept are held. One term is the obligatory “fully-specified-description” (some call it the “preferred term”). Others term types include synonyms, abbreviations and acronyms.

The RELATIONSHIP table has three fields: The Concept-ID, its Related-Concept-ID, and the Relationship-Type. Note the dual relationship to the CONCEPT table.

The Relationship-Type-ID may also be a Concept in the CONCEPT table. In which case, the RELATION table may contain three CONCEPT table relationships. This is the case with SNOMED-CT.

The following data structure represents a method of describing one of the draft versions of the AMDT in a format suitable for management in the PolyBrowser, Authoring Tool.



The “directed acyclic graph” allows for the creation of hierarchies.

This simple structure could hold most of the data that forms a medicine terminology. One modification to the RELATION table would be the addition of a “Numeric-Value” field to be used when an amount rather than a relationship to another concept is required; the other, a “Relation-Group” that groups together multiple relationships that below together. These are shown above.

The use of the structure requires all medicine components and their atomic parts to exist as concepts – that is all but numeric values. Medicine forms, dose units, parts of packs must all be created as concepts. If it is necessary to identify pack subcontents even down to the individual dose unit eg “Thursday’s pill”, then it must be created as a concept. Remember, the contents of “Packs” are themselves concepts, which may have further contents (or “sub-packs”) which are also concepts with defining relationships.

The RELATION table specifies “what” concepts go together, while the RELATION-TYPE specifies “how” concepts go together. Between them they define the concept.

The following table provide an indication of the classes and relationship types as an example. A few of the entries that illustrate what might be entered for “Amoxicillin” are shown below. They may well be inaccurate!

Concept-ID	Concept-Name	Relation-Type	Numeric Value	Relation Group	Related-Concept-ID	Related-Concept-Name
	Medicine category					
	Virtual therapeutic moiety	Is_a				AMDT Core
	Brand-Family Name	Is_a				AMDT Core Class
	Virtual product	Is_a				AMDT Core Class
	Actual product	Is_a				AMDT Core Class AMDT Core Class
	Virtual product pack	Is_a				AMDT Core Class
	Actual product pack	Is_a				AMDT Core Class
	Measurement Unit	Is_a				AMDT Core Class
	mg	Is_a				Measurement Unit
	Dose Form	Is_a				AMDT Core Class
	Capsule	Is_a				Medicine form

Concept-ID	Concept-Name	Relation-Type	Numeric Value	Relation Group	Related-Concept-ID	Related-Concept-Name
	Amoxicillin	Medicine_concept_type				Virtual therapeutic moiety
		Is_a				Virtual therapeutic moiety
	Amoxil	Is a				Brand Family Name
		Has VTM				Amoxicillin
	Amoxicillin 250mg capsule	Medicine_concept_type				Virtual Producty
		has VTM				Amoxicillin
		Active_Ingredient				Amoxicillin trihydrate
		Strength_amount	250			
		Strength_units				Mg
		Strength_per_Unit				Capsule
		Form				Capsule
		Dose_unit				Capsule
	Amoxicillin 250mg capsule, 20	Medicine_concept_type				Virtual product pack
		Is_a				Amoxicillin
		Pack_contains				Amoxicillin 250mg capsule
		Pack_contains_amount	20			
		Pack_contains_amount_units				Capsule
	Amoxil	Medicine_concept_type				Brand Family Name
	Amoxil 250mg capsule	Medicine_concept_type				Actual product
		Is_a				Amoxicillin 250mg capsule
		Is_a				Amoxil
		Strength_amount	250			
		Strength_units				Mg
		Strength_per_Unit				Capsule
		Form				Capsule
		Dose_unit				Capsule
		Virtual_Equivalent				Amoxicillin 250mg capsule
		Has_Pack				Amoxil 250mg capsule, 20
	Amoxil 250mg capsule, 20	Medicine_concept_type				Actual product pack
		Is_a				Amoxil
		Pack_contains				Amoxil 250mg capsule
		Pack_contains_amount	20			
		Pack_contains_amount_units				Capsule
		Is_a				Amoxicillin 250mg capsule, 20

The Poly-browser and Authoring Tool (PAT) used by the National Centre for Classification in Health (NCCH) has to support the following:

1. Concepts from multiple systems
2. Concept poly-hierarchies
3. Concept alternative descriptions
4. Concept inter-relationships of pre-defined types
5. Alternative codes or identifiers belonging to pre-defined systems
6. Associated data of various data-types
7. Lists or groupings of concepts.

The structure currently holds

- CATCH and its associated terms, codes, data and lists
- DOCLE and its associated terms, interrelationships and codes
- ICD-10-AM and its associated terms, codes, and data
- ICPC-2 Plus and its associated terms, codes and groupings
- SNOMED-CT and its associated terms, interrelationships and codes.

The PAT is more complex than the above core tables. The structure of a “complete export” from it may be of interest. It is shown on the next two pages.

