

STANDARD FOR THE UNIFORM SCHEDULING OF MEDICINES AND POISONS

(Scheduling Standard)

Draft for consultation

May 2007

Consultation notes – intended to explain changes from the SUSDP to the SUSMP - are marked in boxes in black italics.

The term 'drugs' has been replaced by the term 'medicines' in the Standard name – see KEY CHANGE 9 at Attachment 1

TABLE OF CONTENTS

PRELIMINARY	1
INTRODUCTION	1
CLASSIFICATION OF MEDICINES AND POISONS	2
Medicines	3
Poisons	4
Availability of medicines and poisons	6
Preparations containing medicines listed in two or more schedules.....	6
Preparations containing poisons listed in two or more schedules.....	6
PRINCIPLES OF SCHEDULING OF MEDICINES AND POISONS	6
Reading the Schedules	7
PART 1 Interpretation.....	9
1.01 Definitions.....	9
1.02 References to substances.....	17
1.03 Specification of concentration, strength or quantity	18
1.04 References to temperatures	18
PART 2 Labelling requirements for medicines and poisons	19
Medicines and poisons	19
2.01 General.....	19
2.02 Signal headings for medicines	20
2.03 Exemptions for signal heading for medicines.....	21
2.04 Signal headings for poisons	21
2.05 Application and exemptions	23
2.06 Prohibitions.....	23
Additional requirements for labelling of poisons other than agricultural and veterinary chemicals.....	24
2.07 Identification Information – immediate wrapper.....	24
2.08 Primary packs and immediate containers	24
2.09 Approved name.....	27
2.10 Statements of quantity, proportion or strength	28
2.11 Exemptions from additional labelling requirements for certain poisons.....	29
2.12 Exemptions from additional labelling requirements for certain containers.....	30
PART 3 Container requirements for poisons other than agricultural and veterinary chemicals.....	32
3.01 Application and exemptions	32
3.02 Child-resistant closures	32
3.03 Containers for poisons other than Schedule 5 poisons	34
3.04 Containers for Schedule 5 poisons.....	34
3.05 Approved containers for poisons	35
3.06 Exemptions from container requirements for certain poisons	35
3.07 Prohibitions.....	36
PART 4 Advertising, sale, supply, possession, storage and dispensing of medicines and poisons	37
4.01 Advertising.....	37
4.02 Sale or supply of Schedule 2 medicines	37
4.03 Sale or supply of Schedule 3 medicines	37
4.04 Supply of certain Schedule 3 medicines to be recorded	37
4.05 Sale or supply of Schedule 4 medicines or veterinary chemicals.....	38
4.06 Possession, use, sale and supply of Schedule 7 poisons.....	38

PRELIMINARY

This document should be read in conjunction with the Scheduling Policy Framework which can be accessed via the following website: <URL will be inserted here>.

INTRODUCTION

This *Standard for the Uniform Scheduling of Medicines and Poisons* (the Scheduling Standard) serves two key purposes.

Firstly, the Scheduling Standard contains the decisions of the Managing Director of the Australia New Zealand Therapeutic Products Authority (the Authority) and the Secretary of the Department of Health and Ageing (the Department) regarding the classification of medicines and poisons into Schedules respectively, as recommendations to Australian States and Territories (for all medicines and poisons) and New Zealand (for medicines in Schedules 2, 3 and 4). The scheduling classification sets the level of regulatory control on the availability of medicines and poisons. In Australia the scheduling of medicines and poisons is implemented through relevant State and Territory legislation. In New Zealand the scheduling of medicines only is implemented through the *Medicines Act 1981* and regulations made under that Act (to be amended in line with Parts 6 and 7 of the Therapeutic Products and Medicines Bill at the commencement of the new joint therapeutic products regulatory scheme).

Secondly, the Scheduling Standard includes model provisions for labelling, containers, storage and possession of medicines and poisons which are intended to be adopted for use in each jurisdiction of Australia, according to local requirements and local law. For this reason Parts 1, 2, 3 and 4 of the Scheduling Standard and many of the Appendices are written in a way which allows them to be readily incorporated into the law of the jurisdictions for uniform application throughout Australia. The New Zealand *Medicines Act 1981*, the *Hazardous Substances and New Organisms Act 1996* and the *Misuse of Drugs Act 1975* include similar provisions for medicines and poisons respectively which can be accessed from the website: <http://www.legislation.govt.nz>.

