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Health Information Standards

PAEREWA PĀRONGO HAUORA

New Zealand Medicines Terminology Recommendation Report

HISO 10024

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*Nominating organisations are correct as at the time the Expert Advisory Committee was established.

Related Documents

The documents listed below were referred to while developing this Recommendation Report.

HISO

- HISO 10030.1: 2008 EPharmaceutical Business Process
- HISO 10030.2: 2008 EPharmaceutical Messaging Standard

Other Publications

- PHARMAC Pharmaceutical Schedule
- HISAC Information Mapping Report Draft v1.7
- NEHTA Australian Medicines Terminology Editorial Rules, 17/12/2007 (see http://www.nehta.gov.au/index.php?option=com_standardscatalogue&m=resource&cid=8&id=146&Itemid=424)
- NEHTA AMT UML Class Diagrams (see http://www.nehta.gov.au/index.php?option=com_standardscatalogue&m=resource&cid=8&id=145&Itemid=424)
- dm+d Editorial Rules (see http://www.dmd.nhs.uk/documentation)
- Health Information Strategy for NZ 2005 HP4155
- Actioning Medicines New Zealand HP4458

EXECUTIVE SUMMARY

The Health Information Standards Organisation (HISO) has been coordinating the development of a range of standards to support the Health Information Strategy for NZ (HIS-NZ) ePharmacy Action Zone. An expert advisory committee, consisting of representatives from across the health and disability sector, was established to consider options for establishing a Medicines Terminology for New Zealand. A Medicines Terminology is essentially a list of medicines based on a standardised naming and coding system.

The development of this document has been an iterative process. It now reflects the considered view of the members of the New Zealand Medicines Terminology Expert Advisory Committee. It is intended to guide the Health Information Strategy Advisory (formally Action) Committee (HISAC) in making a decision on an appropriate medicines terminology for use in New Zealand as well as inform those with an interest in, or who will be impacted by, the introduction of medicines related standards.

Why is a Medicines Terminology required?

In New Zealand there is wide use of electronic medicines information in general practice, community pharmacy and secondary care organisations. Medicines information commonly used includes the PHARMAC Schedule, the Pharmacy Guild Pharmacode product catalogue, wholesaler / supplier catalogues, MIMS, Medsafe's web-accessible database of medicines and published datasheets, health care organisation generated medicines lists, and guidance provided by the NZ Guidelines Group and Best Practice Advocacy Centre, (BPAC).

However, not everyone uses the same resources and the information in each is inconsistent and lacks a common language. As a result:

- Avoidable prescribing, dispensing and administration errors occur;
- It is difficult to establish a view of a person's medication history reliably and efficiently across the continuum of care;
- Decision support capabilities of electronic systems cannot be used reliably, or are severely constrained;
- There is duplicated effort and associated cost in creating, disseminating, maintaining and supporting multiple lists;
- Streamlining and/or integrating business and/or clinical processes is difficult;
- Data cannot be reliably and efficiently aggregated for clinical governance and health planning purposes.

A standardised medicines terminology that is universally used throughout the health and disability system can help to address many of the issues identified above.

What is a Medicines Terminology?

A medicines terminology:

- Is essentially a list of medicines with standardised text descriptions (terms / names) used to refer to each medicine. All medicines listed in the terminology are uniquely identified (coded) at the pack and individual dose level by trade name (brand) and active ingredient name (generic). Also included is information on pack size, strength, dose form, and therapeutic group.
- Identifies the relationships between the components that make up the terminology. It includes the relationships that enable synonyms to be identified, as well as more complex relationships based on pharmacological class, ingredients and packaging.

A medicines terminology is intended to identify medicines, their components, their therapeutic groups, and the relationships between them. It enables safe and accurate identification of medicines regardless of whether they are identified by text or numeric code. It does not include clinical information for decision support (e.g. indications or doses), supply chain information (e.g. prices, stock availability), or funding / claiming information (e.g. subsidy details).

What are the benefits of a Medicines Terminology?

A medicines terminology has the following benefits for the health and disability system:

- ☑ Contributes to safer medication practice;
- ☑ Supports a range of strategic sector initiatives such as ePrescribing, Safe Medication Management and a National Formulary;

- ☑ Supports useable and reliable shared patient medication information, including electronic transfer of medication records, especially admissions and discharges;
- ☑ Contributes to efficiency gains and cost savings;
- ☑ Enables fully supported generic prescribing;
- ☑ Enables consistent decision support and knowledge support;
- ☑ Improves the data used for health planning, etc.

Committee considerations and recommendations

The committee explored the following aspects:

1. Design of the terminology
2. Terminology infrastructure
3. Editorial software
4. Terminology content tracking numbers
5. Risks / Issues and dependencies
6. Vendor impacts
7. Governance and management
8. Establishment

The table below summarises the recommendations being made in this report. Further details can be found in the main body of this document.

Topic	Recommended
Design of the terminology	Adopt and adapt the Australian Medicines Terminology (AMT)
Terminology Infrastructure	Establish our own infra-structure
Editorial Software	Consider the use of domestically made editorial software to manage the data as a conventional relational database
Terminology Content	Legacy Principles • Retain Pharmacodes and full backward compatibility to legacy systems
	Localisation of the data • Fully localised data as an interim solution, leading to full integration with the international SNOMED CT system
	Pharmacological grouping system • Adopt SNOMED CT when revision of medicines hierarchy is complete. It is possible that the New Zealand Medicines Terminology (NZMT) will move ahead before the new SNOMED CT system is available. In that case, we recommend an interim option be used until the new SNOMED CT system becomes available. Four possible interim options have been identified: - WHO ATC (World Health Organisation Anatomical Therapeutic Codes) - Australian Medicines Handbook (AMH) groupings - MIMS classes - British National Formulary (BNF) chapter heading groupings The choice of an interim solution should be addressed during the establishment phase of the NZMT

Topic	Recommended
	Editorial Rules • Use the AMT editorial rules, with appropriate changes from Australia to NZ

	Tracking System
	• Identification Number
	  o Global Trade Identification Number (GTIN) if present, otherwise SNOMED CT Identifier (SCTID)
	• Symbology
	  o The mechanism for representing tracking numbers (the barcode, data matrix, RFID tag, etc) on physical packaging or paper prescriptions should conform to GS1 standards

Governance and Management	• An Editorial Committee be established with responsibility for maintaining the Editorial Rules, and consulting with the sector when seeking to make changes to them. The Editorial Committee will need to be made up of clinical professionals. • A central release centre be established from which the terminology with be available for download. The release centre will also provide support services to the users of the terminology.
Establishment	• That a staged approached be taken to establishing the NZMT and that a formal project be formed to manage the establishment stages.

A number of risks, issues and dependencies have been identified. These are not considered to be show stoppers but it is recommended that these be defined in more detail and addressed as part of the initial set up phase of a NZ Medicines Terminology project.

Summary

In summary, a medicines terminology is a key enabler for Safe Medication Management, ePharmacy, and a National Formulary. It can contribute significantly to patient safety, quality, value for money and efficiency objectives.

The HISO Medicines Terminology Expert Advisory Committee recommends the Australian Medicines Terminology be adopted and adapted for use in the New Zealand health and disability system. Initially and possibly on an ongoing basis, the terminology should be physically located and maintained on New Zealand based infrastructure. It should be governed by New Zealand based experts with formal linkages to the body responsible for the Australian Medicines Terminology, in particular to maximise the re-use of the work done in Australia. The committee also recommends that a formal project be initiated to establish the terminology in several stages. The recommended approach significantly reduces the cost and risk profile for the establishment and ongoing support of a New Zealand medicines terminology.

1 INTRODUCTION

1.1 Background

The Health Information Strategy Advisory Committee (HISAC) is a Ministerial Committee responsible for the governance, oversight and leadership for the implementation of the Health Information Strategy for New Zealand (HIS-NZ), including the oversight and prioritisation of health information standards.

The New Zealand Health Information Standards Organisation (HISO), is charged with developing, endorsing and promoting health information standards.

1.2 The Health Information Strategy for NZ (HIS-NZ)

HIS-NZ identifies 12 ‘Action Zones’ that provide a focus for health information in New Zealand up to 2010. HISAC has identified ePharmacy – Action Zone 4 as a priority in which it will deliver the required standards through HISO, and champion the development of sector-wide General Practice and Community Pharmacy system application solutions.

For each HIS-NZ Action Zone, a detailed ‘Preliminary Scope and Approach’ (PS&A) document has been prepared. This is a core reference for ePharmacy-related activity and is available on the HISAC website: http://www.hisac.govt.nz/moh.nsf/pagescm/7390/$File/PS&A+AZ4.pdf

The ePharmacy PS&A provides information on the current situation and opportunities for improvement that ePharmacy seeks to address, and describes the benefits of ePharmacy.

1.3 EPharmacy context

While ePharmacy in HIS-NZ is primary care focussed, in its broadest context it is a sector-wide approach to improve the quality, accuracy, accessibility and sharing of information about the prescription, dispensing and administration of medicines in and across both primary and secondary care settings.

ePharmacy features include:

- Decision support at the point of prescribing, dispensing and administration;
- Secure electronic exchange of prescriptions;
- Recording of changes to prescriptions;
- Recording of dispensing and administration activities; and
- Authorised access to patients’ medication histories.

ePharmacy will be delivered through a cohesive and efficient set of standards, electronic systems, clinical decision support systems and business processes that will work with the results of the other Action Zones to enable improvements and efficiencies in patient care.

To support ePharmacy, HISO is coordinating the development of a range of standards, initially focusing on:

- Pharmaceutical Business Process and Messaging Standards:
  This set of standards will define a common set of business processes and the data elements that constitute a pharmaceutical transaction message.

- Common Medicines Terminology
  A nationally consistent and standardised list of medicines based on standardised text descriptions (terms / names) and a standardised coding system.

This document relates to the Common Medicines Terminology described above.

Due to the technical nature of the topic, there are a large number of acronyms used throughout this document. These are explained in full in the Glossary of Terms at Appendix E.

1.4 New Zealand Medicines Terminology Expert Advisory Committee

1.4.1 In scope

The scope of work includes:

(a) Assess and make recommendations regarding the approach to progressing the implementation of a New Zealand Medicines Terminology Standard, including:

- Confirm the overarching need for a single Medicines Terminology for New Zealand, specifically an outcome, process and impact analysis (what are the overarching implications of a medicines terminology)
- Confirm whether these needs can be addressed through an existing medicines terminology, and identify any aspects of that terminology that would need to be tailored for New Zealand
- Identify current and potential uses for a single Medicines Terminology across the existing (and potential future) sector medicines information sources, including a NZ medicines list and provide the linkages to and implications for other HIS-NZ Action Zones such as eLabs, GP2GP, etc. The relationship to international identifier / barcoding systems / standards will need to be considered
- Assess the high level clinical, business, licensing and technical implications related to a Medicines Terminology for the NZ health and disability sector and its medicines supply chain including determining the appropriate operating model
- Identify the appropriate stages and processes required to implement a national medicines terminology. A key issue to consider is the transitional requirements to support the sector to adopt a medicines terminology and the critical path issues (e.g. what can we / do we do first). A clear roadmap is needed to transition the medicines terminology into the New Zealand environment in a way that is affordable, supports sector organisations and is practically possible
- Describe options and a preferred approach for discharging effective governance and management of the national medicines terminology in New Zealand, including any necessary linkages to NEHTA and the SNOMED CT IHTSDO, and structure and process reuse opportunities

(b) Assess a range of sector stakeholder perspectives / requirements and the role they could play in the adoption / adaptation, ongoing governance / guidance and management of a Medicines Terminology in NZ. This includes health and disability sector organisations that store and use medicines information as well as those that generate information as part of the supply chain and decision support.

(c) Identify any lessons learnt for incorporation into future HISO work.

1.4.2 Out of scope

The following are excluded from the scope of work:

- Assessment of technologies and the merits of specific vendor products, development of the full implementation programme for adoption and adaptation of the AMT and the implementation of this and other related solutions (e.g. a universal list of medicines) are separate and out of scope.

2 WHY IS A MEDICINES TERMINOLOGY REQUIRED?

2.1 Current situation

In New Zealand there is wide use of electronic medicines information in general practice, community pharmacy and secondary care organisations. Medicines information commonly used includes the PHARMAC Schedule, the Pharmacy Guild Pharmacode product catalogue, wholesaler / supplier catalogues, MIMS, Medsafe's web-accessible database of medicines and published datasheets, health care organisation generated medicines lists, and guidance provided by the NZ Guidelines Group and BPAC.

However, not everyone uses the same resources and the information in each is inconsistent and lacks a common language. For example:

- A medicine can be referred to using different text (names) and these cannot be reliably related / mapped to each other, for example:
  - A prescriber might write "morphine 30mg tablets". Another prescriber might write "Morphine Sulphate, Tab, 30mg". While the human reader can immediately see that these refer to the same medicine, matching these two pieces of text electronically cannot be done reliably. The relationship between morphine and morphine sulphate has to be electronically represented in a database before it can be used by a software system. Similarly strength and dose form, and unit of measure all need to be electronically represented. Electronically represented relationships are vital for decision support and alerting because without these a computer system is not able to reliably connect two medicines that may have an adverse interaction.
- A medicine can have a number of different codes and these cannot be reliably related / mapped to each other, for example:
  - Within a medical practice individual patient's medication histories may be stored as MIMS codes. It does not necessarily follow that the receiving party (e.g. a community pharmacy) uses MIMS or a system that understands MIMS. In the case of prescribing, this makes it difficult to connect a prescription with the right choice of items to dispense;
  - Further, MIMS codes are not transferred to the hospital when the patient is admitted; the medication history is transferred to the hospital as free text. Free text has become the de-facto standard when exchanging information between different parts of the health and disability system as a way of circumventing the differences;
  - Pharmacy Guild Pharmacodes (unique numeric identifiers for brand product) are not used by all information sources.
- The brand product name and equivalent generic medicinal name are not available in all information sources;
- There is no or insufficient 'unit of use' (unit dose) level information available.

As a result:

- Avoidable prescribing, dispensing and administration errors occur;
- It is difficult to establish a person's medication history reliably and efficiently across the continuum of care;
- Decision support capabilities of electronic systems cannot be used reliably or are severely constrained;
- There is duplicated effort and associated cost in creating, disseminating, maintaining and supporting multiple lists;
- Streamlining and/or integrating business and/or clinical processes is difficult;
- Prescribing and other data cannot be reliably and efficiently aggregated for clinical governance and health planning purposes.

A standardised medicines terminology that is universally used throughout the health and disability system can help to address many of the issues identified above.

2.2 What is a medicines terminology[1]?

A medicines terminology:

- Is essentially a list of medicines with standardised text descriptions (terms / names) used to refer to each medicine. All medicines listed in the terminology are uniquely identified (coded) at the pack and individual dose level, by trade name (brand) and active ingredient name (generic). Also included is information on pack size, strength, dose form, and therapeutic group.
- Identifies the relationships between the components that make up the terminology. It includes the relationships that enable synonyms to be identified, as well as more complex relationships based on pharmacological class, ingredients and packaging.

A medicines terminology is intended to identify medicines, their components, their therapeutic groups, and the relationships between them. It enables safe and accurate identification of medicines regardless of whether they are identified by text or numeric code. It does not include clinical information for decision support (e.g. indications or doses), supply chain information (e.g. prices, stock availability), or funding / claiming information (e.g. subsidy details).

2.2.1 Medicines Terminology concepts and coding

A terminology defines, represents and relates concepts. A 'concept' is a discrete unit of thought. For example, some of the concepts and relationships for Panadol 500mg caplet would be:

- Concepts:
  - analgesic
  - paracetamol
  - paracetamol oral dose form
  - paracetamol 500 mg tablet
  - paracetamol 500mg tablet, 12 tablets
  - Panadol
  - Panadol 500mg caplet
  - Panadol 500mg caplet, 12 caplets
  - Panadol 500mg caplet, 12 caplets, blister pack

- Relationships:
  - Panadol 500mg caplet has active ingredient: paracetamol
  - Panadol 500mg caplet has dose form: tablet
  - Proprietary dose form caplet is a: tablet
  - Panadol has sponsor: GlaxoSmithKline New Zealand

2.2.2 Moving from free text to coded information

Can you safely say that:

- codeine phosphate sesquihydrate is the same as codeine phosphate?
- a caplet is a capsule?
- dosulepin is a synonym for doxepin?

If you answered "yes" to any of the above, then you are not correct.

---

[1] Note that the phrase medicines terminology has a very specific meaning, which has been adopted because of its use in other countries.

On the other hand:

- codeine phosphate anhydrous is the same as codeine phosphate
- a caplet is a tablet.
- doseulepin is a synonym for dothiepin
- 'digoxin 0.25 mg tablet' is the same as 'digoxin 250 microgram tablet'
- 'atenolol 50 mg tablets' are the generic of 'Tenormin 50mg tablets'
- 'Triphasil calendar pack' contains 28 tablets of four different colours each of different combinations of ingredients

Matching medicines by text alone is not a simple task. While a human may correctly interpret the relationship between the concepts, computers cannot be relied on to be so intuitive. This makes safe electronic decision support difficult, if not impossible.

A terminology also provides unambiguous identification (coding) of concepts and the correct relationships between concepts in a way that a computer can reliably interpret. The coding of concepts and mapping of relationships between concepts are vital to many aspects of ePharmacy. For example, a computer system can then reliably connect:

- A prescription with the items that may be dispensed;
- Two medicines that may have an adverse interaction;
- A medicine term to other information sources such as subsidy claiming information or drug reference information such as serious interactions and contraindications.