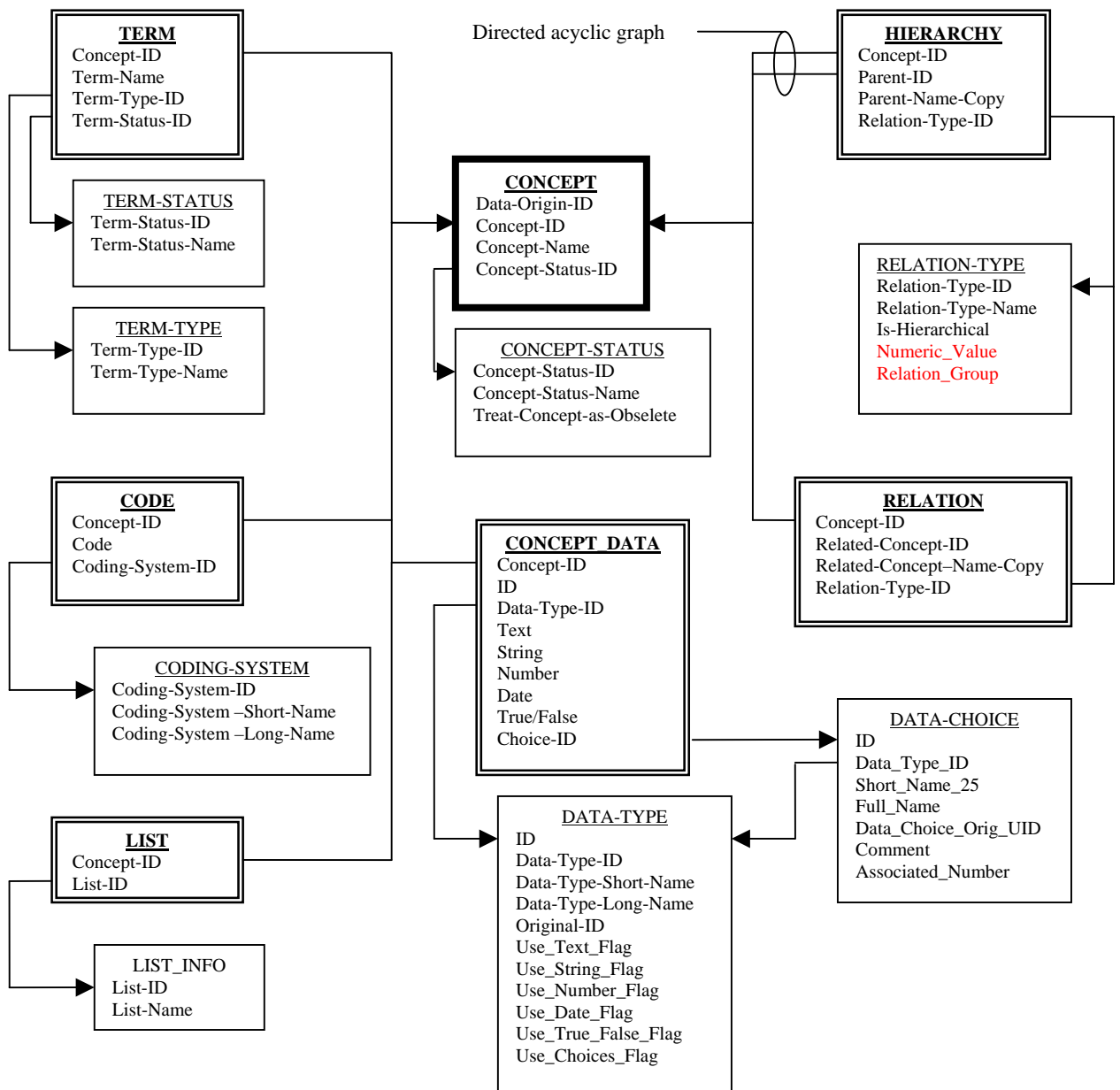
PAT Data Structure – Export Template-4

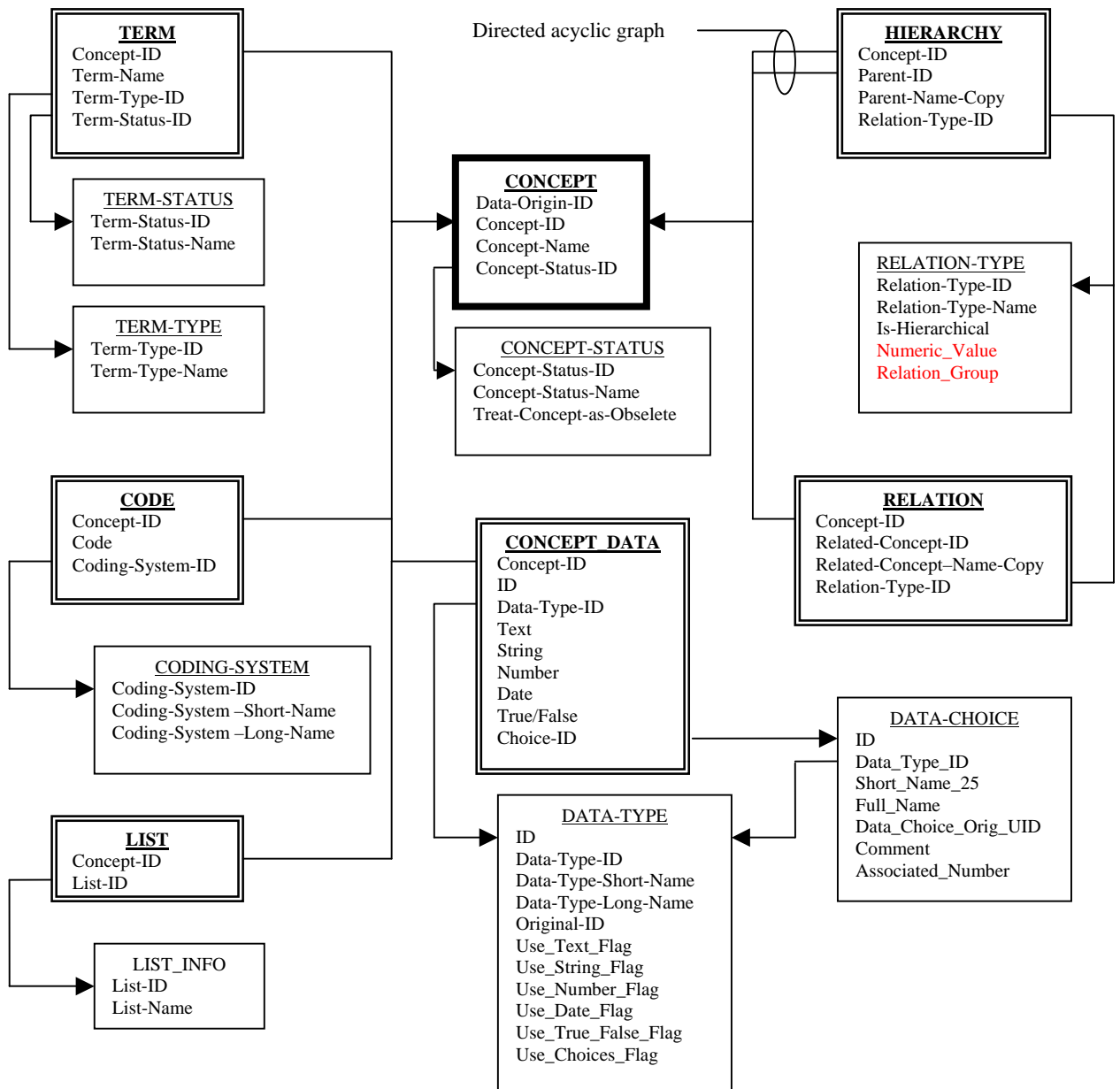
Version 12/8/2003

Template-4 exports all tables and fields necessary to represent the data captured in PAT. The following tables and fields are involved:

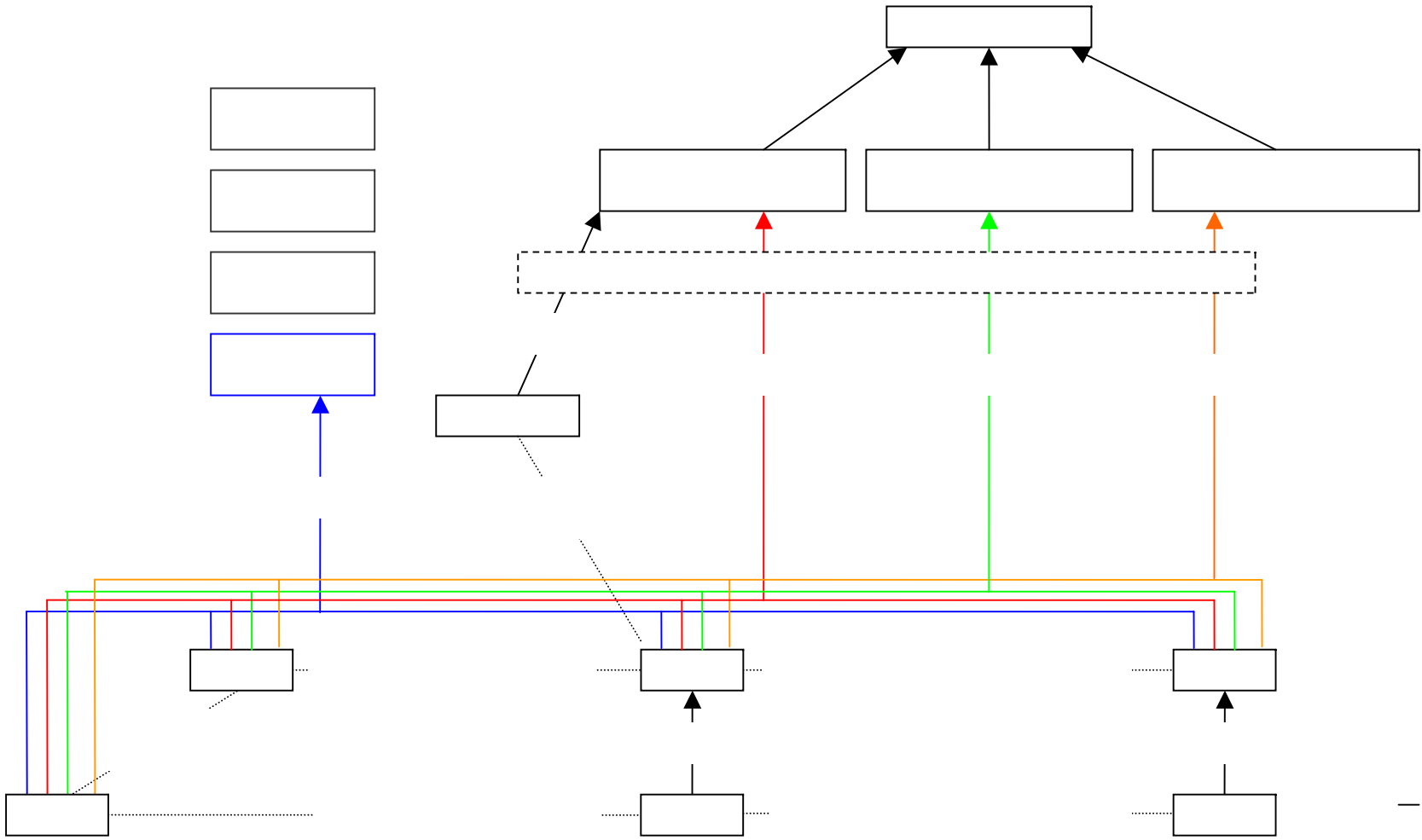
1. “CONCEPT Table”, containing – Data-Origin-ID; Concept-ID, Concept-Name; Concept-Status-ID
2. “HIERARCHY Table”, containing - Concept-ID; Parent-ID; Parent-Name-Copy; Relation-Type-ID
(The "Name" of the Parent is defined in the Concept-Table (1). It may therefore be redundant in (3). However it helps visualisation of the data. In the event of an incomplete export of Concept records, the Parent-Name may be vital.)
3. "RELATION Table", containing - Concept-ID; Related-Concept-ID; Related-Concept – Name-Copy; Relation-Type-ID
(The "Name" of the Related-Concept is defined in the Concept-Table (1). It may therefore be redundant in (4). However it helps visualisation of the data. In the event of an incomplete export of Concept records, the Related-Concept -Name may be vital.)
4. “TERM Table”, containing – Concept-ID; Term-Name; Term-Type-ID; Term-Status-ID
5. “CODE Table”, containing – Concept-ID; Code; Coding-System-ID
6. “CONCEPT_DATA Table”, containing - Concept-ID; Data-ID; Data-Type-ID; (& Data-Entered:...) Text; String; Number; Date; True/False; Choice-ID
(This would then include the "user created data items" such as: Concept-Grouping; Code-Level; Various codes if created as “concept-data” (eg COMHET-Code; Implementation-Code) etc.)
7. "CONCEPT-STATUS Table", containing - Concept-Status-ID; Concept-Status-Name; Treat-Concept-as-Obselete (true/false), as used in (1) above.
8. "RELATION-TYPE Table", containing - Relation-Type-ID; Relation-Type-Name; Is-Hierarchical (true/false) as used in (2) & (3) above
9. "TERM-TYPE Table", containing - Term-Type-ID; Term-Type-Name, as used in (4) above
10. "TERM-STATUS Table", containing - Term-Status-ID; Term-Status-Name, as used in (4) above
11. "CODING-SYSTEM Table", containing – Coding-System-ID; Coding-System –Short-Name; Coding-System –Long-Name, as used in (5) above
12. "DATA-TYPE Table", containing - Data-Type-ID; Data-Type-Short-Name; Data-Type-Long-Name; Original-ID; and the flags that define which data fields are to be used: Use_Text_Flag; Use_String_Flag; Use_Number_Flag; Use_Date_Flag; Use_True_False_Flag; Use_Choices_Flag. (as used in (6) above)
13. "DATA-CHOICE Table", containing - ID; Data_Type_ID; Short_Name_25; Full_Name; Data_Choice_Orig_UID; Comment; Associated_Number, (as used in (6) & (12) above).
14. “LIST_INFO table”, containing LIST-ID and LIST-Name
15. “LIST table” containing List-ID, and Concept-ID

The relationships of these tables are shown in the following diagram.





The following diagram outlines the potential structure or organisation of the medicines hierarchies in a terminology



7. Detailed Description or Specification of AMDT components

7.1 Brand or Family Name

Definition: A Brand or Family Name (BFN) represents a group of actual products which represent the tradename or brand name under which these products are marketed.		
Description: This concept represents the brand name of a group of products. This traditionally also represents one type of clinical therapeutic intent (VTM), however this not always so as some companies market different types of products under the same tradename.		
Associations		
<i>Actual Product – Brand Family Name.</i> Cardinality 1 BFN to many APs. Association type: “has brand name”		
<i>Virtual Therapeutic Moiety- Brand Family Name. Cardinality: Many BFN to many VTM.</i> Association type:”has prescribable active ingredients”. (Note this association may only exist in the terminology representation of the AMDT as the relationship can be inferred.)		
Attribute	Type	Occurrence
BFN identifier	AMDT identifier	1
Unique identifier for the Brand or Family Name		
BFN name	String	1
A name that is used to describe the Brand or Family Name.		
BFN short name	String	1
A name that is used to describe the Brand or Family Name in a form which does not exceed 60 characters.		
Invalidity flag	Integer	0 to 1
Flag indicating that this terminology entry was invalid. VALUE: 0 = valid 1 = Invalid NOTE: The entry needs to be retained in case it was used prior to detection of the error(s) which caused its invalidation.		
Invalidity date	Date	0 to 1

Notes:

Do we need to have a date available from and date available to fields[MRP1]??

7.2 Virtual Therapeutic Moiety

<p>Definition: A Virtual Therapeutic Moiety (VTM) is the abstract representation of the active ingredient(s) or substance(s), which when formulated as a medicinal product, is intended by an authorising health care professional for use in the treatment of the patient.</p>		
<p>Description: The abstract conceptual representation of the material defining a prescriber's therapeutic intent, divorced from formulation, route, dose or strength. A VTM will not be allocated where a product has more than three active ingredients as it not intended to support "generic prescribing" in such situations or where the VP is flagged as never suitable to be prescribed generically eg "generic helicopak"</p>		
<p>Association</p> <p><i>Virtual Product- Virtual Therapeutic Moeity. Cardinality: one</i> instance of Virtual Therapeutic Moiety may be associated with one to many instances of Virtual Product; Association type: Has a virtual therapeutic moiety</p> <p><i>Virtual Therapeutic Moiety - Brand Family Name. Cardinality: Many BFN to many VTM.</i> Association type:"has prescribable active ingredients". (Note this association may only exist in the terminology representation of the AMDT as the relationship can be inferred.)</p>		
Attribute	Type	Occurrence
VTM identifier	AMDT IDENTIFIER	1
Unique identifier for the Virtual Therapeutic Moiety		
VTM name	String	1
Unique name to describe the Virtual Therapeutic Moiety. This will usually be the chemical name of the active ingredient(s) without the salt suffix eg. Amoxicillin sodium (ingredient) = Amoxicillin (VTM). Combination ingredient intent will be represented by the individual VTMs pre-coordinated eg Paracetamol + Codeine.		
VTM short name	String	1
A name that is used to describe the Virtual Therapeutic Moiety in a form which does not exceed 60 characters.		
VTM synonym	String	0 to many
A name that is used to describe the Virtual Therapeutic Moiety in other forms than the preferred manner eg. Aspirin/Sodium salicylate, hypericum/St. Johns Wort.		
VTM prescribing status	Integer (code value)	1
Prescribing status of the product expressed as a code value. VALUES: 1 = valid as a prescribable intent 2 = invalid as a prescribable intent (ie. In situations where good practice suggests that medications should not be prescribed at this level of therapeutic intent abstraction eg hyoscine requires to be specified at the salt level as the therapeutic range is different by an order of magnitude or Warfarin .		
Invalidity flag	Integer	0 to 1

Flag indicating that this terminology entry was invalid.

VALUE:

0 = valid

1 = Invalid

NOTE: The entry needs to be retained in case it was used prior to detection of the error(s) which caused its invalidation.

Invalidity date	Date	0 to 1
------------------------	-------------	---------------

7.3 Virtual Product

Definition: A Virtual Product (VP) is an abstract concept representing the properties of one or more clinically equivalent Actual Products. “Clinical” is defined as having the same active ingredients, strength, dose form, and administrable unit type, and where the Actual Products are considered as clinically equivalent.

Description:

A Virtual Product is an abstract concept representing a template of the properties which constitute one or more pharmacologically and clinically equivalent actual medicinal products.

NOTES:

1. Unless the attribute **virtual product prescribing status** is set to the contrary, Virtual Products are prescribable. Some VP may not be prescribed individually eg as with composite packs, where the composite VP is only available as part of a component pack.
2. The Virtual Product describes a “generic”, virtual or grouping product concept without supplier or trade name information, or packaging information.
3. To facilitate use of the terminology to support pick lists for prescribing, it has been decided that a Virtual Product may consist of more than one item. E.g.: econazole nitrate 150 mg pessaries + econazole nitrate cream 1% which are provided together as a combination in a pack are represented as a single VP entry. The corresponding individual virtual products will also appear as entries within the terminology in their own right though they may not be prescribable (see note 1).
4. Products with more than three components will be named “generic (Product X)” and this product will not be able to be prescribed generically, however the actual relationships with active ingredients and strengths will be represented in the data structure and able to be linked with actual products via the VP class.

Associations

VP-Orderable Dose Form

An instance of Virtual Product may be associated with a zero (in case of a VP containing multiple components) to one (for VPs containing only one component) Orderable Dose Form. NOTE: VPs that are devices will not have a dose form.

Association type: has orderable dose form.

VP-Active Ingredient

An instance of Virtual Product is associated with one to many instances of Active Ingredient.

Association type: “has active ingredient”.

VP-Virtual Product Pack

Many Virtual Product Packs (or VPP Components) are associated with one instance of a Virtual Product. Association type “contains”.

Virtual Product-Virtual Therapeutic Moiety. Cardinality: One instance of Virtual Therapeutic Moiety may be associated with one to many instances of Virtual Product; Association type: Has a virtual therapeutic moiety.

Attributes	Type	Occurrence
Virtual Product (VP) identifier	AMDT IDENTIFIER	1
This uniquely identifies the VP		
Virtual product availability date	Date	0 to 1

Date from which the virtual product becomes available as a prescribable entity. This will allow the pre-population of medicines prior to their launch or release date.		
VTM identifier	AMDT IDENTIFIER	0 to 1
Unique identifier for the associated Virtual Therapeutic Moiety		
Invalidation flag	Integer	0 to 1
Flag indicating that this terminology entry was invalid. VALUE: 0 = valid 1 = Invalid NOTE: The entry needs to be retained in case it was used prior to detection of the error(s) which caused its invalidation.		
Invalidation date	Date	0 to 1
Combination product indicator	Integer (code value)	0 to 1
Flag denoting that the VP is a combination product or is only available as a component of a combination product (i.e. not available in its own right. Examples: Combination product – Conjugated Oestrogens 1.25mg tablets + Norgestrel 150microgram tablets, or Clotrimazole 500mg pessary and Clotrimazole 2% cream (Canesten Combi). Component only – Norgestrel 150microgram tablets. VALUES 0 = single component (active ingredient) product 1 = combination product (identifies VP where components are able to be prescribed separately).		
Virtual Product name	String	1
A name that is used to describe the Virtual Product. A VP will always have a name, even if not prescribable. The order will be substance (using the base ingredient name), strength and then form. Eg Amoxicillin 250mg tablets. The full salt name will be used to differential products where required or where the salt needs to be specified clinically (eg hyoscine hydrobromide).. If an availability date is supplied, this name will be used to describe the medicinal product on and subsequent to that date. Where two or more active substances, list in the order as done by the manufacturer. Where there are more than three active substances, use the title “generic name of Actual Product”.		
Virtual Product short name	String	1
This name is intended to support applications with limited screen or label space. NOTES 1. This ‘short’ version of the medicinal product name may be up to 60 characters 2. Where the VMP name is already 60 characters or less, the complete name will be entered as the short name. The rules for how name shortening will occur will be subject to development and based on common usage.		
Virtual Product synonym	String	0 to many
This allows for situations where a virtual product is known by other names or with variant spellings.		

Virtual Product Pack identifier	AMDT IDENTIFIER	1 to many
Unique identifier for the associated Virtual Product Pack (or Virtual component pack, being an VPP with multi-component flag set).		
Virtual Product prescribing status	Integer (code value)	1
Prescribing status of the product expressed as a code value. VALUES: 1 = valid as a prescribable product 2 = invalid as a prescribable product (ie.is a component) 3 = never valid to prescribe as a VP (ie. In situations where good practice suggests that medications should not be prescribed “generically” eg warfarin, multi-active ingredient medicines, or where a particular device is associated with medicine which requires training. 4 = not recommended to prescribe as a VP (similar to above however is at the discretion of the prescriber).		
Unit dose form type indicator (UDFI)	Integer (code value)	1
This attribute identifies if the VP describes the administerable unit which is taken by the patient or the discrete unit dose applicable (e.g. tablet, ampoule). In some situations there is no standard unit dose form where the medicine is regarded as a continuous substance (that is a consistent physically measurable unit or sub-unit cannot be defined e.g. cream, eye drops) or if it belongs to a category of product for which unit dose form is not appropriate (catheters, colostomy bags, foods) VALUES: 1 = Discrete 2 = Continuous 3 = Not applicable NOTE: where the dose form indicator has the value continuous or not applicable there is no requirement to populate information in unit dose form size, unit dose form unit or unit of measure.		
Unit dose form size (UDFS)	Real	0 to 1
A numerical value		
Unit dose form units (UDFU)	AMDT IDENTIFIER	0 to 1
The unit of measure relating to the size above		
Unit Dose Type (UDT)	AMDT IDENTIFIER	0 to 1