The key relationships that a medicines terminology will represent can be seen in this diagram, which shows key relationships of the Australian Medicines Terminology:

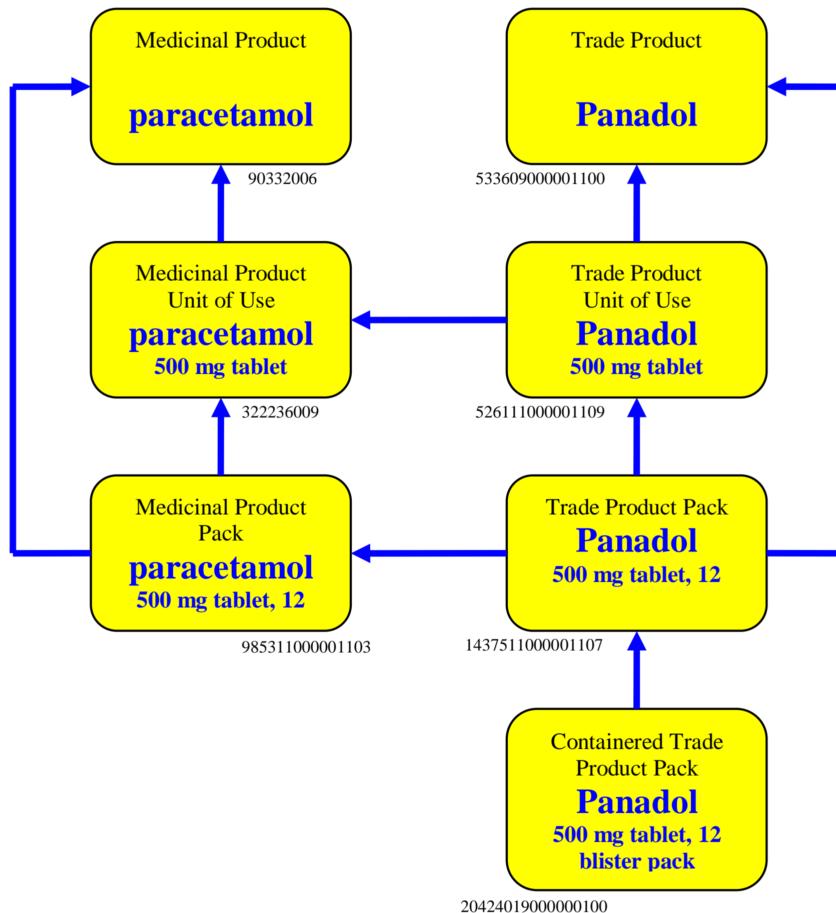


Figure 1: Relationships within the AMT using a NZ product as an example[2]

[2] Example codes shown are as follows: 90332006 and 322236009 are from the SNOMED CT international release; 985311000001103, 526111000001109 and 1437511000001107 are from the dm+d and use UK namespace identifiers; 533609000001100 is an invented ID using

2.3 Practical applications (use cases)

A medicines terminology is largely a “behind the scenes” function of a medical information system. Most users will be aware of the names given to medicines by the terminology, but will not be aware of the codes and relationships of the terminology that enable specific features.

Use cases have been designed to demonstrate the features that a medicines terminology will support, and to enable the specifications and editorial rules to be tested to ensure that it does support those features. The use cases have been included as an appendix, but illustrative examples have been included here to indicate some of the features that a medicines terminology enables.

2.3.1 Example prescribing error

A doctor prescribes amitriptyline hydrochloride 2mg daily, but the dose forms available for amitriptyline do not enable this dose to be given.

What happens now: the pharmacist notices this and phones the doctor to discuss options. Note, in a case like this, as with many prescribing errors, it is likely that the 2mg dose would be entered as a free text instruction and therefore would not be amenable to automated checks by computer systems.

What a medicines terminology allows: the prescribing software can potentially raise an alert before the doctor completes the prescription because the dose amount is not a multiple of the dose unit strength. The medicines terminology records tablet strength and unit of measure separately which supports this kind of automated dose checking.

2.3.2 Example dispensing error

A doctor prescribes *dothiepin 25mg capsule*. The pharmacist selects *doxepin 25mg capsule* in error:

What happens now: if the pharmacist check does not detect the error, it likely goes unnoticed

What a medicines terminology allows: either the prescription is transmitted electronically, or the barcode for *dothiepin 25mg capsule* is printed on the paper prescription. There are two points at which a medicines terminology can help prevent the error. First, the pharmacy software presents only *Dopress 25mg capsule* as a valid choice, because that is the only brand product that matches the prescribing term (electronic prescription or barcode). This makes it almost impossible for the pharmacist to select the wrong product on the dispensing computer. Second, if the pharmacist physically takes the wrong packet off the shelf and scans its barcode, the system generates an alert because it does not match the prescribed product.

2.3.3 Example administration error

A palliative care patient is prescribed methadone 40mg, together with clonazepam and metoclopramide by continuous subcutaneous infusion (using a syringe driver) for pain in the terminal stages of malignant disease.

What Happened? The staff preparing the syringe do not realise the correct methadone preparation to use is four 10mg/1ml ampoules, and instead drew up 40mg (8ml) of the Biodone Forte oral liquid 5mg/ml. This was added to the syringe with the clonazepam and metoclopramide injection.

What a medicines terminology will allow: The prescription for the syringe will be entered electronically and stored in both a human readable and computer interpretable format. Before staff draw up the required amounts of each medicine, they will scan the barcode on the container of each. When the methadone oral liquid is scanned, the computer is able to generate an alert because methadone ampoules are not the same as methadone oral liquid in the terminology database.

an imaginary NZ namespace identifier; and 20424019000000100 is a Pharmacode-based ID using an imaginary namespace where the first part of the SCTID is the NZ Pharmacode.

2.3.4 Relationships between terms

A hospital patient is given an injection of benzylpenicillin and develops a severe itchy rash and difficulty in breathing. The medicine is stopped and replaced by an antibiotic from another therapeutic group. A note of this is included in his discharge notes, which are sent to the patient's GP. Later, a locum prescribes Cilicaine VK.

What happens now: We rely on the doctor to read the discharge notes, and to enter the adverse drug reaction (ADR) into the Patient Management System (PMS), usually as a text note. The locum does not read the discharge notes, and prescribes Cilicaine VK, which contains phenoxymethylpenicillin, an oral form of the penicillin to which the patient is allergic.

What a medicines terminology allows: The discharge notes may be structured to include the ADR with *benzylpenicillin* in a computer interpretable way. In that situation the ADR could be automatically added to the patient's notes, without the need for the doctor to do anything. Even if the discharge notes are not computer interpretable, the doctor can select *penicillin* when entering the ADR to the PMS. This allows decision support software to generate an alert when the locum attempts to prescribe Cilicaine VK, because the medicines terminology provides a link between *Cilicaine VK (phenoxymethylpenicillin 250 mg) tablet* and penicillin.

2.3.5 Bedside Verification

A nurse administers a medicine that has been prescribed by a doctor for a hospitalised patient.

What happens now: Medicines are not currently able to be electronically identified at the unit of use or unit dose level when verifying right patient, right drug, right dose, right form, etc.

What a medicines terminology allows: A medicines terminology includes pack, sub-pack, and unit of use information which can be included on unit of use packaged medicines which may be used to support electronic bedside verification.

2.4 Benefits

A national medicines terminology provides a common term for each medicine that is understood by all (in human readable form) and interpretable by computer systems.

Patients

- ☑ Improved reliability of electronic decision support e.g. ADR and allergy alerting
- ☑ Reduced likelihood of prescription errors due to better access to pharmaceutical decision support systems
- ☑ Enables electronic verification of "right drug, right patient" at both dispensing and administration
- ☑ Contributes to improved patient medication histories
- ☑ Less time spent waiting for prescriptions to be clarified or confirmed due to ambiguities
- ☑ Standardisation throughout NZ has benefits for patients who move from one region to another

Prescribers

- ☑ Enables pharmaceutical electronic decision support systems when prescribing pharmaceuticals
- ☑ Better access to information about drug interactions and polypharmacy
- ☑ Contributes to improved patient medication histories and (standardised) medication charts throughout New Zealand
- ☑ Will better enable generic prescribing
- ☑ Improved ability to interpret medication histories transferred from overseas due to links with international terminology and synonym support
- ☑ Less interruption to clarify or correct ambiguous prescriptions or those in error

Pharmacists

- ☑ Access to the same base data (information) that the prescriber is using
- ☑ Better access to information about drug interactions and polypharmacy
- ☑ Less time spent querying of prescription issues (if prescriptions are written using the terminology they will be less ambiguous)
- ☑ Better streamlining of workflows, including less time taken dealing with prescription issues

Funders and planners

- ☑ Improved potential for reduction in ADRs and allergic reactions and the consequential costs
- ☑ More rational use of medicines due to better access to knowledge support and decision support
- ☑ Efficiency gains when medication histories do not need to be re-keyed when being transferred
- ☑ Efficiency gains as a result of less querying of prescription issues
- ☑ Potential reduction in prescribing, dispensing, and administration errors
- ☑ Better analysis of prescribing trends

Researchers

- ☑ Useful electronic data can be aggregated from prescribing and dispensing systems, minimising the need for re-keying data

Summary

A medicines terminology has the following benefits for the health and disability system:

- ☑ Contributes to safer medication practice
- ☑ Supports a range of strategic sector initiatives such as ePrescribing, Safe Medication Management and a National Formulary;
- ☑ Supports useable and reliable shared patient medication information, including electronic transfer of medication records, especially admissions and discharge;
- ☑ Contributes to efficiency gains and cost savings across the sector;
- ☑ Enables fully supported generic prescribing;
- ☑ Enables consistent decision support and knowledge support;
- ☑ Improves the data used for health planning, etc.

3 OPTIONS ASSESSED

The Committee assessed three potential options:

- To build a new Medicines Terminology
- To adopt and adapt an existing Medicines Terminology
- To use an existing Medicines Terminology

They were assessed for five aspects of a medicines terminology:

1. Design of the terminology
2. Terminology infrastructure
3. Editorial software
4. Terminology content
5. Tracking / identification numbers

The sections below provide analysis of the options assessed and aspects considered.

3.1 Design of the terminology

Design options considered are: build a new terminology, adopt and adapt an overseas one, or utilise an existing NZ medicines database.

3.1.1 Build a new medicines terminology for NZ

This option involves building a medicines terminology from scratch. This option would, in reality, draw on existing terminologies and databases for design ideas, but would distinguish itself by being a novel overall design concept.

- Pros
  - Allows for the simplest possible system to be built for our needs, with no unnecessary features;
  - Gives us total control over the design and content, which simplifies governance issues.
- Cons
  - Makes it more difficult to cross-map to other systems in other countries;
  - Makes it more difficult for software developers to transfer technologies and knowledge to the NZ situation;
  - Requires extensive development time, putting the burden of both design and data creation on us;
  - The end result is likely to look similar to existing systems.

3.1.2 Adopt and adapt

3.1.2.1 Australian Medicines Terminology (AMT)

This option involves using the AMT to provide a structure and principles for organising a NZ Medicines Terminology. It does not necessarily mean utilising the same hardware and software that is used in Australia to create, maintain, and distribute the AMT, (refer to paragraph 3.2 for full details).

- Pros
  - Well designed structure and principles;
  - Has the potential for easy transfer of technologies and knowledge between Australia and NZ, and potentially other jurisdictions around the world;
  - Provides globally unique identifiers for every concept at every level;
  - HISAC has a mandate to harmonise with Australia wherever possible.
- Cons
  - The AMT is in the early stages of use and is not yet proven (however, it has been assessed as robust and easily implemented);

- Possibly has features that are not essential to its core purpose;
- Uncertainty as to future governance because it is expected that the parts of the present AMT will be, in one form or another, adopted as part of the international SNOMED CT core terminology set.

3.1.2.2 UK dictionary of medicines + devices (dm+d)

This option involves using the dm+d to provide a structure and principles for organising a NZ Medicines Terminology. It does not necessarily mean utilising the same software and hardware that is used in the UK to create, maintain, and distribute the dm+d. This committee has not investigated the dm+d as thoroughly as it has the AMT, but is able to identify the following pros and cons:

- Pros
  - A currently functional system;
  - Allows the potential for easy transfer of technologies and knowledge between UK and NZ;
  - Provides globally unique identifiers for every concept at every level (except each unit of use in multi-component packs).
- Cons
  - Uses the current SNOMED CT core for pharmaceutical/biological products, which is recognised as being poorly structured;
  - Uncertainty as to future governance because it is expected that the AMT will be, in one form or another, adopted as part of the international SNOMED CT core terminology set, and this will supersede the dm+d;
  - Could make it difficult to share technologies and knowledge with Australia;
  - Does not provide an identifier for each individual unit of use in a multiple pack;
  - It does not have Trade Product and Trade Family concepts which make it difficult for recording brand information in the absence of greater detail, and so does not fully support secondary care prescribing and clinical records.

3.1.2.3 GS1

GS1 Standards provide a system for allocating unique identifiers to medicines. Global Trade Item Numbers (GTINs) uniquely identify items that are traded, but do not extend to the generic and class concepts that are vital to support ePharmacy. For this reason GS1 has not been considered as a medicines terminology. For a more detailed discussion of GS1, refer section 3.5, Tracking numbers.

3.1.2.4 USA RxNorm[3]

This option involves using RxNorm to provide a structure and principles for organising a NZ Medicines Terminology. It does not necessarily mean utilising the same software and hardware that is used in the USA to create, maintain, and distribute RxNorm. This committee has not investigated RxNorm as thoroughly as it has the AMT, but is able to identify the following pros and cons:

- Pros
  - Well designed structure and principles;
  - Allows the potential for easy transfer of technologies and knowledge between USA and NZ;
  - Provides globally unique identifiers for every concept at every level.

[3] "RxNorm provides standard names for clinical drugs (active ingredient + strength + dose form) and for dose forms as administered to a patient. It provides links from clinical drugs, both branded and generic, to their active ingredients, drug components (active ingredient + strength), and related brand names. NDCs (National Drug Codes) for specific drug products (where there are often many NDC codes for a single product) are linked to that product in RxNorm. RxNorm links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software, including those of First Databank, Micromedex, MediSpan, Gold Standard Alchemy, and Multum. By providing links between these vocabularies, RxNorm can mediate messages between systems not using the same software and vocabulary.

RxNorm is one of a suite of designated standards for use in U.S. Federal Government systems for the electronic exchange of clinical health information." (http://www.nlm.nih.gov/research/umls/rxnorm/ accessed 1/9/2008)

- Cons
  - Support for rINN and British Approved Name (BAN) would need to be added – the US data assumes United States Adopted Names (USAN) throughout;
  - Loss of harmonisation with Australia could present difficulties if joint regulatory environment develops;
  - Not a SNOMED CT-based design, so extra work needed to integrate with SNOMED CT;
  - Medicines, whether prescription or over the counter (OTC) with more than three ingredients are not fully represented at the present time, however this is not a very significant point because we would need to populate it with all NZ products anyway.

3.1.3 Use existing

This option involves using one of the existing databases such as the Pharmacy Guild Pharmacodes, MIMS, Medsafe's SMARTI, or the PHARMAC Schedule as a medicines terminology for interoperability throughout the New Zealand health and disability sector.

- Pros
  - Minimal implementation time for the terminology (it simply involves standardising on one of the existing databases), although adoption throughout the sector would still take time.
- Cons
  - Existing systems are not fully functional as a medicines terminology as they lack consistent and detailed unit of use information, generic medicine information, and pharmaceutical classes; none contain a complete set of features to support ePharmacy;
  - Makes it more difficult to cross-map to other systems in other countries, except that MIMS could presumably support mapping to Australian data;
  - Makes it more difficult for software developers to transfer technologies and knowledge to the NZ situation, except that MIMS would presumably permit transfer to/from Australia.

3.2 Terminology infrastructure

The infrastructure is the software and hardware tools used to store, publish and distribute the terminology data (content).

3.2.1 Contracting to another country

The committee considered the option of contracting to another country. Australia has been used as a specific example to illustrate the pros and cons specifically using the AMT and Australian National Product Catalogue (NPC) infrastructure for the NZ Medicines Terminology data:

- Pros
  - True integration of systems, as there is only one system, maximising transferability between countries;
  - Minimal need to retain and maintain systems in NZ;
  - Ability to directly utilise existing Australian data where there is overlap between Australian and NZ products.
- Cons
  - NZ may move ahead faster than Australia with ePharmacy and may need systems up and running sooner than can be made available by Australia;
  - We want to minimise the cost and impact of the change, so it is important for us to be able to continue producing legacy data. This could be more difficult if we use the Australian infrastructure as they do not have that as a design objective;
  - Having to go through an external system could lead to unwanted delays in getting data about new products distributed to the sector in a timely fashion;
  - We may want to enhance the database design to suit NZ needs and this could be very difficult when the database is shared with Australia.

3.2.2 Establishing our own infrastructure

- Pros
  - Able to move ahead at a pace that suits NZ;
  - Able to select the most appropriate hardware and software for our needs;
  - The hardware requirements are not significant;
  - Doesn't preclude the option of contracting to another country at a later stage.
- Cons
  - We need to purchase the infrastructure.

3.3 Editorial software

The software that will be used to create and maintain the data (medicines terminology content).

3.3.1 Australian and other international SNOMED CT editorial software

We have considered, in principle, the option of using Australian and other international SNOMED CT editorial software to manage domestically hosted data.

- Pros
  - Some editorial software tools exist, and they provide a good base to start with;
  - By using the same editorial software as others, staff expertise will be transferable from one country to another;
  - The software maintenance will be done by others.
- Cons
  - The Australian editorial software tools are undergoing further development and testing so may not be ready in time to support the NZ timeline for deployment of a working medicines terminology;
  - We may need to modify the tools, and this might be difficult when we do not own the source code.

3.3.2 Domestic editorial software

We have considered the option of using domestically made tools to manage the data as a conventional database (see Appendix A).

It is anticipated that the most appropriate set of editorial software tools will be a blend of domestic purpose-built software, and existing overseas software. However, the principle of maintaining the data in a conventional relational database implies the development of purpose-built software, because overseas software usually works by maintaining the data in a SNOMED CT format (as opposed to conventional relational database format).

- Pros
  - Domestic tools will simplify the process of retaining Pharmacodes;
  - Database experts in NZ are familiar with conventional databases and we are confident that they can produce the necessary tools quickly and reliably;
  - Systems for checking the relational integrity of conventional databases are a more mature technology than the equivalent technology for SNOMED CT-based databases;
  - The ability to produce the data in conventional database format simplifies the development path for vendors developing new solutions.
- Cons
  - Domestic editorial software tools will need to be developed.

3.4 Terminology content

3.4.1 Legacy data principles

New Zealand already has a high level of use of electronic medicines information in the health and disability sector. The systems are working, and the prospect of disruptions and the additional work involved in adopting a new database could be a serious disincentive to vendors to adopt a new medicines terminology.

One of the reasons for the high level of use in New Zealand is the Pharmacode. This provides New Zealand with a common identifier for medicinal products throughout the country, and throughout significant parts of the health sector. Pharmacodes are used almost universally in community pharmacy dispensing, wholesaler stock management, subsidy reimbursement, and some decision support systems, although they are not used much outside of these areas. The Pharmacodes do not contain a complete set of higher-level concepts (therapeutic groups and pharmacological groups), but they do provide robust data with a useful degree of functionality.

Other databases within NZ have identifiers that are used within specific systems, for example SMARTI and MIMS, but these identifiers are not much used for communicating medicines information between systems. For this reason the committee has focussed on the legacy issues of the Pharmacode alone.

3.4.1.1 Replace Pharmacodes

It is possible for a new medicines terminology to replace the Pharmacodes in such a way that the new terminology is not compatible with the Pharmacodes and requires modification to existing software in order to have it adopted.

- Pros
  - Should there be any errors present in the Pharmacode database (e.g. two products sharing a single Pharmacode) they can be corrected with the new terminology.
- Cons
  - The cost of conversion of the existing sector systems would not be insignificant given the extent to which Pharmacode is imbedded in these systems;
  - Resistance to uptake of the new terminology caused by the high cost of conversion;
  - Mix of incompatible old and new systems in use during the transition period, which could last several years.

3.4.1.2 Retain Pharmacodes

The committee has explored the option of retaining the Pharmacodes as part of the new terminology. Existing Pharmacodes would be retained, and new Pharmacodes would continue to be issued on the same basis as they are today. Each Pharmacode would be represented in the AMT by a Containered Trade Product Pack concept[4].

A key feature of this option is that the new medicines terminology will be able to be released in a legacy format. Legacy systems will be able to read the data. (Obviously, the fine details and the rich set of relationships present in the AMT data would not be present in the legacy format of the database.)

This option permits an incremental uptake of the new terminology, with the new names and descriptions for the products appearing first in existing systems without any need for software modification. As software is modified, it will be able to take advantage of the richer terminology, while existing software will remain operational.

The generic name codes, which are currently part of the Pharmacode database, are likely to be retained along with the brand product Pharmacodes, however this is not essential to the retention of legacy compatibility. Further research is needed to determine if they can be retained, and in what form. Initial research shows that there are situations where several generic codes map onto a single AMT concept, and this implies that one of the generic codes will be “lost in translation.” This is not expected to adversely affect legacy compatibility.

- Pros
  - Initial uptake of the new terminology (the new names and descriptions for the products) able to take place without requiring modification of existing software or needing new systems for distributing data;
  - No cost of conversion of existing software base until vendor wishes to upgrade;

[4] Any product that gets a CTPP concept will also need a Pharmacode. This will result in some products getting a Pharmacode where they would currently not get one.

  - Lowered resistance to uptake due to optional nature of software modifications;
  - During the transition period, old and new systems will be compatible.
- Cons
  - Some duplication of effort is required to maintain both a new format and a legacy format.

3.4.2 Localisation of the data

If we adopt and adapt an overseas terminology, we have several options regarding how many of the overseas terms we utilise, and how many we create for ourselves. We have looked at three options:

1. Fully localised data, refer 3.4.2.1.
2. Fully localised data as an interim solution, leading to full integration with the international SNOMED CT system, refer 3.4.2.2.
3. NZ specific combination of national and international, refer 3.4.2.3.

Note: Use of international data
We expect to utilise multiple sources when populating the NZMT database. For example, the AMT database may be one of them. While useful data can come from it, there is actually surprisingly little overlap of products sold in Australia and NZ. The AMT cannot provide more than a small percentage of the total data. Existing NZ databases will be far more significant as sources.

3.4.2.1 Fully localised data

This option involves starting with a complete copy of the external database, such as the AMT, and assigning a new, NZ-specific ID to each record in the database. The database is then maintained in isolation from the original parent database e.g. the NZ ID for paracetamol would be unique to NZ and different from the Australian/international ID paracetamol.

- Pros
  - Straightforward governance because there would be no offshore data to align with, and no offshore bodies to work with;
  - Fast development path because it would not depend on progress in other areas such as AMT or SNOMED CT.
- Cons
  - Maintaining cross-maps to offshore/international data would be required to permit international data exchange;
  - NZ data would not be interpretable overseas without access to those cross-maps.

3.4.2.2 Fully localised data as an interim solution, leading to full integration with the international SNOMED CT system

This option involves setting up the NZMT as a totally self-contained system, and progressively replacing IDs with international ones as and when they become available e.g. the ID for *paracetamol* would initially be NZ-specific. When the new international pharmaceutical products part of SNOMED CT is ready for use this ID will be replaced by the international ID for *paracetamol*. The concept will stay the same, with the same text descriptive name, but the ID will change. SNOMED CT fully supports this process through its history mechanism; the process of replacing ID's will be transparent to software that is compatible with the SNOMED CT standard.

- Pros
  - Allows us to rapidly build a self-contained system at a time when there are currently no accepted international SCTIDs for pharmaceutical products;
  - Provides a well defined process for adopting international or Australian IDs when that is appropriate without the need for further changes to the database design;
  - SNOMED CT will include detailed standards for pharmacological product extensions to the core terminology. It is difficult for us to predict the exact details of these standards; this allows us to adopt those standards when they are available.

- Cons
  - All software created to work with the NZMT would be complicated by the need to cope with superseded IDs. However, this would be a requirement in any case to maintain compatibility with SNOMED CT.

3.4.2.3 NZ-specific combination of national and international

This option involves pre-empting the international SNOMED CT standard, and deciding on our own blend of national and international terms. It could involve a clear boundary (for example, all trade concepts could be unique to NZ, and all generic concepts could be international) or a more opportunistic approach (use an international term wherever one exists, even for a trade product).

- Pros
  - NZ data would be interoperable with overseas SNOMED CT data from the beginning.
- Cons
  - NZ would have to be involved in maintenance of the offshore data, or at very least, vigilant to ensure that the offshore data remained correct for NZ;;
  - This option may be a departure from the SNOMED CT standard for how to develop a national pharmaceutical subset of SNOMED CT;
  - While ultimately NZ data could be aligned with international standards through the SNOMED CT history mechanism, this process is likely to be more complex than starting with a fully self-contained system.

3.4.3 Pharmacological grouping system

The SNOMED CT system of classifying pharmaceuticals is under review and is not considered fit for use in its current state. It is anticipated there will be an internationally recognised system of classification under SNOMED CT once that review is complete (possibly by 2010). Until then, we expect an interim system of classification to be needed. The committee has considered several options for potential interim groupings:

- WHO ATC codes – full international recognition, comprehensive, based on drug action, widely used around the world
- Australian Medicines Handbook groupings – used only in the AMH, but considered very logical;
- MIMS classes – widely used throughout NZ and Australia, comprehensive, already support the MIMS interactions data;
- BNF chapter heading groupings – quite widely used, but erratic in parts where the needs of organising a book take precedence over classification of medicines;
- BNF interactions groupings – very suitable for interactions, but not widely used;
- PHARMAC Schedule ATC codes – based on the needs of allocating subsidies, so not well suited to other uses such as recording interactions;
- Martindale codes – expensive and too finely detailed.

3.4.4 Editorial rules

Editorial rules define the way the names of the medicines are composed. They also provide definitions of the concepts that form part of the terminology.

3.4.4.1 Australian editorial rules

We have considered, in principle, the option of using Australian editorial rules. NEHTA has developed a comprehensive set of editorial rules for the AMT. It is possible for two countries to use different editorial rules, yet to share the same terminology. For example, the editorial rules in Australia might call for the preferred term “fluoxetine (as hydrochloride) 20mg tablet” while the editorial rules in NZ call for “fluoxetine 20mg tablet”, yet both terms refer to the same concept with the same identification code. Editorial rules also define areas where different terminologies (different concepts with different identification codes) are to be used. For example, editorial rules in NZ might define “condom” as a dose form, when it is undefined in Australia because condoms are not included in the AMT. Obviously, using Australian editorial rules will involve some localised NZ extensions.

- Pros
  - The Australian editorial rules have been developed from the dm+d editorial rules, and subject to sector review and extensive consultation. They are expected to be fit for purpose;
  - Harmonisation of editorial rules between NZ and Australia means that it is easier, and safer, for health care professionals to move between working in Australia and NZ.
- Cons
  - NZ health care practitioners might find the terminology unusual, although no work has been done to identify whether there are actually any significant differences between Australian and NZ practice when referring to medicines.

3.4.4.2 Domestic editorial rules

We have considered the option of using domestically developed editorial rules:

- Pros
  - It is possible to fine tune the terminology to match NZ usage.
- Cons
  - It would appear to be "re-inventing the wheel".

3.5 Tracking numbers

3.5.1 What are tracking numbers

Tracking numbers identify medicines at a level that allows tracking and management of medicines throughout the supply chain, dispensing, and administering (e.g. bedside verification).

3.5.2 Representing tracking numbers on physical products [5]

Tracking numbers can be affixed to products by the manufacturer e.g. a barcode, a data matrix, a Radio Frequency Identification (RFID) tag, etc or further down the supply chain such as when repackaging or dispensing.

Assigning tracking numbers does not mean they must be affixed to products (it will only be necessary where electronic tracking was actually taking place). Nor does it imply that that a range of pack sizes must be purchased – repackaging is an option.

Whether or not to track is beyond the scope of a medicines terminology.

3.5.2.1 Barcoding and data matrix systems

Barcoding is widely used for stock control and management throughout the world, refer Appendix B. The use of a data matrix (which is considerably smaller and contains more information) is becoming more common and the uptake of RFID is increasing in certain market sectors. A number of barcoding, data matrix and RFID systems exist around the world today, however GS1 has a significant level of acceptance globally, refer Appendix C.

Using a barcode, data matrix or RFID standard for representing tracking numbers on physical items does not, in itself, satisfy all requirements for a tracking system. Other issues include:

1. which numbers should be represented on an item (e.g. a product number); and
2. which database will provide information additional to the item number .

Not only does GS1 provide barcoding symbology and RFID standards, it provides a system that ensures tracking numbers are unique globally. These are known as Global Trade Identification Numbers (GTINs).

3.5.2.2 Current situation

More than 50% of medicines sold in NZ already have a barcode or data matrix on them, and many of these represent GTINs that have been issued in accordance with GS1 standards. Almost all medicines sold OTC have

[5] Mandatory affixing of tracking numbers would require regulatory change

barcodes that are scanned and used with point of sale computer tills. Many packs of prescription and other medicines used to dispense prescriptions have a barcode or data matrix, but these are not used by pharmacy computer systems in favour of the (manually entered) Pharmacode.

Any tracking number system used in the future will have to cater for tracking individual units of use. This is a vital part of bedside verification. Pharmacodes do not provide identifiers for individual units of use, but a medicines terminology does.

Other supply chain information, such as batch number and expiry date, are fully defined by GS1 standards and will not be part of a medicines terminology.

GS1 standards require that GTINs are created by the manufacturer/supplier, and permit more than one GTIN being allocated to the one product under certain circumstances.

3.5.3 Principles for a New Zealand tracking system

3.5.3.1 Base Unit of Trade

The *Base Unit of Trade* is the individual trade package, equivalent to the Australian Medicines Terminology concept of Containered Trade Product Pack (CTTP) and equivalent to the NZ Pharmacy Guild concept of Pharmacode. The Americans call this a *Stock Keeping Unit* (SKU).

In reality, there is not always a single unit of trade. The pharmacist might purchase a carton at a per-carton price, and not only break the carton down into its consumer packs, but break the consumer packs into sub-packs or individual dose units in the course of dispensing. Hence the carton, the pack, the sub-pack, and the single dose unit may all be units of trade.

The idea of deciding that one of the units of trade is the *Base Unit of Trade* allows the provision of a single identifier that serves to identify the product regardless of its packing. This is how the Pharmacode works. On its own it refers to the product pack, but with appropriate contextual information it can be used to identify the product at any packing level including individual unit of use. It is anticipated that the NZMT will allocate a Pharmacode to each product (CTPP), and there may be zero, one, or more GTINs for that product.

3.5.3.2 Unit of Use

The idea that the Base Unit of Trade can be used as a single identifier for a product at any packing level is a sound idea, and one that functions perfectly well provided that all packing levels contain the same units of use. It only breaks down when mixed packs are encountered. An example of a mixed pack is one in which there are multiple units of use in the one pack such as Losec Hp7 containing three medicines: omeprazole capsules, amoxycillin capsules, and clarithromycin tablets. The Base Unit of Trade does not serve to identify a single tablet or capsule taken from a mixed pack like that. This is the justification for identifying the unit of use (also known as unit dose) separately from the Base Unit of Trade.

The Unit of Use is equivalent to the Australian Medicines Terminology concept of TPUU, and has no equivalent in the NZ Pharmacy Guild Pharmacode database.

3.5.3.3 Complex hierarchies of packaging

In principle, it is possible for any packing level to contain mixed contents. For example, a single carton could contain more than one product. Similarly, a single Base Unit of Trade could contain a complex hierarchy of inner wraps, sub-packs, and units of use, any and all of which could have mixed contents.

The Australian National Product Catalogue (NPC) caters to that level of complexity. Each product can have a hierarchy of Traded Unit, Dispatch Unit, Order Unit, Invoice Unit, Consumer Unit and Base Unit. The base unit can have mixed contents, in which case a new hierarchy starts for each different item in its contents list.

3.5.3.4 Simplified hierarchy of packaging

Reducing the complexity to a pair of concepts, Base Unit of Trade and Unit of Use, is a pragmatic approach intended to meet clinical and supply chain needs. Although this simplified system is not capable of capturing all of the complexities of packing that are possible, it is capable of capturing the information needed to track, trace, and identify those packages.

The simplified system allows identification to be split into three categories:

1. Higher logistical units (units that contain more than one Base Unit of Trade, e.g. carton, pallet, shipping container).
2. Base Unit of Trade (trade pack).
3. Lower logistical units (units that contain either a single Unit of Use; or more than one Unit of Use, but less than a Base Unit of Trade, e.g. sub-pack, single dose unit).

3.5.4 Options considered

3.5.4.1 GTIN

It is possible to allocate GTINs to every product pack (base unit of trade) and unit of use, and to use them for tracking purposes.

If this is made mandatory then it will impose an additional cost on some importers and distributors. Not only will they have to allocate GTINs for products that do not already have them, but also they will have to obtain a GS1 company prefix (you must own a company prefix if you are to allocate a GTIN).

If this is not made mandatory, then there will always be product packs and units of use that do not have GTINs. Facilities that track medicines (e.g. hospitals, repacking facilities) will need to be able to allocate GTINs in these cases. This means they will need to obtain their own GS1 company prefixes.

- Pros
  - This is the system being adopted in Australia and the UK;
  - Consistency and simplicity of always using the GTIN for tracking.
- Cons
  - Hospitals and pharmacists need to have GS1 Company Prefixes to use when they label 'in-house' or extemporaneous products, or products that do not already have a GTIN allocated;
  - Products from different repacking facilities may have different GTINs – the medicine packs will not necessarily be interchangeable without relabeling;
  - The NZMT has to include the GTIN(s) of each product, or map to them.

3.5.4.2 SCTID

It is possible to use the SCTID from the NZ medicines terminology for tracking. This involves barcoding the SCTID in a GS1-128 barcode. This barcode would have to be added to all medicine packs coming into NZ (it is not used overseas).

- Pros
  - Consistency and simplicity of always using the SCTID for tracking;
  - Every medicine will already have an SCTID, or there will be a process for getting one allocated quickly by a central authority.
- Cons
  - Many packs will already carry GTINs for supply chain management, so the NZMT ID will occupy extra barcode real estate on the pack;
  - Adding the NZMT barcodes will be an additional cost to importers/distributors and may act as a disincentive to bring a product to the NZ market;
  - Unapproved medicines imported under section 29 of the Medicines Act will not have NZ packaging, so would have to have barcodes added on stickers.

3.5.4.3 GTIN if present, otherwise SCTID

This allows use of existing GTINs, but avoids the need to allocate a GTIN for items that do not have one. In that case the SCTID will be used for tracking.

- Pros
  - Products that already have a valid GTIN barcode on them will not need an additional barcode;
  - Likely to lead to a better overall rate of barcoding because no action needs to be taken for products that are imported with valid barcodes on them;

- Anyone can add the correct barcode (SCTID) to a medicine without the need to own a GS1 company prefix;
- Barcodes added by different repacking facilities will always be identical – the medicine packs will remain interchangeable;
- Choice of SCTID or the more common and compact GTIN when barcoding for point of sale (e.g. supermarkets).

- Cons
  - More complex because barcode scanners will have to be able to process both GTIN and SCTID barcodes;
  - The NZMT has to include the GTIN(s) of each product that has one, or map to them.

3.5.4.4 Barcoding of higher logistical units

SNOMED CT and the AMT do not capture higher logistical units so they cannot provide identifiers for them.

GS1 standards do provide for higher logistical units. Each unit can be given its own GTIN, either by increasing the logistical indicator digit by one (leaving the rest of the GTIN the same as the product in the container) or by allocating a completely new GTIN for the new logistical unit. Alternatively, each unit can be given a Serial Shipping Container Code (SSCC). When an SSCC is used the GTIN of the contents is also used, and this enables "direct read" of the contents. Even when an SSCC is not used, the GTIN of the contents can be used instead of the GTIN of the unit by using the appropriate Application Identifier (AI). This also enables "direct read" and reduces the need to allocate GTINs for every packaging configuration.

The philosophy of GS1 when it comes to interpreting identifiers on higher logistical units has been that the supplier should communicate information about the details of the transport unit (the information associated with the GTINs of the units) to the customer prior to, or at the time of despatch. This is changing as GS1 introduces the Global Data Synchronisation Network (GDSN), which provides a centralised way to communicate that information.

The Australian NPC is a centralised database of information associated with GTINs, and this means that suppliers in Australia no longer need to communicate information about GTINs directly to the customer. It is sufficient to keep the NPC up to date.

The appropriate use of "direct read" logistical unit identifiers can enable most of the information about logistical units to be expressed in terms of the Base Unit of Trade. Provided the customer has access to the information about the BUT (from the NZMT) they can interpret the contents of any higher logistical unit without need to refer to the GDSN, refer to another database such as the NPC, or to receive the information direct from the supplier.