A description of the entity/‘thing’ that can be handled.																																																									
<p>Unit dose form type information is composed of the four parts above: DoseFormIndicator (UDFI), unit dose form size (UDFS), unit dose form units (UDFU) and unit of measure (UOM).</p> <p>EXAMPLES:</p> <table border="1"> <thead> <tr> <th>VP</th> <th>UDFI</th> <th>UDFS</th> <th>UDFU</th> <th>UDT</th> </tr> </thead> <tbody> <tr> <td>Atenolol 50mg tablets</td> <td>Discrete</td> <td>1</td> <td>tablet</td> <td>tablet</td> </tr> <tr> <td>Frusemide 20mg/2mL injection 2mL ampoule</td> <td>Discrete</td> <td>2</td> <td>mL</td> <td>ampoule</td> </tr> <tr> <td>Hydrocortisone 1% cream</td> <td>Continuous</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Mesalazine 1g/actuation foam enema</td> <td>Discrete</td> <td>1</td> <td>actuation</td> <td>actuation</td> </tr> <tr> <td>Digoxin 50microgram/mL oral liquid</td> <td>Continuous²</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Metronidazole 200mg/5mL oral suspension</td> <td>Discrete</td> <td>5</td> <td>mL</td> <td>measure</td> </tr> <tr> <td>Amoxicillin 500mg injection vial</td> <td>Discrete</td> <td>1</td> <td>vial</td> <td>vial</td> </tr> <tr> <td>Chloramphenicol 0.5% eye drops</td> <td>Continuous</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Salbutamol 100microgram/actuation inhaler</td> <td>Discrete</td> <td>1</td> <td>actuation</td> <td>actuation</td> </tr> <tr> <td>Crepe bandage 10cm</td> <td>Not applicable</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>			VP	UDFI	UDFS	UDFU	UDT	Atenolol 50mg tablets	Discrete	1	tablet	tablet	Frusemide 20mg/2mL injection 2mL ampoule	Discrete	2	mL	ampoule	Hydrocortisone 1% cream	Continuous				Mesalazine 1g/actuation foam enema	Discrete	1	actuation	actuation	Digoxin 50microgram/mL oral liquid	Continuous ²				Metronidazole 200mg/5mL oral suspension	Discrete	5	mL	measure	Amoxicillin 500mg injection vial	Discrete	1	vial	vial	Chloramphenicol 0.5% eye drops	Continuous				Salbutamol 100microgram/actuation inhaler	Discrete	1	actuation	actuation	Crepe bandage 10cm	Not applicable			
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Orderable dose form identifier	AMDT IDENTIFIER	0 to 1																																																							
Description of the orderable dose form. This involves selecting the dose form from a pre-determined terminology or vocabulary. VP can only have one form, combination packs will have form “non applicable”																																																									
Active ingredient identifier	AMDT IDENTIFIER	1-many																																																							
Identification of the active ingredient contained in the VP																																																									
Basis of strength ingredient identifier	AMDT IDENTIFIER	1																																																							
Identification of the active ingredient which is used as the ingredient for the purposes of describing the strength of the medicines. This will always be populated except for devices.																																																									
<p>EXAMPLE:</p> <p>Amoxicillin 250mg injection vials contain amoxicillin sodium but the strength is expressed as the quantity of amoxicillin (substance). Amoxicillin is the basis of strength substance (BoSS) and therefore the identifier for “amoxicillin” (substance not VTM) would be put in this field. In most cases this will be the same concept as the virtual product ingredient.</p> <p>Another situation is where two AP are clinical identical however one medicine has active ingredient as a salt and the other is not fully specified. In that case the ingredient and BoSS would defer to the non fully specified ingredient. (Eg Carace – Lisonopril, Zestril – Lisonopril dihydrate)</p> <p>NOTE: There is the potential to confuse the VTM (amoxicillin) with the BOSS (amoxicillin substance). These are subtly difference concepts as the former is a therapeutic intention. In many cases these will appear to be the same, however not always.</p>																																																									
Pharmaceutical strength		0 or 1																																																							

² This preparation does not have a standard administered dosage unit so is treated as continuous

The amount or quantity of ingredient (as identified by the **basis of strength substance identifier** as indicated above).

This attribute indicates the quantity of the substance per defined unit of measure in the Virtual Product (e.g. one tablet, one mL) measured by weight or volume per unit or concentration. An ingredient may be present without a strength in some cases. Strength for 2mL ampoule will use the administered dose unit (eg ampoule volume) as the denominator eg 10mg per 2 mL (not 5mg/mL). This is to prevent simple overdose errors and to aid calculation of doses and volumes for liquid medications.

Pharmaceutical strength has 4 components, where a strength is provided the strength value numerator (SVN) and strength value numerator unit (SVNU) are mandatory. Strength value denominator (SVD) and strength value denominator unit (SVDU) are used to fully express 'per' strengths.

For each type of dose form unit the SVD and SVDU represent the Unit Dose Form Size (UDFS) and the Unit Dose Form Unit (UDFU) as described above. This information supports conversion of ordered units eg 1 tablet into Pharmaceutical Strength eg 500mg.

EXAMPLES:

Paracetamol 500mg tablets

<i>Ingredient</i>	<i>SVN</i>	<i>SVNU</i>	<i>SVD</i>	<i>SVDU</i>
Paracetamol	500	mg	see footnote ³	

Paracetamol 250mg/5mL oral suspension

<i>Ingredient</i>	<i>SVN</i>	<i>SVNU</i>	<i>SVD</i>	<i>SVDU</i>
Paracetamol	250	mg	5	mL

Hydrocortisone 1% cream

<i>Ingredient</i>	<i>SVN</i>	<i>SVNU</i>	<i>SVD</i>	<i>SVDU</i>
Hydrocortisone	10	mg	1	g

	Strength value numerator (SVN)	Real	0-1⁴
	The numerator of the amount of ingredient substance, e.g. 25 where the strength conforms to the expression '25mg per 1 mL'.		
	strength value numerator unit (SVNU)	AMDT IDENTIFIER	0-1⁵
	The unit of measure associated with the previous numerator value, e.g. mg. Where the strength conforms to the expression '25mg per 1 mL'. The values are drawn from the Unit of Measure table.		
	strength value denominator (SVD)	Real	0 or 1
	The denominator of the amount of ingredient substance this corresponds to the weight or volume of the administerable dose form, e.g. 1 where the strength conforms to the expression '25mg per 1 mL'.		

³ Pharmaceutical Strength is fully specified as a ratio. In the case of solid dose forms such as tablets the denominator could be the weight of the tablet (which includes actives and inactives), however this is usually not stated.

⁴ Mandatory if pharmaceutical strength provided.

⁵ Mandatory if pharmaceutical strength provided.

	<p>strength value denominator unit (SVDU)</p> <p>The denominator of the amount of ingredient substance this corresponds to the weight or volume of the administerable dose form, e.g. ml where the strength conforms to the expression '25mg per 1 mL'.</p>	<p>AMDT IDENTIFIER</p>	<p>0 or 1</p>
<p>The unit of measure associated with the previous numerator value, e.g. mL. Where the strength conforms to the expression '25mg per 1 mL'. The values are drawn from the Unit of Measure table.</p>			

Notes: A VP is not available when all associated APs are not available

7.4 Actual Product

<p>Definition: An Actual Product (AP) is a single dose (device) unit of a finished dose form, attributable to an identified supplier.</p>		
<p>Description: An Actual Product is a medicinal product or device that has been made available by a supplier. This class represents the actual dosage unit that can be given to the patient or taken.</p>		
<p>NOTES</p> <ol style="list-style-type: none"> An instance of the Actual Product shall provide sufficient information to uniquely identify the product but not the size of pack that the supplier makes available for dispensing. Examples: Betnovate 0.1% ointment (Sigma) Biodone Forte 5 mg/mL syrup 100mL bottle (Biomed) Sofra-tulle gauze dressing 10 cm x 10 cm (Aventis) Each Actual Product is associated with an identifiable supplier who is the company listed on the packaging. The terminology may include AP entries for products which are not available separately, for example Estraderm patches which are only available as part of an Estracombi combination pack. These will be flagged as not being prescribable. 		
<p>Associations</p> <p>Virtual Product Each instance of Actual Product shall always be associated with one instance of Virtual Product and shall 'inherit' from this instance of Virtual Product all of its properties Association type: ISA</p> <p>Actual Product Pack Each instance of Actual Product shall always be associated with one to many instances of an Actual Product Pack. Association type = "contains"</p> <p>For combination product packs the association may be with an Actual Pack Component (which is an APP with the combination flag set)</p> <p>Brand/Family Name Each instance of Actual Product is associated with one instance of the Brand Family Name. Association type = "is a brand of"</p> <p>Actual Product Excipients Each instance of Actual Product is associated with zero to many Actual Product Excipients Association type = "has excipient ingredient"</p> <p>Note: this is intended at the current time to reference only excipients listed in the editorial policy as potentially having clinical significance. Should an accessible and authoritative source of information on excipients in each actual product, drawn from a terminology of excipient ingredients become available then this may be included subject to editorial policy.</p>		
Attributes	Type	Occurrence
Actual Product identifier	AMDT IDENTIFIER	1
Unique identifier for the Actual Product		