4 RECOMMENDED APPROACH

4.1 Recommendations

The recommended approach outlined below will:

- Help to address the current problems identified in this report
- Support the Health Information Strategy for NZ
- Have a realistic likelihood of uptake across the health and disability sector in NZ

The table below summarises the recommended options for each of the topics considered in the report:

Topic	Recommended
Design of the terminology	Adopt and adapt the AMT
Terminology Infrastructure	Establish our own infrastructure
Editorial Software	Consider the use of domestically made editorial software to manage the data as a conventional relational database
Terminology Content	Legacy Principles • Retain Pharmacodes and full backward compatibility to legacy systems
	Localisation of the data • Fully localised data as an interim solution, leading to full integration with the international SNOMED CT system
	Pharmacological grouping system • Adopt SNOMED CT when revision of medicines hierarchy is complete. It is possible that the NZMT will move ahead before the new SNOMED CT system is available. In that case, we recommend an interim option be used until the new SNOMED CT system becomes available. Four possible interim options have been identified: - WHO ATC codes - Australian Medicines Handbook (AMH) groupings - MIMS classes - BNF chapter heading groupings The choice of an interim solution should be addressed during the establishment phase of the NZMT.
	Editorial Rules • Use the AMT editorial rules, with appropriate changes from Australia to NZ
	Tracking System • Identification Number o Global Trade Identification Number (GTIN) if present, otherwise SNOMED CT Identifier (SCTID) • Symbology o The mechanism for representing tracking numbers (the barcode, data matrix, RFID tag, etc) on physical packaging or paper prescriptions should conform to GS1 standards

4.1.1 Tracking system – specific recommendations

Recommendation for identification numbering and on-pack symbology for the Base Unit of Trade (BUT)

It is recommended:

1. The concept of *BUT* is considered equivalent to the concept of *CTPP*. They are synonyms;
2. The CTTP for every medicinal product should have on-pack symbology, specifically a barcode and additionally a data matrix if the manufacturer is willing to do so (for future proofing purposes)
3. The barcode (and data matrix where used) should contain at least one of the SCTID of the CTPP, or the GTIN of the CTPP;
4. Where a new barcode (and data matrix where used) is being added, preference should be given to using the SCTID, except where space or technological issues require otherwise;
5. Where the barcode (and data matrix where used) uses a GTIN, the GTIN should be notified to the NZMT team, and included in the NZMT as an equivalent to the CTPP;
6. GTINs can be either 13 or 14 digits long;
7. An Application Identifier for an SCTID should be sought from GS1 (as an international AI for a SNOMED CT identifier).

Recommendation for identification numbering and on-pack symbology for the lower logistical units

It is recommended:

1. Where practicable, for sub-packs and unit of use products (UUs) to be barcoded additionally a data matrix if the manufacturer is wiling to do so;
2. The barcode (and data matrix where used) should contain at least one of the SCTID of the TPPSubpack/TPUU or the GTIN of the TPPSubpack/TPUU;
3. Where a new barcode (and data matrix where used) is being added, preference should be given to using the SCTID, except where space or technological issues require otherwise. Note that a repacking facility should not allocate GTINs to units that do not already have them – the SCTID should be used in these cases;
4. Where the barcode (and data matrix where used) uses a GTIN, the GTIN should be notified to the NZMT team, and included in the NZMT as an equivalent to the appropriate TPPSubpack or TPUU;
5. GTINs can be either 13 or 14 digits long;
6. An Application Identifier for an SCTID should be sought from GS1 (as an international AI for a SNOMED CT identifier).

Recommendation for identification numbering and on-pack symbology for the higher logistical units

The on-pack symbology for higher logistical units is out of the scope of any regulatory scheme for barcodes. Nevertheless, higher logistical units should use identifiers that allow “direct read” of the contained Base Unit of Trade identifier and quantity. Additional supply chain data may still need to be communicated directly from the supplier to the customer, but in the absence of that communication, “direct read” should still allow the contents of the logistical unit to be identified.

Note: Although GS1 standards include “direct read” of quantities some further standards development may be necessary in this area. Under GS1 the “direct read” is usually the immediate contents of the unit (e.g. “direct read” of a pallet would tell you how many cartons it contains, but not how many packets in those cartons). A full implementation of the “direct read” system would enable you to find quantities expressed in Base Units of Trade on every higher logistical unit.

5 RISKS / ISSUES AND DEPENDENCIES

5.1 Key risks / issues

5.1.1 Adoption and adaptation of the AMT

The key risks related to adoption and adaptation of the AMT are:

- That the AMT structure will not be compatible with, or will need to be significantly altered to conform to the SNOMED CT international release;
- That changes are made to the AMT structure without consulting NZ (this is in part to do with whether we put our content into their database or share their database / content and partly to do with how aligned we need to be at the local extension level);

  Discussion

  The most extreme situation would be one where the NZMT is developed and goes into use, while both the AMT and the SNOMED CT core undergo radical evolutionary change to the core concepts making them incompatible with the NZMT. This would leave NZ with a self-contained, fully functional, but unique medicines terminology. It would still function as an extension to the international SNOMED CT core, but one that joined the core at a non-standard point. This is a worst-case scenario, and would leave us in a very similar situation to the UK where the dm+d is a unique system found in no other country, yet it is an extension to SNOMED CT.

- That there are changes to Trans-Tasman relations or other intellectual property issues arise with the use of SNOMED CT and NEHTA systems;
- That NZ content is not suitable for initial populating of the medicines terminology database, or that this process takes longer than anticipated;

  Discussion

  Preliminary research and prototyping have demonstrated that NZ content is available and suitable for populating the database. It is recognised that this process depends on text recognition, and therefore all data will require verification and checking by editors. It could possibly take an expert team of clinical and technical people about six months to create a functional terminology and associated management and distribution system, but with some non-critical fields not fully populated. Some data can come directly from the AMT. It should be noted that an estimated 20–30% of the trade product data has any overlap with NZ.

- That there is a lack of support for a medicines terminology or at least what we are recommending. We could spend a long time developing a NZ medicines terminology and there could be little or no up-take;
- That there is an expectation that this will be a quick and cheap process because the AMT is in place and suitable for adoption and adaptation. Whilst establishing a functional terminology and associated management and distribution is estimated to take about six months, getting the terminology integrated into the various systems used in the sector will take some time and should not be underestimated. There will be parties that wish to use the terminology in its standalone (unintegrated) form and it will be important from a clinical safety perspective that the NZMT is fully maintained while the integration efforts are underway.
- That this does not work as expected and we may identify issues during implementation because we have not seen it in action. We strongly recommend a limited pilot as proof of concept to ensure that all issues can be teased out;
- That IHTSDO or NEHTA fail.

5.1.2 Implementation in NZ

The key risks identified that are related to implementation in NZ are:

- The usual project risks related to establishing the NZMT (e.g. scope creep / management, expectation management, issues identified during implementation that could not be foreseen, etc) and acceptance and uptake by the sector (vendors, end-users, current content providers) including transition between legacy and new;

- That implementation of the NZMT takes too long and other more immediate steps are taken in the sector to resolve local requirements;
- That the vendor user interfaces and functionality will be of variable quality so that the follow-on benefits will not be fully achieved.

5.2 Key dependencies

The key dependencies identified are:

- Establishment of resources with capacity and capability to produce a New Zealand National extension to SNOMED CT, and associate governance, processes, etc;
- An operational and governance framework that identifies respective roles and responsibilities as well as relationships with regard to the governance, use, maintenance and support of the medicines terminology;
- Sufficient ongoing operational funding and resources, including funding and resources available to users. An appropriate funding model is necessary to ensure uptake;
- Licensing/IP: SNOMED CT, Pharmacode, AMT licenses; obtaining SNOMED CT namespace identifiers; obtaining a GS1 Application Identifier for SCTIDs The required investment is justified;
- Continuing ongoing relationships with entities such as Pharmacy Guild, PHARMAC, MIMS, IT Vendors, Medsafe, NEHTA, Ministry of Health Sector Services, etc.

  Discussion

  Risks / issues and dependencies will be defined in more detail and addressed as part of the initial establishment phase of a NZ Medicines Terminology project. Standards development, project management, and training / education programmes all need to be of sufficient quality to ensure the success of this project.

5.3 Other AMT considerations

The committee recognises that the AMT represents a work-in-progress and that no AMT-based systems have yet gone live. This means that some development work will be necessary, both in preparing an AMT-based design for use (predictable issues), and bedding in the system (unpredictable issues).

Some areas that will require consideration are:

- Preferred term, deciding on rules that give a preferred term suited to NZ practice;
- Label terms and short terms, deciding on rules that give terms suited to NZ practice;
- Fine tuning of the dose forms;
- Identification of prescribing terms (suitability for splitting packs and suitability for generic prescribing);
- Editorial rules governing preferred terms where the basis of strength is different from the specific active ingredient;
- Fine tuning of salts of hydration in the substance table and in the preferred term;
- System for identifying the country in which an organisation is the sponsor;
- Resolving any questions about the self-referential medicinal products (where base/salt issues arise);
- Synonyms need to be identifiable as former BAN, rINN, USAN, etc;
- The AMT continues to evolve and it will be necessary to decide on a specific version to implement.

Of these areas, some are strictly technical, and some are best resolved in discussion with NEHTA. The following will need to be given careful consideration in order to ensure that the medicines terminology accurately reflects current practice in New Zealand:

- Dose forms

  Some different dose forms are clinically significant, such as tablet and modified release tablet, and some are not clinically significant, such as tablet and film-coated tablet. The AMT dose forms do not make any distinction between clinically significant differences and clinically insignificant differences, although work is underway in this area.

Any shortcomings in the list of dose forms used need to be identified before implementation, and will involve the study of use cases.

- Immediate release

  Traditionally some dose forms include the words “immediate release” to differentiate them from sustained release formulations. The AMT does not include any “immediate release” dose forms. It may be appropriate to have “immediate release” as a dose form, or as some other part of the preferred term.

- Prescribing terms

  Suitability for splitting packs and suitability for generic prescribing are not simply matters of fact, but matters of best practice. For this reason it may be appropriate that they are not included in the medicines terminology, however an awareness of both of these concepts is needed in defining how the terminology will be used in prescribing and dispensing systems. It is important to note that in Australia the dispensing unit is generally the original pack, whereas in NZ it is the individual tablet, ampoule or ml.

- Basis of strength is different from the specific active ingredient

  The prescriber and the pharmacist agree that “metoclopramide 10mg” means “metoclopramide hydrochloride monohydrate equivalent to 10 mg metoclopramide hydrochloride anhydrous”. The preferred term could be either of these, or something in between. It should represent the needs of New Zealand prescribers and pharmacists.

These need to be specifically considered as part of the initial establishment or implementation phases of a NZ Medicines Terminology project.

6 VENDOR IMPACTS

6.1 Initial vendor uptake

The initial uptake will involve new names and descriptions for the products only. This does not involve the uptake of new unique identifiers (the Pharmacode will be retained, and new products will continue to be given Pharmacodes), but it does result in a consistent text description being used. The use of a consistent text description helps avoid ambiguity and confusion arising from different use of abbreviations, salt and hydrated forms, dose forms, and synonyms.

6.1.1 Lots and Toniq

The new data can be distributed in a Pharmacode-compatible database format using existing distribution channels. While users will notice a change in the way some products are named and described, the initial uptake will otherwise be invisible to the vendor and the user.

6.1.2 MIMS, PHARMAC Schedule, and other medicines dictionaries

The new names and descriptions will need to be imported into the vendor-specific database. This process involves matching based on Pharmacodes. Vendors will need to develop algorithms to automate the import process. The extent to which the automated process is successful depends on the nature of the vendor-specific database, but using the Pharmacode should enable many products to be processed automatically. The PHARMAC Schedule closely maps to the Pharmacodes, so the process should be almost entirely automatic for this database. Once the new names and descriptions are imported into the vendor-specific database, the data can be distributed using existing systems. While users will notice a change in the way some products are named and described, the initial uptake should otherwise be invisible to the end user. Users will not need to upgrade their software.

6.1.3 GP (primary) and hospital (secondary) systems

Initial uptake involves new names and descriptions coming in from the underlying medicines dictionaries used and will depend on individual vendors and how they choose to implement the new terminology. In primary health, most systems are expected to acquire the new names and descriptions without the need for software enhancement. This process might not be so straightforward for hospital systems; for some of them the new names and descriptions might only become available as software enhancements are acquired or developed.

This needs to be examined further as part of the NZMT establishment project.

6.2 Vendor software enhancement

Software enhancement involves adding new functionality that draws on the richness and interoperability of the new terminology, while continuing to keep legacy data available and useable.

6.2.1 Prescribing

The new terminology will provide a set of prescribing terms that are powerful and flexible enough to express the therapeutic intent of the prescriber, yet standardised enough to make them unambiguous and computer interpretable. Prescribing modules that take advantage of the new terminology will have the following advantages:

1. Support for generic prescribing including one-click conversion of brand-name to generic prescription.
2. Helpful defaults that assist in prescribing appropriate quantities where products are dispensed OP (Original Pack).
3. Full integration to knowledge support and decision support facilities can put a full range of resources and guidelines at the prescriber's fingertips during the prescription-writing dialogue (search for the medicine only once to get access to all of the alerts and information for it).
4. Produce a computer interpretable prescription so that automated dispensing and administration verification can take place.
5. Utilise computer interpretable medicines information in referrals/discharges to speed the process of re-prescribing, regardless of who made the original prescription.

6.2.2 *Dispensing*

1. Automated dispensing verification can take place on receipt of a computer interpretable prescription.
2. Re-keying becomes unnecessary on receipt of a computer interpretable prescription, increasing efficiency and minimising transcription errors.
3. Full integration to knowledge support and decision support facilities can put a full range of resources and guidelines at the pharmacist's fingertips during the dispensing dialogue (no need for a separate search to get access to all of the alerts and information for the medicine being dispensed).
4. Produce a computer interpretable dispensing notification so that automated administration verification can take place.

6.2.3 *Repackaging and bedside verification*

1. Unique codes exist for every unit of use, facilitating barcoding when re-packaging.
2. Automated administration verification can take place on receipt of a computer interpretable prescription/dispensing notification.
3. Full integration to knowledge support and decision support facilities can put a full range of resources and guidelines at the administerer's fingertips on scanning the barcode on the package.

7 GOVERNANCE AND MANAGEMENT CONSIDERATIONS

7.1 Editorial Commitee

It is recommended that an Editorial Committee be established with responsibility for maintaining the Editorial Rules, and consulting with the sector when seeking to make changes to them. The Editorial Committee will need to be made up of clinical professionals.

The establishment of an Editorial Committee will need to be specifically considered as part of the initial establishment or implementation phases of a NZ Medicines Terminology project.

7.2 Submission and Governance of new medicines information

It is envisaged that new NZMT data will come from:

- Medsafe when new products are registered (most new data will come this way)
- PHARMAC e.g. request an amendment
- Health care professionals requesting additions, amendments, and deletions
- Pharmaceutical companies advising of new products or changes to existing products
- Horizon scanning by editorial committee members
- Possibly from prescription data (anonymous copies of all free text ePrescriptions could be forwarded to the editorial committee, alerting them of the need to add to the terminology)

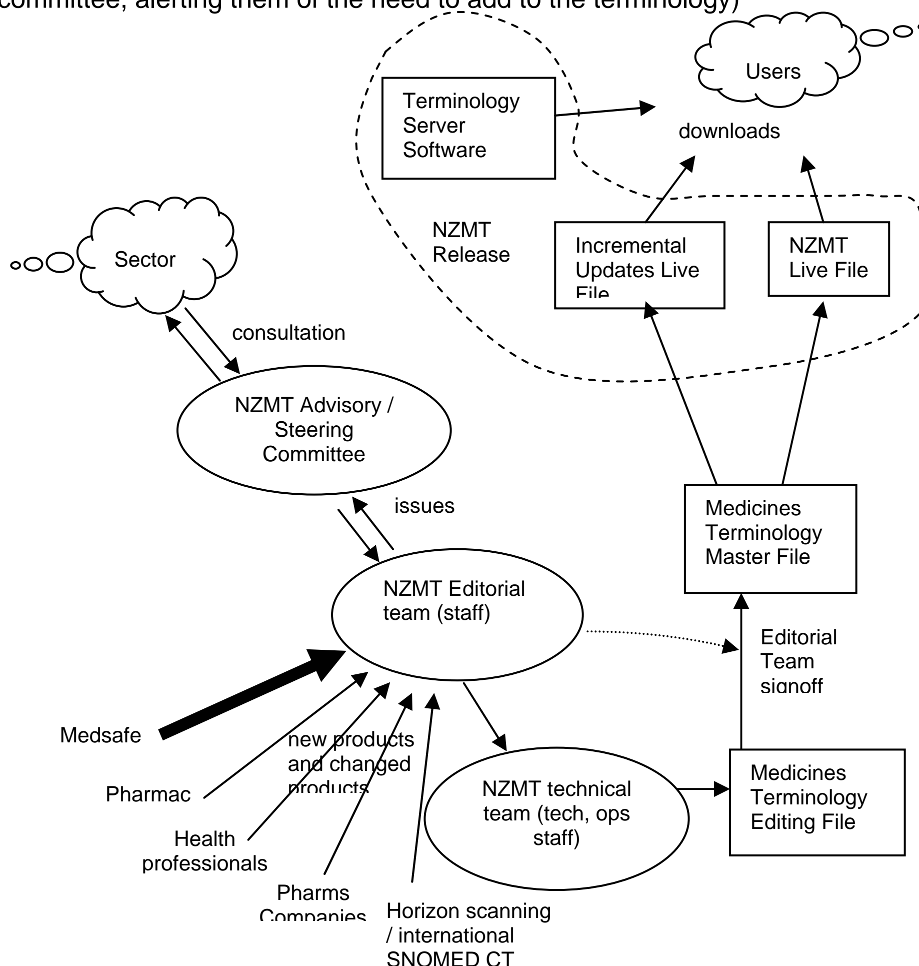


Figure 2: Key Governance and Management Relationships

8 ESTABLISHMENT ROADMAP

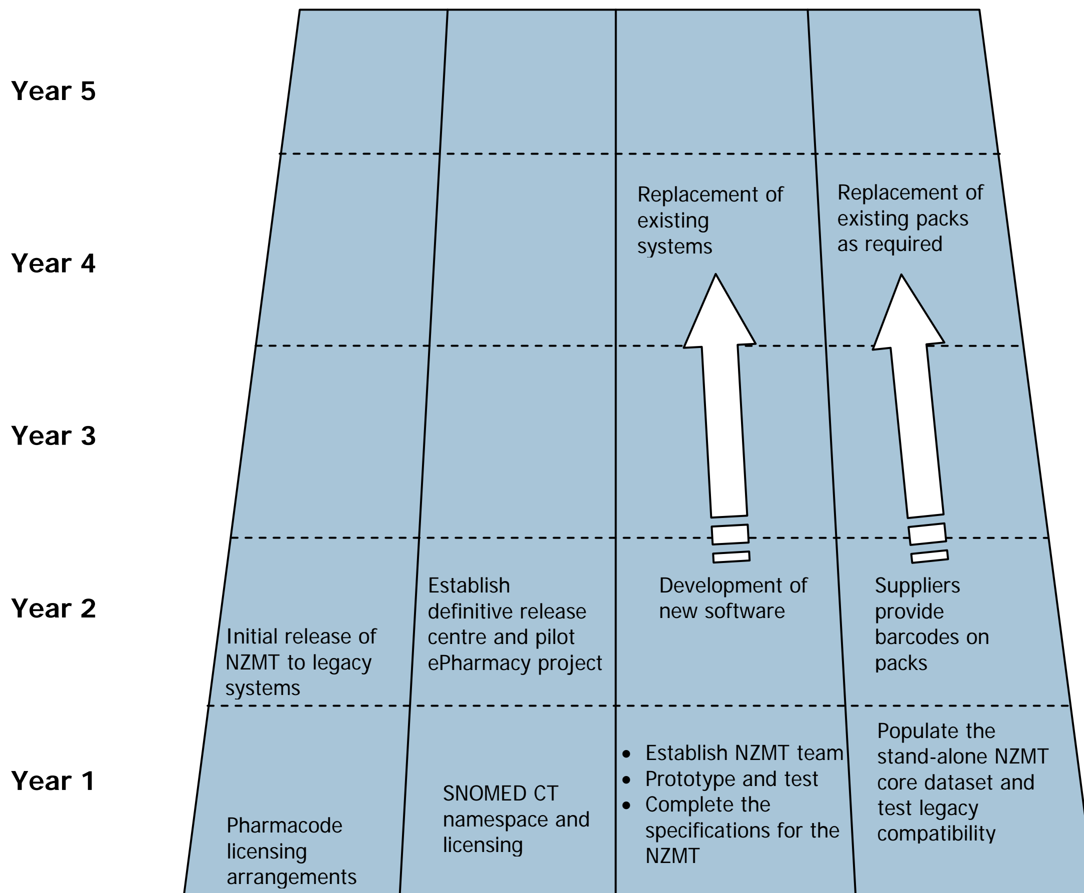


Figure 3: Establishment Roadmap

The following establishment stages have been identified:

1. Decision to proceed and funding approved.
2. Reach an arrangement with the Pharmacy Guild of NZ to allow the Pharmacode licensing arrangements to be changed in an appropriate way to support the NZMT.
3. Complete arrangements with IHTSDO to allow NZ to create national releases of SNOMED CT, including obtaining the necessary namespace identifiers to support the NZMT as a SNOMED CT extension. (Note that it is also recommended that GS1 be approached with a view to allocating an application identifier to be used when barcoding a SCTID).
4. Establish management of Pharmacodes and NZMT, making any necessary changes to existing management systems.
5. Complete the specifications for the NZMT. This involves prototyping and testing the terminology, as well as resolving the following issues:
   - Investigate Australian tools in more detail, including consultation with their software developers;
   - Select an interim solution for pharmacological grouping: recommended options are WHO ATC codes, Australian Medicines Handbook groupings, MIMS classes and BNF chapter heading groupings;
   - Address AMT issues identified in section 5.3.
6. Populate the stand-alone NZMT core dataset.

   Data will be sourced from existing databases, and every concept will be assigned a SCTID from the NZ namespace. Pharmacodes will be preserved as part of the NZMT.

The process will involve checking the accuracy and clinical safety of the new data using both traditional proofreading techniques and clinical pharmacists checking the data. This will bring the data to a state in which it will be ready for release in all three formats: legacy Pharmacode database format, NZMT relational database format, and NZMT SNOMED CT format. The legacy Pharmacode database format will be identical to the existing Pharmacode database, the only change being that the text names and descriptions will conform to the new editorial rules of the NZMT.

It is critical that the compatibility of the data with legacy systems be thoroughly tested.

7. Initial release of NZMT.

   The legacy Pharmacode database format will be released through the same channels as the existing Pharmacode database. This will enable software that uses the Pharmacode database directly (e.g. Toniq, Lots) to pick up the new text descriptions immediately. For example when the pharmacist currently sees "FLUOXETINE HYDROCHLORIDE 20mg tabs" they will see something like "fluoxetine (as hydrochloride) 20mg tablets" or "fluoxetine 20mg tablets", or whatever is arrived at after consultation with users. The change is subtle and represents the fact that a consistent, and new, set of editorial rules has been applied to the same data. The Pharmacodes would remain unchanged, and new products would continue to be allocated Pharmacodes according to the existing allocation process.

   Other databases such as MIMS and the PHARMAC Schedule will be able to pick up the new text descriptions using the Pharmacode as link. Once this is done, they will be able to make their own releases utilising the new text descriptions.

8. Establish release centre.

   A central NZMT release centre will be established from which the full NZMT (all three formats) will be available for download. It is also considered appropriate for there to be a terminology server provided as part of the release, to facilitate uptake of the new system (a terminology server reduces the development time needed for new software that uses the terminology, and facilitates localisation of the terminology data so that systems are not dependent on network or Internet connectivity).

   A pilot ePharmacy project will be established to test the new features of the terminology.

9. Development of new software.

   Existing health software systems will need enhancement to utilise the new terminology.

   Core standards for prescription-writing and dispensing software modules could be established.

   Possible enhancements include:

   - Storing and transmission of patient medication history using the new terminology;
   - Supporting electronic transmission of prescription item via printed barcode on script or electronic message.

10. Pack level GTINs (supply chain barcode) introduced progressively. This will require medicine sponsors to register their GTIN as part of the registration process. As GTINs become available, they will be added to the NZMT database.

11. As international SNOMED CT codes become available for substances, dose forms, medicinal products, trade products, etc, these will supersede the NZ namespace codes. This will not affect the Pharmacode which will continue to be associated on a one-to-one basis with the product pack (all CTPP records will have NZ namespace identification to support this), but will potentially affect all other concepts in the NZMT.

Uptake rates

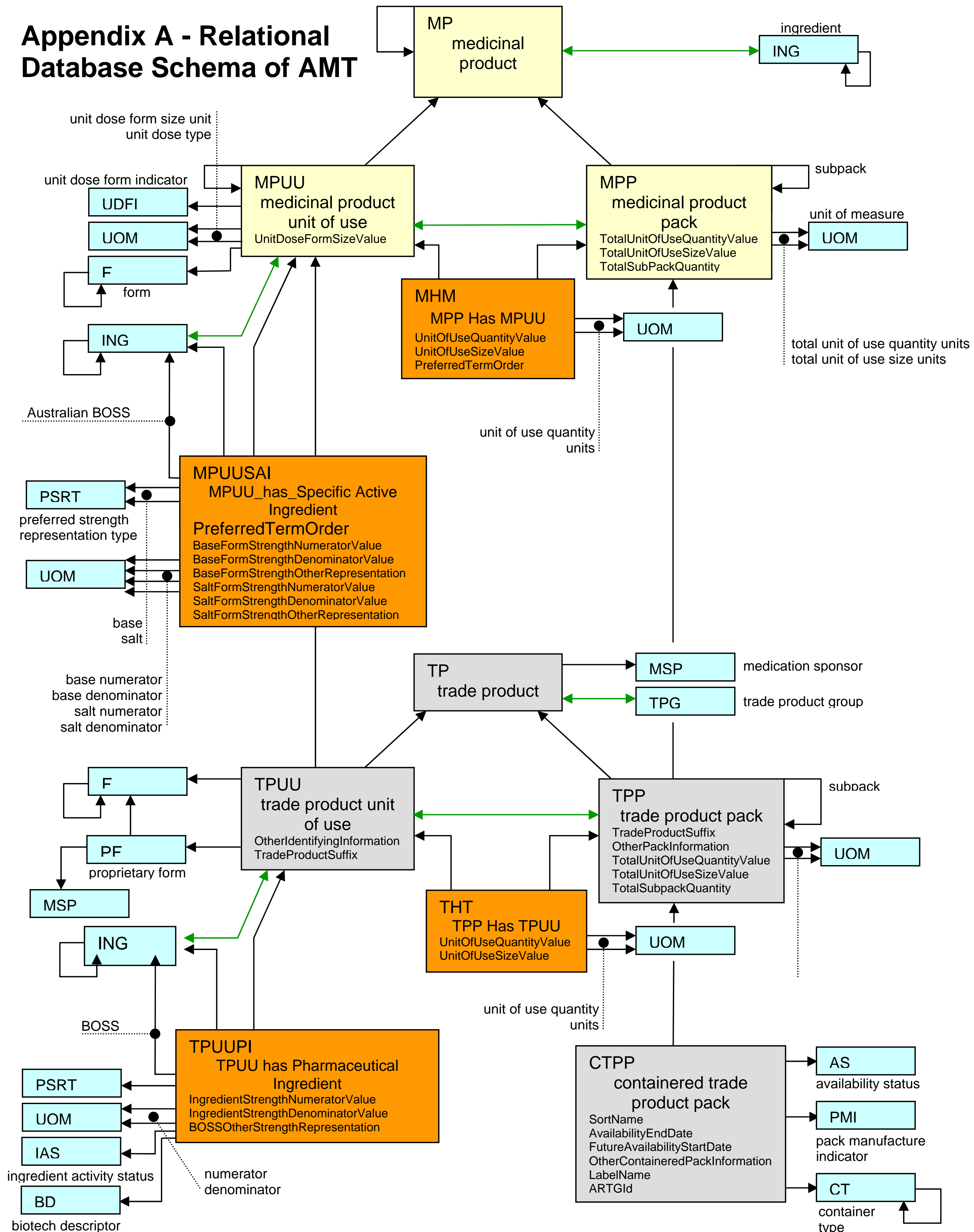
Given that the vendors will play an important role in the uptake of the terminology it is important that they are actively engaged in the implementation project. It is anticipated that user demand once a standalone terminology is released will provide considerable incentive for the vendors to incorporate it in the systems.

We anticipate considerable uptake by Year 4.

Timings

The establishment roadmap is based on the assumption that the project is adequately funded and resourced.

Appendix A - Relational Database Schema of AMT



Appendix B – Summary of barcoding in other countries

Barcoding in the USA

The US FDA allocates National Drug Code (NDC) numbers to all medicinal products. The NDC numbers are 10 digit identifiers. The FDA distributes the data in freely available text files.[6]

The NDC numbers are therefore similar to Pharmacodes. The main differences are:

1. Each NDC number consists of three parts: an FDA-allocated supplier number combined with two supplier-allocated product numbers. The FDA is therefore not fully in control of the NDC numbers.
2. The NDC numbers are not subject to a licence and are freely available for download from the Internet.
3. Although information on active ingredients is included in the NDC data, it is not structured to support generic substitution.[7]

In the US it is mandatory for manufacturers and suppliers to print the NDC number on the product pack as a barcode. This is in addition to any other barcode that might also be on the pack. This has been the case since April 26, 2004.[8] It applies to most prescription drugs and OTC drugs commonly used *in hospitals* (not all OTC drugs).

The barcode must be on the drug's immediate container, as well as the outside container or wrapper. The NDC number is usually applied to the "trade package" or "stock keeping unit".

The FDA rule does not apply to all packing. The FDA claims that "no hospital would dispense a drug directly from a shipping container to a patient … [so barcoding all packing] would not be helpful insofar as medication errors are concerned." [9] With regards to barcoding the unit of use, the FDA does not *require* this because it is not practicable in all cases.

The barcode must be a linear barcode that meets either EAN.UCC or HIBCC (Health Industry Business Communication Council) standards.[10] Because the NDC has been in existence since 1969 [11], the NDC has been barcoded for over 30 years and has been around long enough to influence the development of the GS1 system. Accordingly, an NDC can be identified in a barcode by the prefix "3" or "03" depending on the GS1 data symbology chosen, and the FDA labeller code can usually be aligned with the GS1 company prefix. This means that it becomes very simple to express the NDC number as a GTIN, and there is no particular need in most cases to assign any other GTIN to the product.

NDC numbers are the standard way of verifying dispensing and administration of drugs in the US.[12] Example systems are Meditech[13] and RxScan.[14]

Barcoding the unit of use

When applying a barcode to the unit of use, some pharmaceutical labellers create a different NDC number for the unit of use (using the fact that the last one or two digits of the NDC represent the "trade package size") and some create a different 14-digit GTIN (using the fact that the first digit of a 14-digit GTIN is a logistics indicator). The first option keeps the barcode down to 12 digits, which especially suits retail sales, and the second requires, obviously, 14 digits.

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6 "The National Drug Code Directory," http://www.fda.gov/cder/ndc/

7 For example, managing generic substitution is something that the end user has to set up themselves under the Meditech system, as explained in the following quote: "Alternate NDC numbers can also be set up in the dictionary to link drugs that are equal in every way except for manufacturer. Both primary and alternate NDC numbers are recognized by the system to match bar code information with the medication associated with prescriptions on the patient profile." - "MEDITECH - Bedside Medication Verification," http://www.meditech.com/productbriefs/pages/ProductBriefsCSBMV.htm

8 "FR Doc 04-4249," http://www.fda.gov/OHRMS/DOCKETS/98fr/04-4249.htm

9 Ibid.

10 Ibid.

11 HDMA, "HDMA Guidelines for Bar Coding in the Pharmaceutical Products Supply Chain," December 2005, page 6, http://www.gs1.org/sectors/healthcare/members/general/downloads/HDMA_Guidelines.pdf.

12 HDMA, "FDA's Bar Code Label Requirements for Human Drug Products; General Questions Related to Drugs and Biologics," http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/080102/02N-0204_emc-000026-02.doc

13 "MEDITECH - Bedside Medication Verification."

14 "RxScan - RxScan," http://rxscan.com/rx.shtml

Both of these systems have drawbacks when combination packs are encountered, however, in practice this is not necessarily a limitation: bedside administration generally takes place in hospitals, and hospitals do not generally use combination packs. Therefore, there may be little or no need to barcode individual units of use from combination packs.

When units of use from combination packs are barcoded by a labeller who has a FDA labeller code, it would be expected that the labeller would issue each unit of use with a new, unique, NDC code. The NDC code would *not* have the same product identification portion (middle portion) as the kit (the combination pack is considered to be a kit). Difficulties would arise for labellers who do not have a FDA labeller code (e.g. hospitals). The solution to those difficulties would appear to be vendor-specific because the standards are silent about how to deal with them.

"Direct read" quantities

When applying a barcode to packing levels above the "trade package" (e.g. carton, pallet, shipping container) a different 14-digit GTIN can be created using the fact that the leading digit is a logistics indicator. The 14-digit GTIN can be encoded in a GS1-128 barcode that can include batch number and expiry date, as well as quantity.

The HDMA recommends that pack levels above the "trade package" are barcoded with both a GTIN and a quantity. This is known as a "direct read quantity," and avoids the need for suppliers to communicate the pack quantity separately (via electronic communication or database distribution).[15]

Technical note:

1. For arcane reasons the 10-digit NDC number is sometimes converted to an 11-digit format for storage in a database. However, the FDA rule does not permit the 11-digit format to be used on the barcode.
2. The 10 digits, plus the leading digit "3", and the check digit, mean that the minimum size of barcode symbology is a 12-digit format. This means that the 12-digit UPC format, the EAN-13 and EAN-14 formats, as well as GS1-128 can all be used to represent the NDC number.

Barcoding in the UK

In the UK the Department of Health recommends that all manufacturers of medicines and devices provide a Global Trade Item Number (GTIN) on products, and is committed to adding these GTINs to the dm+d database. The department also recommends that hospitals have their own GS1 Company Prefixes so that they can allocate their own GTINs for extemporaneous preparations (they also recommend the use of the GS1 system for patient identification). [16]

The GTINs are not currently present in the dm+d, so for the meantime there is no national database from which product codes can be obtained. This means that every time a new product is purchased, the details of the code and the product have to be entered manually into the pharmacy computer system,[17] obtained from a third party database, or received in an electronic message. It would appear that manual entry is common.

Bedside verification is not well advanced in the UK. According to the Department of Health (16 February 2007): "To date, we are only aware of one bedside verification system for medication in the UK […] Charing Cross Hospital." [18]

Barcoding the unit of use

In *Recommendations and Guidelines for product coding within the UK Pharmaceutical Supply Chain*[19] only a pack level identifier is mentioned (page 10), while the option of a unit of use identifier is left for "consideration" (page 11). In *Voluntary Application Guidelines; Good Draft Status For the harmonisation of identification, labelling and eMessaging standards within the European Pharmaceutical Industry*[20] (page 20) single unit dose labelling is

15 HDMA, "HDMA Guidelines for Bar Coding in the Pharmaceutical Products Supply Chain," page 55

16 Helen Lovell, "The Department of Health and Coding For Success In England," http://www.ihf-fih.org/pdf/43-5%20lovell.pdf.

17 "Coding for Success: Simple technology for safer patient care : Department of Health - Publications,"

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_066082.

18 Ibid.

19 "Product_Coding_In_UK_Pharmaceutical_Supply_Chain.pdf (application/pdf Object),"

http://www.gs1.org/sectors/healthcare/members/general/downloads/Product_Coding_In_UK_Pharmaceutical_Supply_Chain.pdf

20 "EHI_Draft_Guidelines.pdf (application/pdf Object)."

described using the logistics indicator of “0” in a GS1-14 GTIN. Combination packs would require each unit of use to have a separate GTIN, not just a logistics indicator of “0”.

“Direct read” quantities

The issues will be the same as for the US (see above).

Barcoding in Australia

Australia is implementing a GTIN-based system for barcoding medicines. The Australian National Product Catalogue (NPC) is under development, and is intended to be a database of GTINs for all medical products in Australia. The NPC is hosted by GS1 Australia on GS1net™ [21] It stores a 13-digit GTIN for each product (”trade package”) and a 14-digit GTIN for higher logistical levels using the logistical indicator.

Barcoding the unit of use

In the NPC, GTINs are allocated to products at the pack level, with no logistical indicator. [22] This would appear to allow the possibility that a unit of use GTIN can be derived by appending a “zero” logistical indicator. There is a problem with this: there is nothing to stop a manufacturer using a different logistical indicator, e.g. “1”, for the Unit of Use. Furthermore, if an entirely different GTIN were to be allocated to the unit of use, there would appear to be no way to enter it into the NPC. This means that barcoding of the unit of use must use either the *pack* GTIN (possibly with “0” logistical indicator digit), or the SCTID for the unit of use (from the AMT). We are not sure which of these options is recommended for use in bedside verification in Australia.

We have been unable to discover any examples of bedside verification systems for medication currently in use in Australia.

“Direct read” quantities

Direct read quantities are theoretically not needed in Australia because the NPC will contain all of the required quantity data for every GTIN.

Barcoding in Canada

Canada is currently investigating options for eprescribing and electronic health records. At present, bedside verification and barcoding of medicines do not appear to be a priority in Canada.

Refer
http://www2.infoway-inforoute.ca/Documents/Infoway_Business_Plan_2008-2009_Eng.pdf

“Backgrounder_Electronic Health Projects.pdf (application/pdf Object),”
http://www.infoway-inforoute.ca/Admin/Upload/Dev/Document/Backgrounder_Electronic%20Health%20Projects.pdf

21 GS1, “Healthcare industry,” http://www.gs1institute.com.au/industry/healthcare/

22 “GDD Core Attribute Guide,” November 2007, http://www.gs1au.org/assets/documents/services/gs1net/datamodel_item/s_gs1net_attcore.pdf

Appendix C – Summary of worldwide GS1 use

According to a GS1 Europe task force (2006):

- In Ireland, the pharmaceutical industry (represented by manufacturers, wholesalers, logistics companies and pharmacists) have adopted the GS1 System and are working together on a country-wide implementation initiative
- In England, a similar initiative to that in Ireland (as above) is well underway. The adoption of the GS1 System is a key recommendation of an industry-wide report,‘ Underpinning Patient Safety’ published in Summer 2005
- In England, PaSA (Purchasing and Supply Agency) strongly recommends the use of the GS1 System for all products and services (pharmaceuticals, medical devices, food, services) procured for the NHS. Additionally, the NHS Connecting for Health (now part of the National Programme Framework for IT) has adopted the GS1 System within its strategic Dictionary of Medicines and Devices project
- The Netherlands Pharmaceutical Association is migrating to the GS1 System commencing 2008
- Today there are over 3000 user organisations of the GS1 System where ‘Health’ is their core market. The large majority of these operate in the pharmaceutical market
- Surveys show that approximately 90% (more in some Member States) of pharmaceutical products are already identified by the GS1 System at the consumer unit level in most European countries
- Throughout Europe, almost all electronic ordering (typically based on EDI techniques) between pharmacists and manufacturers, and wholesalers and manufacturers, use GS1 eCom based message standards
- In the USA, the FDA have recommended the adoption of the GS1 System for the labelling of most medicines and biologics at the point of use
- In the USA, the HDMA (Healthcare Distribution Management Association) base its recommendations for barcoding on the GS1 System of barcodes
- In Japan, the use of the GS1 System is mandatory for all medical devices as well as pharmaceuticals
- In Australia, the NSW Health Board has strongly recommended the use of the GS1 System for pharmaceutical procurement [23]

23 “EHI_Draft_Guidelines.pdf (application/pdf Object),” pages 11-12, http://www.gs1.org/sectors/healthcare/members/general/downloads/EHI_Draft_Guidelines.pdf

Appendix D – Use Cases

A series of high-level use-cases have been developed as a means of providing a range of perspectives on the practical use of a Medicines Terminology. They will be further developed as part of the Medicines Terminology implementation project to inform systems and process design as well as to establishment measures against which the success of the project and the terminology itself can be assessed.

Note: 'Current practice' is indicative only and may differ from area to area.

COMMUNITY

Prescribe

Process

The writing of prescriptions in a community setting. The prescriber assesses the patient and takes into account any allergies, adverse effects, interactions and other factors before deciding on a medicine to prescribe. In some cases computer assisted decision support is provided during the consultation.

The prescriber selects a medicine, dose form, strength, and amount, adds instructions to the patient, decides period of supply and produces a prescription. In some cases computer assisted decision support is provided during the prescribing process, usually in the form of alerts for potential drug interactions, duplications, etc. Usually the prescription is given to the patient, but in some cases is communicated by phone or fax to the pharmacy.

Community Prescribing Scenario

Dr Wilson has decided to prescribe nifedipine extended release 30mg tablets to be taken once daily in the morning for Mrs Jones.

Current practice

Dr Wilson types "nif" and selects "nifedipine 30mg tablet: slow release" from the list. This text is printed as part of the prescription, which the doctor signs and gives to the patient.

Future practice using NZMT

Dr Wilson types "nif" and selects "nifedipine 30mg tablet: slow release" from the list. For a straightforward prescription like this the doctor will experience exactly the same steps, but the medicine selected will have a computer interpretable code associated with it. This will enable electronic transmission of the prescription, as well as electronic transmission of the patient's medication history at some future date.

A medicines terminology will enable some enhancement of the prescribing process for the doctor, enabling on-demand conversion of a brand name to a generic prescription and more intuitive browsing of medicines by generic names.

A medicines terminology will also make it possible for computer assisted decision support during the prescribing process to check the patient's medication history and current conditions for interactions, duplications, appropriateness of dose, etc.

Requirements to enable a NZMT

1. Each product must have a generic name associated with it. Both brand and generic names need to have strength and dose form.
2. It must be possible for the prescriber to navigate a hierarchy of generic products and pharmacological classifications, and that hierarchy must be appropriate to the needs of the prescriber.
3. A description of dosage, including dosage quantity, route, frequency of administration and period of treatment.

4. It must be possible for a “pick list” of prescribing terms [24] to be derived from the medicines terminology that is appropriate to community prescribing.

AMT requirements fulfilment

Core concepts: TPP, TPUU, TP, MPP, MPUU, MP

Prescribing terms can be provided as a *navigation subset*.

Note: The AMT does not provide concepts that fully define a prescription. Specifically, a medicines terminology must be supplemented with standardised ways of expressing route, frequency of administration, and period of treatment.

Dispense

Process

The supply of medicines by a community pharmacy. The key steps are

- Ensuring the completeness of the information on the prescription e.g. patient details, legibility, legal and subsidy requirements, or, in the case of supply without a prescription ensuring that the legal requirements of the supply are being met (e.g. Pharmacist Only Medicine requires recording of details).
- Verification of the appropriateness of the prescribed item using any relevant information eg suitability of the prescribed item, dosage, possible interactions
- Checking acquired patient records for possible interactions, consistency of treatment and evidence of non-adherence or misuse.
- Providing advice and counselling to the patient
- Giving the prescription items to the patient
- Reordering new supplies from the supplier
- Submitting the prescription to the DHB’s payment agent, Ministry of Health Sector Support for reimbursement. A national database of pharmaceuticals claimed is kept for planning and funding decisions in a pharmaceutical data warehouse.

Community Dispensing Scenario

Mrs Jones has been given a written prescription for “nifedipine 30mg tablet: slow release dose I daily, 3 months supply”.

Current Practice

Mrs Jones presents the prescription to a pharmacist. The pharmacist re-enters the information on the prescription as part of the transaction record of the pharmacy’s own information system. The pharmacist can see that there are three possible brands that could be dispensed: Adalat Oros, Adefin XL, and Arrow-Nifedipine XR. She can also see that Adalat is only partially funded, while the other two brands are fully funded.

The pharmacist then follows the key steps outlined above, resulting in the patient being given the medicine, new supplies being ordered if necessary, and a reimbursement claim being prepared for submission. During this process the pharmacist may consult other references such as MIMS to check details of indications, interactions, classification, use in sport, and so on.

Future practice with a medicines terminology

A medicines terminology will enable:

- Electronic transmission of the prescription (or bar-coding of prescription items on a printed prescription) will enable the information to enter the pharmacy’s information system without re-keying. The pharmacist can immediately see that there are three possible brands that could be dispensed: Adalat Oros, Adefin XL, and

[24] Prescribing terms define the active ingredients, form, and strength of a medicine. They can be generic e.g. “paracetamol tablets 500mg” or use a brand name e.g. “Panadol tablets 500mg”.

Arrow-Nifedipine XR. She can also see that Adalat is only partially funded, while the other two brands are fully funded.

- Prescribing, dispensing and other information-sharing will be based on an in-built standard medicines terminology and standard schedule that is updated monthly. This will simplify access to additional resources eliminating the need for text-based searches.
- Pharmacists will be able to access a complete electronic pharmaceutical history that relates to individual patients, as appropriate and within agreed privacy rules.
- It will be possible to send an electronic confirmation to the prescriber that the prescription has been dispensed and the patient received the medicine.
- It will be possible to support real-time claiming of reimbursements without requiring further action from the pharmacist.
- A medicines terminology will also make it possible for computer assisted decision support during the dispensing process to check the patient's medication history for interactions, duplications, etc.

Requirements to enable a NZMT

1. A description of a medicine, at various levels of abstraction (generic and brand) allowing accurate selection of product.
2. All trade products must be related to the appropriate generic name.
3. A description of unit of use, subpack, outer pack, the active ingredients, strength and dose form: using both generic and trade names and must include the product at the level used for reimbursement.
4. It must be possible for a prescribing term to be matched to a list of products that can be dispensed.

AMT requirement fulfilment

Core concepts: CTPP, TPP, TPUU, MPP, MPUU

Note: the AMT does not provide concepts that fully define a prescription. Specifically, a medicines terminology must be supplemented with standardised ways of expressing route, frequency of administration, period of treatment, and instructions to the patient.

HOSPITAL

Prescribe

Process

Prescription of a medicine for an individual patient in a secondary care setting. In Secondary Care, a medicines chart is kept for all patients currently admitted to the hospital. Authorised prescribers are able to add (prescribe), change, or remove (stop) medications on this chart for patients under their care. This is an authorisation/instruction for a pharmacist to make a supply of the medicine to the patient, so that the person caring for the patient may administer the medicine according to the prescriber's instructions. In the future, this information will be recorded in an electronic prescribing system rather than a paper based medicines chart.

Almost any medicinal product may be prescribed, including Controlled Drugs, Prescription Medicines, Restricted Medicines, Pharmacy Only Medicines and general sale medicines, whether they are approved for supply in New Zealand or supplied as unapproved medicines (e.g. under Section 29 or for a clinical trial). Sometimes products that are not medicines are also prescribed – e.g. TED (clot prevention) stockings after surgery.

The basic requirements that must be included are the date prescribed, the identity of the patient, the name, and dose of the Medicine (and form if relevant), the route, the frequency (and times of administration if relevant) and some form of authorisation (currently a signature).

Note: While there may be a duration of treatment (e.g. an oral antibiotic for 5 days), most orders are open-ended – i.e. they are valid until stopped.

Secondary Care Prescribing Scenario

Mrs Jones has just arrived at the Emergency Department of a large hospital in Auckland as she has had a bad cold for a week and is finding breathing more & more difficult. She is seen by one of the doctors (Dr Stevens) who diagnoses her as having pneumonia and decides to admit her for Intravenous antibiotics and rehydration.

On admission, Dr Stevens asks Mrs Jones what medicines she takes regularly at home. As she left home in rather a hurry, she has not brought the medicines with her. She thinks she takes three tablets each day; one is small, round and orange and she thinks it thins her blood. Another is 'Betaloc ninety-something' for her heart and 'Simva something' for her high cholesterol. She usually takes one of each of these at night before she goes to bed as it is the only time she can remember to take them.

Current Practice

Dr Stevens is working in a busy emergency department and it is already 10:00pm; Mrs Jones' regular GP and community pharmacy are long closed, and it is too late to get the lady's daughter to bring in the medicines from home. She decides the best course of action is to do her best with the medicines so she doesn't miss out on her night-time doses. She prescribes Betaloc 95mg and Simvastatin 20mg at night on the medication chart / electronic prescribing system and these are administered by the nurse. Dr Stevents also prescribes two antibiotics for Mrs Jones' pneumonia - Cefuroxime 750mg IV q8h and Roxithromycin 150mg BD – the first doses of these are also administered.

The following morning, a clinical pharmacist (Sarah) visits Mrs Jones and determines that she usually visits a community pharmacy in Devonport. Sarah phones the pharmacy and finds out that Mrs Jones has been collecting regular prescriptions for Metoprolol (Betaloc®) 95mg and Simvastatin (Lipex®) 40mg nocte for several years. In addition, she has also been taking Aspirin (Cartia®) 100mg (a small round, orange tablet that helps prevent clots as described by Mrs Jones), an Alendronate 70mg (Fosamax®) tablet once each week on Wednesday to strengthen her bones, and some Timolol 0.5% eye drops for her Glaucoma.

Sarah goes back to talk to Mrs Jones and confirms that the information she has obtained from the pharmacy is correct; she then documents these in Mrs Jones' notes and leaves a note for a doctor to correct the strength of the Simvastatin from 20mg to 40mg and add the Aspirin, Alendronate & Timolol to the medicine chart/electronic prescribing system when Mrs Jones is reviewed today.

Future practice with a medicines terminology

Dr Stevens has access to a repository of medicines that have been dispensed from community pharmacies throughout the region. (The medicines terminology will not by itself result in such a repository, but is an enabler.) Dr Stevens accesses the repository and sees that Mrs Jones has been regularly collecting Metoprolol 95mg tablets, Simvastatin 40mg tablets and Aspirin 100mg tablets with directions to take one at night. She also sees the Alendronate 70mg with directions to be taken once weekly and the Timolol eye drops. She confirms these with Mrs Jones and prescribes them on the medication chart along with the two antibiotics and these are administered by the nurse.

Dr Stevens enters the medicines she wants to prescribe directly into an electronic prescribing or order entry system. These are then transmitted to the pharmacy computer system electronically.

A medicines terminology will also make it possible for computer assisted decision support during the prescribing process to check the patient's medication history and current conditions for interactions, duplications, appropriateness of dose, etc.

The following morning, Sarah visits Mrs Jones and determines that she usually visits a community pharmacy in Devonport. Sarah phones the pharmacy and confirms that the medicines prescribed for Mrs Jones match what she has been taking at home. Mrs Jones tells her that sometimes she doesn't take the Simvastatin tablets as they give her an upset tummy and that she only uses the Timolol eye drops when she remembers.

Requirements to enable a NZMT

1. A description of a medicine, at various levels of abstraction, from fully specified generic and brand information through to incompletely specified generic and brand information.
2. All trade products must be related to the appropriate generic name.

3. A description of dosage, including dosage quantity, route, frequency of administration and period of treatment.
4. It must be possible for a “pick list” of prescribing terms to be derived from the medicines terminology that is appropriate to prescribing in a secondary care setting.

AMT requirements fulfilment

Concepts: TPP, TPUU, TP, TF, MPP, MPUU, MP, ING, UOM, F

Prescribing terms can be made available as a *navigation subset*.

Note: The AMT does not provide concepts that fully define a prescription. Specifically, a medicines terminology must be supplemented with standardised ways of expressing route, frequency of administration, and period of treatment.

Open Issues

1. The need for the terminology to extend to cover the route
2. The need to prescribe without specifying the unit of use/dose form and the terms that might be used for this

Dispense

Process

Making a prescribed medicine available for administration to an individual patient in a secondary care setting. Once one or more medicines have been prescribed (see previous section), information about them must be transmitted to the pharmacy so they can be supplied. The basic requirements that must be included are the date prescribed, the identity and location of the patient, the name and dose of the Medicine (and form if relevant), the route, the frequency (and times of administration if relevant) and some form of authorisation (currently a signature).

If the prescription is not appropriate the dispensing agent contacts the prescriber to clarify/adjust the prescription.

If the hospital utilises an imprest system, any medicine(s) not available on imprest will most likely need to be dispensed by the hospital’s pharmacy department. This involves selecting an appropriate pack from stock using the dispensing application and creating a label for each container dispensed.

Many hospitals currently also dispense to individual patients (without Pyxis Medstations).

If the hospital utilises the Pyxis Medstation system, the hospital pharmacy transmits an electronic message to the Pyxis system for each order that has been reviewed and approved by a Clinical Pharmacist. This order is then automatically sent to the Pyxis Medstation on the patient’s ward, allowing the relevant medicine to be removed for administration.

Secondary Care Dispensing Scenario

Mrs Jones has been admitted to hospital suffering from pneumonia. Dr Stevens has obtained a list of the medicines she takes regularly at home and has prescribed them on the hospital medicine chart or entered them into the hospital’s electronic prescribing system.

Current Practice

One of more of the following will be true for each medicine prescribed on the chart – either:

1. The medicine is available immediately from the imprest cupboard on the ward.
2. The medicine chart must be faxed to the pharmacy who will dispense the medicine and send it to the ward.
3. The medicine chart must be faxed to the pharmacy who will transcribe the details of the prescription into their computer system. The medicine will then be available from an automated dispensing cabinet on the ward (e.g. the Pyxis Medstation system®).

Future Practice using NZMT

Medicines that have been entered directly into an electronic prescribing or order entry system are transmitted to the pharmacy computer system electronically, avoiding the need for the medicine chart to be faxed to the pharmacy. This also avoids the transcription step – another potential source of error.

Once the prescribed medicines have been reviewed by a clinical pharmacist, they are messaged electronically to the automated dispensing system which allows them to be removed for administration to the patient.

Requirements to enable a NZMT

1. A description of a medicine, at various levels of abstraction (generic and brand) allowing accurate dispensing of medicines.
2. All trade products must be related to the appropriate generic name.
3. A description of unit of use, subpack, outer pack, the active ingredients, strength and dose form: using both generic and trade names.
4. It must be possible for a prescribing term to be matched to a list of medicines that can be dispensed.

AMT requirements fulfilment

Concepts: TPP, TPUU, TP, TF, MPP, MPUU, MP, ING, UOM, F

Administer

Process

Administration of a medicine for an individual patient in a secondary care setting.

Health professionals may be required to administer a medicinal product to a patient in a number of circumstances. These include:

- Nurse administration to a patient under their care
- Hospital doctor (e.g. Anaesthetist, Gastroenterologist) administers anaesthetic or other medicine to patient under their care
- Midwife administration to a patient under their care
- Pharmacist administration to patient in pharmacy

In each case, the professional is required to correctly identify the medicinal product to be administered and to check that the product is in date. Instructions for the reconstitution and route of administration of the medicinal product need to be followed.