<p>- The AP identifier can be used to link product instances to supporting information from knowledgebases and supporting information such as approved product or device information..</p>										
size/weight	String	0 to 1								
<p>Information relating to the size of an appliance where this information is not captured within the AMP name eg incontinence sheaths where the size may be expressed in mm, by description (small) or both. Where size is not captured in AP name, size/wt will capture information.</p> <p>EXAMPLES:</p> <table border="0"> <tr> <td>Jade Naturalflex sheath</td> <td>25mm small</td> </tr> <tr> <td>Urosheath</td> <td>28.5mm small</td> </tr> <tr> <td>Biotrol Elite colostomy bag</td> <td>Starter hole</td> </tr> <tr> <td>Biotrol Elite colostomy bag</td> <td>25mm</td> </tr> </table> <p>NOTE: the length of this field may be up to 100 characters</p> <p>By using a text field rather than a structured field it will be difficult to sort.</p>			Jade Naturalflex sheath	25mm small	Urosheath	28.5mm small	Biotrol Elite colostomy bag	Starter hole	Biotrol Elite colostomy bag	25mm
Jade Naturalflex sheath	25mm small									
Urosheath	28.5mm small									
Biotrol Elite colostomy bag	Starter hole									
Biotrol Elite colostomy bag	25mm									
other identifying information	String	0 to 1								
<p>Occasionally colour is useful in determining which of a number of optional devices is appropriate.</p>										
Invalidity flag	Integer	0 to 1								
<p>Flag indicating that this terminology entry was invalid.</p> <p>VALUE: 0 = Valid 1 = Invalid</p> <p>NOTE: The AP instance needs to be retained in case it was used prior to detection of the error(s) which caused its invalidation.</p>										
Invalidity flag date	Date	0 to 1								
<p>Value of date that Invalidity flag set indicating that this terminology entry was invalid. Author of invalidity should be captured in the update log file.</p> <p>NOTE: The AP instance, even when subsequently found to be invalid, needs to be retained in case it was used prior to detection of the error(s).</p>										
Device flag	Integer	1 to 1								
<p>Flag indicating that this product is a device.</p> <p>VALUE: 0 = A medication 1 = A device</p>										
Actual Product Pack identifier	AMDT IDENTIFIER	1 to many								
<p>Unique identifier for the associated Actual Product Pack (or Actual component pack, being an APP with multi-component flag set).</p>										
Virtual Product identifier	AMDT IDENTIFIER	1								

Unique identifier for the associated Virtual Product.		
Brand Family Name Identifier	AMDT IDENTIFIER	0-1
Unique identifier for the associated Brand Family Name		
Actual Product Prescribing status	Integer (code value)	1
Flag denoting that the AP is a component of a combination pack and can not be prescribed as an individual item. (i.e. not available in its own right). VALUES: 1 = valid as a prescribable product 2 = invalid as a prescribable product (ie.is a component)		
Actual Product name	String	1
A name that is used to describe the Actual Product as a unique fully specified name as used by the pharmaceutical manufacturer. NOTES: 1. This is the 'long' or fully specified version of the product name 2. If the actual product name starts with the virtual product name (can occur with 'generic brands') then the strength and manufacturer may be entered in brackets to differentiate the AP from the VP eg Aspirin 300mg (Bayer). This should only be done where necessary to ensure a unique AP name. 3. For devices additional identifying information may be required in the name eg.Biotrol Elite colostomy bag + 25mm + Beige + (B Braun Medical) 4. If the AP changes its name then this becomes a new AP.		
Date of availability from AUS⁶_[MRP2]	Date	0-1
Date from which the AP is available in Australia. This allows commencement of distribution for products available at a future known date		
Date of availability from NZ⁷	Date	0-1
Date from which the AP is available in New Zealand. This allows commencement of distribution for products available at a future known date		
Date of availability to AUS⁸	Date	0-1
Date from which the AP becomes unavailable in Australia.		
Date of availability to NZ⁹	Date	0-1
Date from which the AP becomes unavailable in New Zealand		
Actual Product short name	String	1
This name is intended to support applications with limited screen or label space. NOTES <ul style="list-style-type: none"> This 'short' version of the medicinal product name may be up to 60 characters Where the VP name is already 60 characters or less, the complete name will be entered as the short name. 		

⁶ One of the fields "Date of availability from" must be populated

⁷ One of the fields "Date of availability from" must be populated

⁸ One of the fields "Date of availability to" must be populated

⁹ One of the fields "Date of availability to" must be populated

<ul style="list-style-type: none"> The rules for how name shortening will occur will be subject to editorial policy 		
Actual Product sort name	String	1
<p>A version of the product name used to sort the products into ascending order by dosage strength or product size. This name is not for display</p> <p>Eg Adalat005tablet Adalat010tablet Adalat020tablet</p> <p>NOTE: Medicines with numerals in the name will not sort in ascending strength/size order due to the way sort works in text fields. Hence by normalising the numeral with leading zeros the sort function will produce the desired result. The sort name will default to the short name in most cases.</p>		
Combination product indicator	Integer (code value)	0 to 1
<p>Flag denoting that the VP is a combination product or is only available as a component of a combination product (i.e. not available in its own right. Examples: Combination product – Conjugated Oestrogens 1.25mg tablets + Norgestrel 150microgram tablets. Component only – Norgestrel 150microgram tablets.</p> <p>VALUES: 0 = single component (active ingredient) product 1 = combination product</p>		
Sponsor	Reference List ID	1
<p>Identifies the sponsor using a list of sponsors held within an associated reference file.</p>		
Actual Product Pack Container Type identifier	AMDT IDENTIFIER	1
<p>Used to identify the container type used in the actual product pack or Actual Pack Component. This concept eg bottle, tube, blister pack.</p>		
Manufactured Dose form identifier	AMDT IDENTIFIER	1
<p>Identifies the manufactured dose form for the Actual Product</p>		

Notes:

7.5 Virtual Product Pack

Definition: A Virtual Product Pack (VPP) is an abstract concept representing the properties of one or more quantitatively equivalent Actual Product Packs.		
Description: This virtual concept is used to identify and group Actual Product Packs which contain the same quantities of the same Virtual Products		
Associations		
Virtual Product		
Each instance of Virtual Product Pack is always associated with one instance of a Virtual Product. Association type: contains		
Virtual Pack Components		
Each instance of Virtual Medicinal Product Pack can be associated with zero to many instances of Virtual Pack Components. These may be marketable packs in their own right or component packs which are not separately available. This is a recursive relationship where the VPC is identified by a flag, rather than as an independent entity.		
Association type: contains		
Actual Product Pack		
Each instance of Virtual Product Pack is associated with one to many instances of Actual Product Pack. Association type: ISA		
Attributes		
	Type	Occurrence
Virtual Product Pack identifier	AMDT IDENTIFIER	1
Unique Identifier of the Virtual Product Pack		
Virtual Product Pack Name	String	1
The description or full name that is used to describe the Virtual Product Pack. This will consist of the following: VP name + VPP Quantity & VPP Quantity UOM		
Examples: Atenolol tablets 50mg 30 tablets Frusemide 20mg/2mL injection 2mL ampoules (5) Hydrocortisone 1% cream 30g Salazopyrin 1g/actuation foam enema 80g Digoxin 50microgram/mL oral liquid 45mL Metronidazole S Suspension 200mg/5mL 100mL Amoxicillin 500mg injection vial Chloramphenicol 0.5% eye drops 10mL Salbutamol 100microgram/actuation inhaler 200 actuations.		
VPP short name	String	1
See earlier discussion re short names.		