Once the medicine has been prepared for administration (i.e. removed from imprest, Individually Patient Dispensed container or Pyxis Medstation) it must be safely transported to the patient in a labelled container. At this point, the 5 R's of medication administration must be checked:

- Right Patient; Right Medication; Right Time & Frequency of Administration;
Right Dose; Right Route of administration

It is envisaged that at some point, at least some of these points will also be verified via scanning barcodes attached to the patient & each medicine. If all points are correct, the medicine is administered and recorded on the patient's administration record.

Secondary Care Administering Scenario

Mrs Jones has been admitted to hospital suffering from pneumonia. Dr Stevens has obtained a list of the medicines she takes regularly at home and has prescribed them on the hospital medicine chart or entered them into the hospital's electronic prescribing system. The pharmacy has made the medicines available either through imprest, individual patient dispensing or via automated dispensing cabinets.

Current practice

The nurse scans the medication chart and determines what needs to be administered to Mrs Jones. He or she takes the required quantity of each medication required (e.g. 1 tablet each of Metoprolol, Aspirin, and Simvastatin) and places them in a plastic pot labelled with Mrs Jones' name and hospital number. The plastic pot containing the medicines and the chart are taken to Mrs Jones' bedside and her wristband checked. The nurse administers the medicines to Mrs Jones and records the administration on the medicine chart.

Future practice using a NZMT

The nurse logs into the electronic medication chart for Mrs Jones and sees that Metoprolol, Aspirin, and Simvastatin are due to be administered. She obtains them from the automated distribution cabinet situated on the ward and places the unit-dose packaged tablets into a plastic pot labelled with Mrs Jones' name and hospital number in both human and machine readable format.

After visually checking Mrs Jones' wristband, the nurse scans the barcode on the wristband followed by the barcode on each of the unit-dose packaged tablets. If any of the tablets do not match the original prescription (order), the system generates an alert, halting the administration. If the medications are correct, the time of administration and the identity of the nurse are recorded.

Requirements to enable a NZMT

1. A description of a medicine at the unit of use level.
2. All units of use must be related to the appropriate prescribing terms.

AMT requirements fulfilment

Concepts: TPUU, MPUU, TP, MP, UOM, F, ING

NEW PRODUCTS

New medicinal product

Process

Adding a new generic product to the terminology without any trade products, or prior to adding its trade products.

The NZMT team may receive information about new medicines in various ways including:

- A supplier sends advance notice.
- A clinician may request availability of product on NZMT.
- The NZMT maintenance teams notice a new product in horizon scanning medicines information resource.
- A new chemical entity is approved for use in a clinical trial
- Occasionally actors other than suppliers will apply for products such as 'tap water' to be added to the NZMT to facilitate their own objectives such as processing claims for subsidy.

On receipt of the details, the NZMT team will follow a process to confirm the details and then enter the details into the NZMT.

New Products Scenario

An immigrant to New Zealand has been receiving a medicine that is not available in New Zealand. A clinician wishes to record details of the medicine in the patient's record.

Current practice

The details are recorded in text-only format in the clinician's computer system.

Future practice using NZMT

A system exists for adding the new medicine to the NZMT so that it can be recorded in a computer interpretable fashion. The NZMT team will review every such new medicine thoroughly, to ensure that alternative medicine names do no result in duplicate entries for the same medicine. Any duplicate entries that are identified can be retired according to the standard SNOMED process for retiring duplicate entries, which ensures data is not lost.

Requirements to enable NZMT

1. Ability to identify generic names of medicines, and associate them with active ingredients and appropriate units of measure.
2. Ability to retire duplicate entries without loss of data.

AMT requirements fulfilment

Concepts: MP, MPUU, ING, UOM

SNOMED process for retiring duplicate entries.

New trade product

Process

Adding a new (approved) trade product or new (approved) trade product pack to the NZMT. The NZMT team may receive information about a new product or a new product pack in various ways including:

- A pharmaceutical company makes an application to Medsafe for approval to market a new medicine in New Zealand; or
- A pharmaceutical company notifies the NZMT team (using the specified form) that it is marketing a new product pack of an existing approved medicine.

On receipt of the details, the NZMT team will follow a process to match the details to the relevant Medicinal Product (MP) and Medicinal Product Unit of Use (MPUU), confirm the details and then enter the details into the NZMT.

Current practice"

Applications to Medsafe (for approval) and the Pharmacy Guild (for a Pharmacode) are separate and take place in no particular order.

Future practice using NZMT

Applications received by Medsafe can be referred to the NZMT team immediately, so that the correct terminology and code can be assigned early in the processing of the application.

To enable NZMT

Ability to fully identify products using brand name, generic name, dose form, strength, unit of use, pack and subpack.

Ability to generate appropriate unique codes, including new Pharmacodes.

Ability to create a new product pack entry within one working day.

AMT requirements fulfilment

MP and MPUU must already exist. The above use case applies in cases where they do not already exist.

Concepts: MPP, TP, TPUU, TPP, CTPP

Unapproved medicines

Process

Adding a new unapproved trade product to the NZMT. Information on the prescribing, dispensing and administration of unapproved medicines is required for completeness of the EHR. A number of scenarios support the use case for Section 29 medicines e.g.

A patient is enrolled in a clinical trial or post marketing study with an unapproved medicine, this could be noted in the patient's EHR in order to maintain an accurate treatment record.

Patients moving to New Zealand, who are stabilised on a current medication regimen, some of which are not approved in New Zealand, want to be assured they can continue the same treatment once they are living here.

Complementary or herbal medicines which may be prescribed should also be able to be uniquely identified and recorded in the EHR to allow for identification of potential interactions between complementary and prescribed medicines.

- A pharmaceutical company makes an application to PHARMAC for listing an as yet unapproved medicine on the pharmaceutical Schedule; or
- PHARMAC's Exceptional Circumstance panel approve funding for an unapproved medicine; or
- A DHB needs to use an unapproved medicine.

Clinical trail product scenario

The New Zealand branch of a pharmaceutical company has been requested by its parent company to be involved in Phase IV, post marketing studies to delineate additional information including the medicine's risks, benefits and optimal use, but the medicines is the first in its class and not yet registered for use.

Current practice

Once informed, the patient's doctor, who is not involved in the trial, enters the fact the patient is enrolled in the trial as a text code in their computer system as this is the only way the information can be recorded. However, the product subsequently becomes licensed and the patient continues treatment with it, but there is no way to connect the licensed product to the trial product.

Future practice using a NZMT

A Medicines Terminology would allow unique identifiers to be ascribed to the trial product, and would incorporate an internationalised identifying component, which is then associated with the medicine throughout its lifetime, both as a trial product and as a licensed product. Even if the international identifier becomes available after the NZ trial, the SNOMED system provides for retiring and replacing of identifiers without loss of data, so the connection between the trial medicine and the licensed product is retained.

Requirements to enable a NZMT

1. Human and machine readable identification of medication information that is linked through the unique identifiers to an internationalised coding system in both generic and trade name terms. Internationalised codes would identify country (countries) where available.
2. The name, strength and form of the unapproved medicine, plus the pack size and sponsor company.
3. The licence status of the medication and any relevant history (e.g. trial outcomes, clinical trial drug, changes to licence status)

Open Issues

1. The ability to indicate the country in which the medicine is available, and the sponsor's name in that country is not currently part of the AMT
2. License status is not part of a medicines terminology, and would be stored in a related database, but if it is needed and the NZMT is the only database populated with the particular medicine, then the NZMT needs to carry that information too.

Detailed Scenario

1. A patient with Lou Gehrig's disease has seen evidence that a medicine available overseas but not registered or licensed in New Zealand has led to positive treatment outcomes for some patients. He has tried a number of treatments with limited success, and now discusses this potential option with his specialist, who agrees to access it under Section 29 and to use it off-label. To ensure the patient's EHR is updated with the correct drug and dosage information, the Medicines Terminology would be populated with an internationalised code that is then given a specific NZ code. Should another prescriber choose to offer the same unlicensed medicine to a patient in the future, the product code is already recorded in the MT.
2. Immigrants to New Zealand are often stabilised on medication regimens in their home country. Some of these medicines may not be licensed in New Zealand but it would be detrimental to patient health outcomes and safety to switch to another, often older, product, which may have been used unsuccessfully in the past. Currently a prescriber would record the information about the unlicensed product in free text in the patient's notes. Should the need arise for another prescriber to have access to this information, MT would ensure the prescriber is selecting exactly the right product even though they may be unfamiliar with it and have no experience with its use.

Real-time user-created record of new product

Process

Allowing approved clinicians and pharmacists to add terms for Section 29 medicines to the NZMT in real time. A central terminology server will issue interim codes on the basis of a completed and authorised online application form. This issuance will be instant, and the new code will immediately go live. Any other authorised person attempting to add a new term for that product will have the option of using the already added interim one – creating instant data alignment.

This system will not be available to suppliers, who will have to rely on the product approval process, or a conventional application form, for a new listing.

The NZMT team will review the new data as described in the above use cases, and subsequently issue a definitive entry for the new product. Any interim code(s) will be linked to the definitive code using the SNOMED system for retiring and replacing codes. This will ensure that information does not get lost.

OTHER

Electronic health record

Process

The recording of unambiguous medicines information in an Electronic Health Record (EHR). In almost every clinical decision, a patient's current and historical medication information will have some bearing, to a greater or lesser extent, depending on each situation. For example, when assessing how to change a patient's anti-hypertensive regime because of poor control, current and past medication history will be one of the prime considerations.

Current and historical medication information provided by a patient may not be sufficiently detailed and cannot always be relied on. Medication information provided at the interfaces of patient care (e.g. patient admitted to hospital from GP) may not be available in rich detail and, as a result, less granular, more generalised pieces of information may be recorded.
A patient's electronic medication profile and history information that has been collected and electronically stored in an appropriate level of detail over a period of time provides a clear and accurate record for all authorised users to access to support the safe, efficient and effective ongoing care of the individual patient.

It is important that the text descriptions that identify medicine concepts and medicinal products used in clinical care recorded in the medication profile are in an unambiguous electronic coded and human readable form.

EHR Scenario

Ted Teacher has suffered from hypertension for a number of years. He has recently moved house to be nearer his grandchildren, but, when reviewed by his new GP, Dr Pain, it is discovered that Ted's blood pressure has become less controlled than everyone would wish.

Dr Pain takes a history from Ted who has a written copy of his "current" medications from his previous GP (Bendrofluazide 2.5mg tablets, one daily; Atenolol 50mg tablets, one daily, Enalapril 5mg tablets, one daily; Aspirin 75mg dispersible tablets, two daily; paracetamol 500mg tablets, two up to four times a day for pain relief (osteoarthritis)) but has no information about any past medication history. He does his best to get this.

Ted is very vague, but Tilly is sure that Ted had some medication in a "green and white box" – "Adalat" maybe, for a few months quite some time ago (2-3 years) but that it was stopped because of a lack of effect. Neither she nor Ted are sure, but they think it was tablets, and had a "10", and that they were taken twice a day.

Before that, there was a medicine called "Ismo – or something like that" – Ted had a couple of doses but it caused excruciating headaches and it was stopped straight away; Dr Pain acknowledges that Ismo is likely to be isosorbide mononitrate but realises that there are multiple dosage forms and presentations for this, and on further questioning they but have no further information about the type or dose that was taken.

Current practice

Dr Pain tries to update his PMS with Ted's medication details. He selects "Adalat 10mg tablets" from his drug look-up feature and adds a note that the drug was ineffective. He is unable to select "isosorbide mononitrate" from his look-up list because he can't find it (it isn't actually listed at all because his system only works on brand names) – so instead he just adds a free-text "note" that Ted gets excruciating headaches with "isosorbide".

6 months later Ted returns to the GP Practice and sees a locum covering for Dr Pain. Ted has newly diagnosed heart failure and the locum decides to try Ted on Duride tablets based on some new clinical trial data. He asks Ted if he has ever had Duride before – Ted says no.

The locum generates a prescription for Duride using the PMS system which Ted gets dispensed at the Pharmacy. That night Ted takes the first dose and gets an excruciating headache and calls an ambulance. The ambulance staff take a history from Ted and discover that he had a similar headache some years ago when he took a different tablet.

Future practice using a NZMT

Dr Pain tries to update his PMS with Ted's medication details. He selects "Adalat 10mg tablets" from his drug look-up feature and adds a note that the drug was ineffective. He then selects "isosorbide mononitrate" from his look-up list and adds an alert to this medication to indicate that Ted gets excruciating headaches with this drug.

6 months later Ted returns to the GP Practice and sees a locum covering for Dr Pain.

A) Ted has newly diagnosed heart failure and the locum decides to try Ted on Duride tablets based on some new clinical trial data. He asks Ted if he has ever had Duride before – Ted says no. As the locum generates a prescription for Duride using the PMS system an alert pops up which states that Ted has had isosorbide mononitrate before and that it gave him excruciating headaches.

Or

B) Ted has newly diagnosed heart failure and as part of the consultation the locum looks at Ted's medication profile. He sees the alert against isosorbide and asks Ted about it. Ted explains about the headaches.

The locum decides not to prescribe the Duride and instead decides to optimise the enalapril dose and increases it to 10mg daily.

(The medicines terminology will not by itself result in the clinical record, rather is an enabler.)

Requirements to enable a NZMT

1. A description of a medication, at various levels of abstraction, from fully specified generic and brand information through to incompletely specified generic and brand information
2. A description of dosage, including dosage quantity, frequency of administration and period of treatment.

AMT requirements fulfilment

Concepts: CTPP, TPP, TPUU, TP, TF, MPP, MPUU, MP, ING

Allergies, alerts, and decision support

Process

The use of electronic decision support (such as allergy, interactions and adverse reactions alerts) in the provision of care using medicines (including prescribing, dispensing and administering medicines).

The provision of care using medicines is becoming more complex and the requirement to provide evidence-based, high quality care is more challenging: there is a greater range of options to choose from, and patients rightly expect good care and minimal error.

To do this requires information about the patient (clinical and medicines) and information about the medicine itself, which may be provided either “actively” (as part of an application) or “passively” (for browsing).

Desirable attributes of decision support functionality for medicines include:

- Suitability checking - is medicine X suitable to be administered to patient A? For example, contraindications and precautions, interactions (drug:drug, drug:food and drug:complementary medicine), sensitivities (e.g. allergies, previous adverse reactions), dosage, formulary and funding
- Monitoring - is medicine X working well for patient A? For example, compliance checking, surveillance for adverse effects, monitoring parameters (renal function, therapeutic drug monitoring, electrolytes), dosage optimisation

Decision support could be used across the spectrum of e-pharmacy activities. For example:

Electronic Health Record (EHR):

- patient has a complete medication history contained within the EHR
- Reactions to medicines are documented within a patients medication history (e.g. adverse reaction or allergy)

Prescribe medicine:

- prescribing system checks newly prescribed medicines against medication history within the EHR to identify any potential interactions. Prescriber can decide whether to continue or not depending on clinical significance
- prescribing system checks newly prescribed medicines against EHR for any potential contraindications or precautions there may be, for the patient to have the particular medicine (e.g. other co-morbidities that preclude the use of the medicine, impaired renal or liver function)
- prescribing system should recognise prior reactions (such as allergies) and warn the prescriber at point of prescribing. The prescriber can choose to ignore warning and continue to prescribe the medicine or note the warning and prescribe an alternative medicine
- prescribing system checks newly prescribed medicines against medication history within the EHR to identify any duplications

Dispense medicine:

- dispensing system is linked to the EHR and is also able to identify potential interactions, sensitivities and co-morbidities of the individual. The pharmacist can contact prescriber prior to dispensing to clarify prescription and provide advice on alternative medicines.

Administer medicine:

- patient bedside verification could also be connected to EHR, therefore warns of the potential problem and the nurse/carer is able to contact prescriber to confirm they wish for a medicine to be administered.

It is important that the text descriptions identifying medicine concepts and medicinal products used in clinical care and recorded in the medication profile be in an unambiguous electronic coded and human readable form.

Scenario

Mrs Brown presents to the Emergency Department of her local hospital with what appears to be cellulitis following a sand fly bite. She has had a previous anaphylactic reaction to penicillin and suffers from asthma but she is acutely unwell and having trouble giving an accurate history. The Doctor initially prescribes flucloxacillin 1 gram iv four times a day.

Current practice

Due to the difficulty obtaining a history, the Dr decides to check Mrs Brown's history with the GP's practice and is informed of the prior anaphylaxis with penicillin. On learning of the reaction, the doctor switches the patient to cefazolin 2 grams iv twice a day, documents the allergy on her medicine chart and adds her regular asthma medications to the chart - flixotide 125mcg Inhaler 2 puffs twice and day and salbutamol 100mcg Inhaler 2 puffs when required. The pharmacist notes the patient's allergy to penicillin when reviewing the medicine chart and advises the doctor of the potential cross-sensitivity with cephalosporins and penicillins. Given the severity of the prior reaction they decide to avoid the risk of reaction to a cephalosporin, and on the advice of the microbiologists, the antibiotic is switched to clindamycin 300mg, iv four times a day.

Currently, prescribing in hospitals entails hand written medication charts. Medication histories are often reliant on patient/carer recall and occasionally notes or copies of previous prescriptions from GPs, support tools such as yellow cards and previous admission/discharge summaries (all of which are prone to transcription error). Other sources can be checked (e.g. phoning the community pharmacy - if the patient can remember the name of the pharmacy) but this can be time-consuming and may not be practical in every situation. Information relating to allergies or adverse reactions can be even more difficult to obtain.

Flucloxacillin is from the family of penicillin antibiotics and Mrs Brown is therefore at risk of a further anaphylactic reaction if she is given this antibiotic. In Mrs Browns case, an appropriate antibiotic is eventually prescribed, however it could have taken some time to get to this point resulting in either a further anaphylactic reaction or delays to patient therapy.

Future practice using a NZMT

The doctor enters the prescription into the hospital's electronic prescribing tool (e.g. e-medication chart), which is linked to the EHR. Mrs Brown's past medication history immediately triggers a warning to the Dr that she has had a past reaction to penicillin and the system queries whether the prescriber wants to continue prescribing the flucloxacillin.

The doctor changes the prescription to cefazolin 2 grams iv bd and the system again presents him/her with an alert warning of cross-sensitivity between cephalosporins and penicillins. The Dr is able to choose whether to continue to prescribe or amend the script and is provided with links to further information sources to inform the decision (e.g. formulary, local guidelines etc).

If the prescriber chooses to continue prescribing the cefazolin, the system will document this decision and record it in the EHR. There will also be alerts at both the dispensing (or profiling with a PYXIS medstation), and administration points in the process. This will enable the pharmacist to query the medicine with the prescriber, advise them of the significance of the cross-sensitivity and provide them with alternative options. The nurse (or person administering the medicine) is also able to check with the prescriber at the point of administration, if there has been no pharmacist input at the time of giving the first dose.

Requirements to enable a NZMT

The terminology must enable information to be recorded at different levels of detail ranging from partially to fully specified generic and brand names of a substance as well as by unit of use, subpack, outerpack, and dose form and strength.

The terminology must be able to identify a family or class of medicines e.g. Mrs Brown's allergy is recorded in her EHR as anaphylaxis to penicillin. When the doctor prescribes flucloxacillin the medicines terminology needs to be able to connect this medicine with penicillin.

Ideally, the terminology needs to be able to make connections to other families of medicines where there is a potential for cross-sensitivity (in this example, cephalosporins are not penicillins but there is a potential for the same reaction to occur with this class of medicines in penicillin sensitive individuals).

Clinical information about the use of medicines is outside the scope of the medicines terminology but the terminology needs to link with sources of this information.

1. An individual patients medication record
2. Human and computer readable description of medication information, specifically:

   A description of a medication at various levels of abstraction, from fully specified generic and brand information though to incompletely specified generic and brand information
3. A structure on which to build information about medicines; in that a piece of information may be relevant to a whole family or class of medicines (e.g. an allergy or adverse effect that persists across a class of medicine - NSAIDs, penicillins etc) or it may be relevant only to a single substance.
4. Information about medicines in clinical use

AMT requirements fulfilment

MP, MPP, MPUU, MPUUSAI, TP, TPP, TPPUU, TPUUPI

Extemporaneous products

Process

This scenario describes the situation when a prescriber wishes to order an item which is not made by a pharmaceutical supplier and so is not available as a pre-made item.

There are two main examples where this happens:

1. The desire for a pre-made item (e.g. betamethasone valerate 0.1% cream) to be diluted to a "one tenth" strength using a cream base to produce, in this example betamethasone valerate 0.01% cream. The prescriber is usually not aware of the base cream that the dispensing pharmacist will use to dilute the betamethasone 0.1% cream.
2. The prescriber wishes to specify an extemporaneous product as a recipe made from scratch. The prescriber may know only the active ingredients he/she wishes to be in the cream (e.g. dithranol 3% with coal tar 5% cream) or additionally he/she may also be able to specify the base cream that the other ingredients are to be added to (e.g. dithranol 3% with coal tar 5% in white soft paraffin). Suitable preservative may also have to be added.

In both cases, the prescriber will fill in the details as far as he/she can. The prescriber will also specify the total quantity of the finished product to be prepared/supplied.

Similarly for a specially prepared cough mixture, eye drops, suppositories, capsules etc, or the extemporaneously compounded products listed in Section C of the Pharmac Pharmaceutical Schedule which are not commercially available.

The pharmacist receiving the order will create a compounding worksheet using either the recipe itself, or will use reference materials (e.g. Pharmaceutical Codex, eMixt Formulation in Pharmacy Practice by D. Woods, or a local formulary), or professional judgement to define the recipe, determining all the ingredients (including additional preservatives and other excipients if necessary) and calculating the quantities required to make the item.

In all cases, when preparing and dispensing an extemporaneously prepared product, the dispensing pharmacist will be able to specify a full set of individual components used to create it, and the quantity of each component used (for reimbursement purposes). Some quantities will be approximate when used to make up to a given volume or weight of finished product. An additional overage quantity will be necessary to incorporate to compensate for loss during the compounding process.

Future practice using a NZMT

A medicines terminology will allow generic decision support based on the active ingredients used to make the extemporaneous product (drug interaction, contraindication, duplication)

A medicines terminology will enable extemporaneous products in a patient's medication history to be interpreted and understood by practitioners other than the prescribing and dispensing practitioners.

Requirements to enable a NZMT

1. An ability to describe the “ingredients” of an extemporaneous preparation at various degrees of specificity
2. An ability to attach a “local name” to a recipe
3. It must be possible for the dispense message to contain more ingredients than the original prescription message, as additional ingredients may be specified by the dispensing pharmacist in order to compound the final product
4. It must be possible for the dispense message to contain the quantity and quantity units of each dispensed ingredient, it must also be possible to not have to give an accurate quantity. There should perhaps be a flag for such guesstimate quantities (such as approximately 95g)
5. Unique identifiers are required (human and machine readable) for products (generic and brand) allowing accurate selection of product.
6. There must be interoperability between prescribing and pharmacy software supporting electronic transmission of medicine information.
7. Reimbursement of claims for the provision of subsidised prescribed items is necessary, including compliance with Pharmac extemporaneous preparation rules.

AMT requirement fulfilment

Concepts: ING, UOM

Open Issues

1. Controlled Drugs need to be included in an Extemporaneous Item e.g. methadone oral liquid formulations and syringe driver type formulations (morphine plus metoclopramide etc). Quantities of the CD will need to be referred to in words, and current legislation (other than a specific exception) requires it to be in the prescriber's handwriting.
2. The AMT currently does not support guesstimate quantities.
3. The AMT currently does not have a concept set aside for an extemporaneous preparation

Schedule publication

Process

Publication of the New Zealand Pharmaceutical Schedule includes all of the following:

1. The community Schedule book published 3 times year
2. Section H for hospital pharmaceuticals published 3 times year
3. The Interactive Schedule on PHARMAC's website
4. The Schedule data files (XMLSchedule and SiMPle.mdb) distributed each month
5. The pdf Special Authority forms available from PHARMAC's website
6. The HTML Special Authority forms generated by electronic Special Authority system (ESA), practice management systems (PMS) and Hospital systems

The Schedule is freely available to all subscribers worldwide, and is used in international comparisons and for research.

PHARMAC Schedule Scenario

Each month PHARMAC publishes the Schedule in all formats at www.pharmac.govt.nz without any restriction on who may access it.

Requirements to enable NZMT

Open licensing terms essential, preferably under terms similar to the Creative Commons Attribution licence: http://creativecommons.org/international/nz/

Open Issues

The SNOMED license terms are more restrictive than the present PHARMAC Schedule is subject to, and less restrictive than the current Pharmacodes are subject to.

Supply chain

Process

The purchasing of medicines in the supply chain. Unambiguous identification of medicines and their unit of measure (e.g. sub-pack, pack, carton) is essential to support the movement of medicines from suppliers (e.g. pharmaceutical companies) to customers (e.g. pharmacies).

Pharmacies in NZ purchase medicines from a range of suppliers. Most orders will be for medicines that are registered for use in NZ, but some patients (e.g. overseas visitors or NZ residents with special treatment needs) will require medicines not registered within NZ. Some pharmacies order medicines at customised dose and volume for specific patients (extemporaneous patient-specific orders).

The smallest unit of purchase is typically an unbroken pack (with a specific form, strength, brand and packsize defined), but may be smaller (e.g. a patient-specific order for a unit), or greater (e.g. a number of packs bundled together).

To support purchasing, the following are required:

- A common identifier for the medicine
- A common terminology for an 'each' unit
- A common terminology for active ingredient substance, strength measure and volume measure (for patient-specific orders)
- A list of suppliers for each medicine

Supply Chain Scenario

Happy-Days Pharmacy is running short of CureMyProblem 10mg tablets (30 tablet packs), manufactured by PharmaCompany, and registered for use within NZ. This pack is supplied by a number of suppliers, but Happy-Days have negotiated a contract with Super-Cheap Supplier. Happy-Days places an order for the required quantity of the CureMyProblem packs.

Current practice

The pharmacy's software must be configured with the supplier's **pack identifier** for each possible supplier (often the Pharmacode is used as the common identifier, but this is not universal); and conversion ratios between the pharmacy's each unit and supplier's **each unit** (usually 'pack', but may not always be so).

Future practice using NZMT

The pharmacy system and all suppliers have a common reference for medicine identifiers and packsize.

Requirements to enable a NZMT

Relationship between medicine terminology and supplier's pack identifiers and each units.

AMT requirements fulfilment

A medicines terminology on it's own will not offer significant benefit over and above what is currently in place in NZ.

To achieve significant supply chain benefits, a single common repository of products, suppliers and pricing information that is cross-referenced to the Medicines Terminology is required (similar to the National Product Catalogue (NPC) planned for Australia)

Open Issues

Whether the functionality of a medicines terminology depends on an NPC-like database, or whether it can function alone.

Appendix E – Glossary of Terms

[Have all these been used in the document??? I don't think so, so I haven't checked all for accuracy.

You may want to add the abbreviations used in section 1.1]

Term	Definition	Reference
ADR	Adverse Drug Reaction	
AI	Application Identifier (a GS1 identifier)	
AMH	Australian Medicines Handbook	
AMT	Australian Medicines Terminology	
AMT Concept	Australian Medicines Terminology concept, refer 2.2.1	
AS	Available status	
ATC codes	Anatomical Therapeutic Chemical classification	
BAN	British Approved Name (BAN). Locally unique non-proprietary names assigned to pharmaceuticals in Britain	
Barcode	A barcode is a way of representing data in a machine-readable form	
BD	Biotech descriptor (an AMT concept)	
Bedside Verification	A medicine barcoding system that would provide a tool for those administering medication	
BNF	British National Formulary	
Clinical Decision Support System	Clinical decision support systems are "active knowledge systems which use two or more items of patient data to generate case-specific advice".	
Community Pharmacy	Any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or where prescription orders are compounded and dispensed other than a hospital pharmacy	
Concept	A 'concept' is a discrete unit of thought, refer 2.2.1.	
Contraindication	A clinical reason not to give a medicine	
Controlled Drug	A medicine that may not be prescribed, supplied or administered other than in accordance with the Misuse of Drugs Act 1975	Misuse of Drugs Act 1975
Cross-maps	A work consisting of contents of two different nomenclature, classification or knowledge structures, together with a set of relationships between the two.	
CT	Container Type (an AMT concept)	
CTPP	Containered trade product pack (an AMT core concept)	
Decision Support	Access to or provision of relevant guidance based on the task the user is performing combined with specific stored information about the patient	
DHB	District Health Board	
dm+d	UK Dictionary of Medicines and Devices	
Editorial Rule	The Editorial Rules define how names are allocated to	

Term	Definition	Reference
	medicines	
Editorial Software	Software used for entering, verifying, correcting, and publishing data in a medicines terminology system	
ePharmacy	A holistic system of transactions governing the pharmaceutical supply chain, including patient and clinical services, payment and electronic records administration, management and reporting and other functions.	
Extemporaneous	Compounding of a medicine that is not commercially available. In the context of Pharmacy, this is where the pharmacist is required to mix or 'compound' the medicine in the pharmacy for the specific needs of the patient.	
F	Form (an AMT concept)	
GP	General Practitioner	
GS1	The GS1 System is an integrated system of global standards that provides for accurate identification and communication of information regarding products, assets, services and locations. It incorporates GS1 BarCodes – an internationally recognised system of barcodes.	
GS1 HUG	GS1 Health Users Group	
GTIN	Global Trade Identification Number (a GS1 identifier)	
Health care provider or practitioner	A person, facility or organisation that provides Patient health care services, including services to promote health, to protect health, to prevent disease or ill-health, treatment services, nursing services, rehabilitative services or diagnostic services.	
Health Network Code of Practice	Released in 2002, amended October 2006 The Health Network Code of Practice details the security practices needed to comply with the Health Information Privacy Code for health providers and health and disability information users.	SNZ HB 8169:2002
IAS	Ingredient activity status (an AMT concept)	
ICD-10	I10 (ICD–10 CM). A coding system based on International Classification of Diseases	
IHTSDO	International Health Terminology Standards Development Organisation	
ING	Ingredient (an AMT concept)	
Knowledge Support	Access to relevant information at the point of knowledge need based on the task the user is undertaking	
Legacy	Earlier versions of software, hardware, data, format, etc that is currently in use	
LOINC	Logical Observation Identifiers Names and Codes. A coding system	
Martindale's List	Pharmacy, pharmacology and clinical pharmacology	http://www.martindalecente

Term	Definition	Reference
	and toxicology terms and codes available online	r.com/Medical.html
MCNZ	The Medical Council of New Zealand.	
Medical Device	Any device, instrument, apparatus, or contrivance, including component parts and accessories thereof, that is manufactured, imported, sold, or supplied for use wholly or principally on or by one or more human beings for a therapeutic purpose; and includes bandages and other surgical dressings, except medicated dressings where the medication has a curative function that is not limited to sterilising the dressing	Medicines Act 1981
Medication	A treatment or therapy using medicines	
Medicines Dictionary	Collection of information pertaining to a specific medicine.	
Medicines Encyclopaedia	Extensive, clinically determined information about a specific Medication.	
Medicines Terminology	A set of terms that provide human readable (terminology) and computer processable (codes) capable of identifying all drugs by active ingredients, generic and proprietary drug names, drug classification or grouping structures, and at the pack (distribution) and individual dose (prescribing) level	
Medsafe	New Zealand Medicines and Medical Devices Safety Authority. It is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in New Zealand.	
MHM	MPP has MPUU (an AMT linking concept)	
MIMS	Medicines information resource in both electronic and print formats	
MoH	Ministry of Health	
MP	Medicinal product	
MPP	Medicinal product pack	
MPUU	Medicinal product unit of use (an AMT core concept)	
MPUUSAI	MPUU has Specific Active Ingredient (an AMT linking concept)	
MSP	Medication Sponsor (an AMT concept)	
NEHTA	National E-Health Transition Authority	
NGO	Non-Government Organisation	
NPC	(Australian) National Product Catalogue	
NZMT	New Zealand Medicines Terminology	
NZPhvC	New Zealand Pharmacovigilance Centre – national centre for monitoring adverse events associated with medicines, vaccines or any product for medicinal use	
OP	Original Pack	
OTC	Over the Counter	
PF	Proprietary form (an AMT concept)	

Term	Definition	Reference
PHARMAC	New Zealand Pharmaceutical Management Agency	
PHARMAC Schedule	A list of the approximately 2000 medicines and therapeutic products subsidised on prescription by the Government.	
Pharmaceutical Claims Data Mart (Pharms DM)	Pharms DM contains claim and payment information from pharmacists for subsidised dispensing that have been processed by the New Zealand Sector Services General Transaction Processing System (It is jointly owned by the Ministry of Health and PHARMAC)	
Pharmacist	A health practitioner who is, or is deemed to be, registered with the Pharmacy Council established by the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of pharmacy	Medicines Act 1981
Pharmacode	The Pharmacy Guild of NZ coding system used to rationalise the ordering procedure for pharmacies throughout New Zealand. Pharmacode is a registered trademark	
Pharmacy	A place where pharmacy practice is carried on	Medicines Act 1981
Pharmacy Council of NZ	The Pharmacy Council is responsible for registration of pharmacists, the setting of standards for pharmacists' education, scopes of practice and conduct.	Health Practitioners Competence Assurance Act 2003 (HPCAA)
Pharmacy only medicine	A medicine declared by regulations, may be sold by retail only by a person under the supervision of a pharmacist in a pharmacy or a hospital or by a person in a shop with a licence to sell that medicine.	Medicine Act 1981
Pharmacy Practice	Includes, without limitation, the following (a) the compounding and dispensing of prescription medicines, restricted medicines, or pharmacy only medicines: (b) the supply of a medicine by a pharmacist to suit the needs of a particular person: (c) the sale of prescription medicines, restricted medicines, or pharmacy only medicines	Medicines Act 1981
Pharmhouse	Now known as Pharmaceutical Claims Data Mart (Pharms DM)	
PHO	Primary Health Organisation	
PMI	Pack manufacture indicator (an AMT concept)	
PMS	Practice Management System	
Polypharmacy	The use of multiple drugs to treat multiple concurrent disorders in the same patient	
Prescribe	In medical practice, the act of authorising an order to supply or administer a substance used or capable of being used to prevent, treat, or palliate a disease, or the symptoms or effects of a disease for the purposes of clinical treatment of a patient under the authorising person's care. The provision, by a prescriber, of a authorisation to a person under their care allowing them to receive, possess and use prescription medicines for the	

Term	Definition	Reference
	purposes of treating a diagnosed condition. In health sector practice, the act of authorising an order to supply, possess or Administer a prescription, pharmacist-only, pharmacy or general sale medicine used or capable of being used to prevent, treat, or palliate a disease, or the symptoms or effects of a disease for the purposes of clinical treatment of a Patient under the authorising person's care.	
PSRT	Preferred strength representation type (an AMT concept)	
READ Codes	A therapeutic and diagnostic coding system designed for use in Primary Care. Now contained in SNOMED CT	
RFID	Radio Frequency Identifier	
rINN	International non-proprietary name	
SCTID	SNOMED CT Identifier	
Section 29	A section in the Medicines Act 1981 that authorises the supply of an unapproved medicine to a medical practitioner for the treatment of a specific patient. A 'Section 29 medicine' is a medicine which is being supplied under that provision.	Medicines Act 1981
SMARTI	System for the Management of Activities, Risks and Therapeutic Information	Medsafe Database
SNOMED	Systemised Nomenclature of Medicine	
SNOMED CT	Systemised Nomenclature of Medicine – Clinical Terms. A clinical terminology coding system.	
SNOMED CT Concept	Systemised Nomenclature of Medicine – Clinical Terms concept, refer 2.2.1.	
SSCC	Serial Shipping Container Code (a GS1 identifier)	
THT	TPP Has TPUU (an AMT linking concept)	
TP	Trade product (an AMT core concept)	
TPG	Trade product group (an AMT concept)	
TPP	Trade product pack (an AMT core concept)	
TPUU	Trade product unit of use (an AMT core concept)	
TPUUPI	TPUU has Pharmaceutical Ingredient (an AMT linking concept)	
TF	Trade Family (an AMT concept)	
UDFI	Unit dose form indicator (an AMT concept)	
UOM	Unit of measure (an AMT concept)	
USAN	United States Adopted Names (USAN) are unique non-proprietary names assigned to pharmaceuticals marketed in the US	
WHO ATC codes	World Health Organisation Anatomical Therapeutic Chemical classification	