VPP synonym name	String	0 to many
Synonyms are occasionally required		
Combination pack indicator	Integer (code value)	0 to 1
<p>Flag denoting that the virtual medicinal product pack is a combination product pack or is a only available as a component of a combination product (i.e. not available in its own right). This must be distinguished from packs which contain medicines with multiple components incorporated into one dosage unit eg Panadeine (paracetamol and codeine) which are a single component pack.</p> <p>VALUES: 0 = single component 1 = multi-component or combination pack.</p>		
Combination Virtual Product Pack identifier	AMDT IDENTIFIER	0 - many
<p>Unique identifier for the Virtual Product Pack (Virtual Component Pack) where it exists as a component of the VPP. This is a VPP with combination product flagged which will identify the sub-packs within a combination or multi pack</p>		
Number of component packs	Integer	0 - many
This indicates the number of the individual component packs within each VPP		
Invalidity flag	Integer	0 to 1
<p>Flag indicating that this terminology entry was invalid.</p> <p>VALUE 0= valid 1 = Invalid</p> <p>NOTE: The entry needs to be retained in case it was used prior to detection of the error(s) which caused its invalidation.</p>		
Invalidity date	Date	0 to 1
Virtual Product identifier	AMDT IDENTIFIER	1
Identifier used to uniquely identify the Virtual Product which is the administerable unit in the VPP.		

Virtual Product pack quantity				
<p>Virtual product pack quantity has two components - a quantity and unit of measure.</p> <p>It represents the amount of the Virtual Product expressed by mass, volume, number of entities or otherwise in a container, intermediate container or package as supplied. Note the VP will not describe some internal package components eg blister packs unless in future the presence of such is clinically regarded as differentiating one virtual product from another.</p> <p>EXAMPLES: Qty Units of measure 28 Tablets 10 mL 3 Vials 60 gram 200 dose 5 cartridges</p>			1	
	Pack Quantity (PQ)		Real	1
	A numerical value.			
	Pack Quantity Measurement (PQUMP)	Unit of	AMDT IDENTIFIER	1
	The unit of measure associated with the previous number. This is sourced from a vocabulary of containers			

Notes: A VPP is not available when all associated APPs are not available

7.6 Actual Product Pack

<p>Definition: An Actual Product Pack is the packaged product that is supplied for direct patient use or from which Actual Products are supplied for direct patient use. It may contain multiple components each of which may or may not be an APP in their own right.</p>		
<p>Description: An Actual Product Pack contains information concerning a medicinal product that has been made available by a manufacturer and/or supplier as a packaged entity.</p>		
<p>Associations</p> <p>Actual Product Each instance of Actual Product Pack shall be associated with one instance of Actual Product and shall 'inherit' from this instance of Actual Product all of its properties Association type: contains</p> <p>Virtual Product Pack Each instance of Actual Product Pack shall be associated with one instance of Virtual Product Pack and shall 'inherit' from this instance of Virtual Product Pack all of its properties. Association type: ISA</p> <p>Actual Component Pack Each instance of Actual Product Pack may be associated with zero to many instances of other Actual Product Packs where these are component packs. The APC is not a separate class but is identified by a flag on APP. Recursive Association type: contains</p>		
Attributes	Type	Occurrence
Actual Product Pack identifier	AMDT IDENTIFIER	1
Unique identifier for the parent instance of Actual Product Pack.		
Actual Product Pack Name	String	1
<p>The description or full name that is used to describe the Actual Product Pack. Refer to notes on Actual Product name. This will consist of the following:</p> <p>AP name + VPP quantity + VPP quantity unit of measure</p> <p>Examples: Tenormin tablets 50mg 30 tablets Lasix 20mg/2mL injection 5 x 2mL ampoules Sigmacort 1% cream 30g Mesalazine 1g/actuation foam enema 80g Lanoxin 50microgram/mL oral liquid 45mL Flagyl S Suspension 200mg/5mL 100mL Moxacin 500mg injection vial Chloromycetin 0.5% eye drops 10mL Ventolin 100microgram/actuation inhaler 200 actuations.</p>		
APP short name	String	1
See earlier discussion on short names.		

APP synonym name	String	0 to many
Synonyms may occasionally be required.		
Invalidation flag	Integer	0 to 1
Flag indicating that this terminology entry was invalid. VALUE: 0 = valid 1 = Invalid NOTE: The entry needs to be retained in case it was used prior to detection of the error(s) which caused its invalidation.		
Invalidation date	Date	0 to 1
Virtual Product Pack identifier	AMDT IDENTIFIER	1
Unique identifier for the parent instance of Virtual Medicinal Product Pack.		
Actual Product identifier	AMDT IDENTIFIER	1
Unique identifier for the parent instance of Actual Product		
Combination pack indicator	integer (code value)	0 to 1
Flag denoting that the APP is a combination product pack or that the pack is only available as a component pack of a combination product pack (ie not available in its own right). VALUES: 0 = single component 1 = combination pack 2 = component only pack		
Combination Actual Product Pack identifier	AMDT IDENTIFIER	0 – many
Unique identifier for the Actual Product Pack (Actual Component Pack) where it exists as a component of the APP. This is a APP with combination product flagged which will identify of the sub-packs within a combination or multi pack		
Number of component packs	Integer	0 to 1
This indicates the number of individual component packs within each APP		
Date of availability from AUS¹⁰	Date	0 - 1
Date from which the APP is available in Australia. This allows commencement of distribution for products available at a future known date		
Date of availability from NZ¹¹	Date	0 - 1
Date from which the APP is available in New Zealand. This allows commencement of distribution for products available at a future known date		
Date of availability to AUS	Date	0 - 1
Date when the APP became unavailable in Australia		
Date of availability to NZ	Date	0 - 1

¹⁰ One of the fields “Date of availability from” must be populated

¹¹ One of the fields “Date of availability from” must be populated

Date when the APP became unavailable in New Zealand

Notes:

8. Ancillary Terminology for AMDT

In addition to the main 'six class' terminology, there are a number of other terminology/vocabulary structures which hold information which is referenced by the AMDT.

These are

- Dose Form
- Ingredient
- Administerable Dose Unit
- Container
- Units of Measure
- Product Sponsor

8.1 Dose Form

Definition: The dose form is the summary representation of the multiple characteristics of the medication relating to its inactive ingredient behaviour, manufacturing process and delivery characteristics which enable the administration and delivery of a medication.		
Description: Medications pass through different physical forms during the journey from the end of the manufacturing process (the manufactured dose form), through to the point where the medicine is administered to the patient (the orderable dose form). Orderable dose forms are the dose forms the person writing a prescription expects the patient to take. Manufactured dose forms in which the product is manufactured and transported. As the dose form is a defining characteristic of medication, and is linked with knowledge regarding medicine administration it is important that there is a standard defining list of dose forms. In the AMDT this list will as far as possible be drawn from the TGA list of approved dose forms. The dose form must be distinguished from the administerable or measurable dosage unit, although at times these concepts share descriptions or terms eg "tablet (as dose form)" and "tablet (as dose unit)".		
Associations		
Attributes	Type	Occurrence
Dose form identifier	AMDT IDENTIFIER	1
The form information shall be represented as a code taken from the associated AMDT list of medicinal product forms. Examples: effervescent tablet, sachet, injection		
Dose form name	String	1
Name of dose form eg. Tablet, solution, metered dose inhaler.		
Dose form type	integer (code value)	1 to many
Flag used to indicate whether the dose form is orderable, manufactured or both. VALUE: 1 manufactured 2. orderable		
Invalidity flag	integer	0 to 1
Flag indicating that this terminology entry was invalid. VALUE: 0 = Valid 1 = Invalid		

NOTE: The dose form instance needs to be retained in case it was used prior to detection of the error(s) which caused its invalidation.

Invalidity flag date

date

0 to 1

Value of date that Invalidity flag set indicating that this terminology entry was invalid. Author of invalidity should be captured in the update log file.

NOTE: The dose form instance, even when subsequently found to be invalid, needs to be retained in case it was used prior to detection of the error(s).

Notes:

8.2 Ingredient

Definition: The Ingredient is the chemical entity or most granular form of the entities which constitute medicines.		
Description: Ingredient describes the substances which may act as ingredients in medicines. This is a defining characteristic of medicines. In the AMDT ingredients can be classified into three main classes: ingredient salt (eg amoxicillin trihydrate), ingredient base (amoxicillin) and clinically relevant excipients. Other organisations eg TGA have additional classes of ingredients (eg. Proprietary ingredients) which are of relevance to their business process and do not impact on the AMDT. Ingredients naming allows for synonyms, abbreviations and both a fully defined and preferred name.		
Attributes	Type	Occurrence
Ingredient identifier	AMDT IDENTIFIER	1
Identification of the ingredient salt to which this set of information relates.		
Identification of the ingredient NOTE: <ol style="list-style-type: none"> 1 This identifier shall be used to identify a substance that acts as an ingredient of a Virtual Product or a clinically relevant excipient of an Actual Product. For example quinine sulphate, amitriptyline hydrochloride, amoxicillin sodium. 2 Ingredients may be fully specified including salts, ingredient base or may be more loosely described without the salt if that is appropriate, or the only information available. 		
Ingredient name	String	1
Pharmaceutical product designation in the form of a name. NOTES: <ol style="list-style-type: none"> 1. The name should where possible be an official name from the list of TGA approved names. 2. The length of this field will be up to 255 characters 		
Ingredient synonym	String	0 to many
Pharmaceutical product designation in the form of a synonym. NOTES: The length of this field will be up to 255 characters		
Ingredient status	Integer	1
Indicates if the ingredient is an active or inactive ingredient. VALUE <ul style="list-style-type: none"> 1=ingredient salt 2=ingredient base 3=inactive excipient 		
Invalidity flag	Integer	0 to 1

Flag indicating that this terminology entry was invalid.

VALUE:

0 = valid

1 = Invalid

NOTE: The entry needs to be retained in case it was used prior to detection of the error(s) which caused its invalidation.

Invalidity date	Date	0 to 1
------------------------	-------------	---------------

Notes:

8.3 Administerable Dose Unit

Description: Used to describe the orderable or administerable unit contained within a pack		
Attributes	Type	Occurrence
Unit dose type	AMDT IDENTIFIER	1
Identification of the Administerable unit dose type. That is the unit dose administered or taken by the patient. It is the entity or thing that can be handled or counted. Sometimes also described as “the each”		
Unit dose type name	String	1
Name used to describe the unit dose type Eg tablet, vial, ampoule, actuation, measure For some dose forms eg creams or drops there is no unit dose form type and these are coded as continuous.		
Invalidity flag	Integer	0 to 1
Flag indicating that this terminology entry was invalid. VALUE: 0 = valid 1 = Invalid NOTE: The entry needs to be retained in case it was used prior to detection of the error(s) which caused its invalidation.		
Invalidity date	Date	0 to 1

Notes:

8.4 Container

Definition: The container is the packaging type in which the actual products are delivered.		
Description: The container is the type of Actual Product Pack or pack component in which the Actual Products are delivered or contained. Examples bottle, blister pack, tube, metered dose inhaler.		
Attributes	Type	Occurrence
Container identifier	AMDT IDENTIFIER	1
Identification of the container type		
Container name	String	1
<p>NOTES:</p> <ul style="list-style-type: none"> The name should where possible be an official name from the list of TGA approved names. The length of this field will be up to 255 characters. 		
Container synonym	String	0 to many
<p>Pharmaceutical product designation in the form of a synonym.</p> <p>NOTES:</p> <p>The length of this field will be up to 255 characters.</p>		
Invalidity flag	Integer	0 to 1
<p>Flag indicating that this terminology entry was invalid.</p> <p>VALUE:</p> <p>0 = valid</p> <p>1 = Invalid</p> <p>NOTE: The entry needs to be retained in case it was used prior to detection of the error(s) which caused its invalidation.</p>		
Invalidity date	Date	0 to 1

Notes:

8.5 Sponsor

Description: Used to identify sponsors of medicinal products		
<hr/>		
Attributes	Type	Occurrence
Sponsor identifier	AMDT IDENTIFIER	1
Identification of the medicinal product sponsor or sponsor. NOTE: This identifier will be taken from a table of sponsors		
Sponsor name	String	1
Name used to describe the sponsor - 255 characters		
Sponsor short name	String	1
Short Name used to describe the sponsor – 10 characters		
Sponsor address	String	0 to 1
Sponsor city	String	0 to 1
Sponsor postcode	String	0 to 1
Invalidity flag	Integer	0 to 1
Flag indicating that this terminology entry was invalid. VALUE: 0 = valid 1 = Invalid NOTE: The entry needs to be retained in case it was used prior to detection of the error(s) which caused its invalidation.		
Invalidity date	Date	0 to 1

8.6 Unit of Measure

Description: Used to describe the unit of measure within the medicine terminology		
<hr/>		
Attributes	Type	Occurrence
Unit of measure identifier	AMDT IDENTIFIER	1
Identification of the unit of measure that is used to define the amount of active ingredient or strength in medicines.		
Unit of measure name	String	1
Name used to describe the unit of measure Eg. mL, g.		

9. Mapping tables

The medicines terminology needs to map to:

1. Nationally used classification systems for the purposes of:
 - Navigation groupings according to therapeutic class
 - Groupings to support linkage with medicines knowledge bases eg medicine interactions
 - Groupings to support analysis of medicine utilisation
2. Existing terminologies which are widely used in clinical practice.

In managing a transition strategy to the universal use of the AMDT identifiers and core data it will be necessary for existing systems to map to the AMDT, even if only for the initial purpose of transmitting the AMDT identifiers in messages and medication data transmission.

The initial maps to be developed as part of phase two will include (but are not necessarily limited to) the following terminologies: SHPA, ATC, MIMS, MDRef, APPCAT, Pharmacode (NZ only), PBS (Aust. only).

10. Attachment A: Contributors.

The following individuals and organisations have participated in the HL7 Medicines Terminology working group which has developed this model in collaboration with the UK National Health Service Information Authority and Blue Wave Informatics.

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