The requirements for labelling and containers in this Scheduling Standard are intended to integrate with existing legislative instruments for labelling and containers. Labelling and packaging of medicines and agricultural and veterinary chemicals are also dealt with through the relevant product registration schemes provided for in legislation relating to therapeutic products or agricultural and veterinary chemicals. Labelling requirements imposed on medicines and agricultural and veterinary chemicals through the adoption of the Scheduling Standard incorporate the signal headings,¹ which reflect the Schedule which applies to the product, and may also include general requirements for dispensing labels, first aid statements, warning statements and general safety directions.

The labelling and packaging of poisons which are packed and sold solely for industrial use are exempt from all labelling and container requirements included in this Scheduling Standard as they are covered by the Australian Safety and Compensation Council *National Code of Practice for the Labelling of Workplace Substances*² (the ASCC Code).

As there is no national registration scheme in Australia for domestic products (such as cosmetics, toiletries and household cleaners), appropriate labelling and container requirements for these products are imposed through adoption of Parts 1, 2 and 3 of this Scheduling Standard into State/Territory legislation.

¹ Refer Sections 2.02 and 2.04 of this standard

²The ASCC Code (NOHSC:2012 (1994)) can be accessed from www.ascc.gov.au

This Scheduling Standard is a consolidation of the amendments resulting from decisions made by the Authority through the Managing Director (medicines) or the Department through the Secretary (poisons). The predecessor to this Scheduling Standard in Australia, the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP), as decisions of the former National Drugs and Poisons Schedule Committee, formed the basis of this Scheduling Standard. Further information on the scheduling amendments made by the Managing Director or the Secretary can be accessed from the following websites:

<URL will be inserted here>

This Scheduling Standard is presented with a view to promoting uniform:

- scheduling of medicines throughout Australia and New Zealand;
- scheduling of poisons in Australia;
- signal headings on labels for medicines throughout Australia and New Zealand;
- signal headings on labels for agricultural and veterinary chemicals in Australia;
- labelling and packaging requirements for poisons throughout Australia;
- additional controls on the availability and use of medicines throughout Australia and New Zealand; and
- additional controls on the availability and use of poisons in Australia.

The various legislative instruments which integrate with the Scheduling Standard include:

- the *Agricultural and Veterinary Chemicals Code Act 1994*
- the *Agricultural and Veterinary Chemicals Code Regulations 1995*
- the (proposed) Australian Therapeutic Products Act 2007
- the (proposed) New Zealand Therapeutic Products Act 2006
- the (proposed) New Zealand Medicines Act 2006
- the (proposed) Australia New Zealand Therapeutic Products Order (Medicine Standards) No. X of 2007 – General Requirements for the Labelling of Medicines
- the (proposed) Australia New Zealand Therapeutic Products Order (Medicine Standards) No. X of 2007 – Packaging Requirements for Specified Therapeutic Products
- the (proposed) Australia New Zealand Therapeutic Products Order (Medicine Standards) No. X of 2007 – General Requirements for Homoeopathic and Anthroposophic Medicines
- the (proposed) Australia New Zealand Therapeutic Products Order (Medicine Standards) No. X of 2007 - Child-Resistant Packaging Requirements for Medicines
- the (proposed) Medicine Label Statements for the Australia New Zealand Therapeutic Products Regulatory Scheme

CLASSIFICATION OF MEDICINES AND POISONS

Medicines and poisons are classified by placing them in Schedules to this Scheduling Standard. The scheduling classification represents the degree of control recommended over their availability to the public in order to protect public health and safety.

It is intended that substances in the electronic Scheduling Standard are flagged as either being medicines, agricultural and veterinary chemicals or domestic and other chemicals. This differentiation supports a single Australian/New Zealand framework for medicines and helps distinguish the different issues associated with medicines and poisons.

For the purposes of the Scheduling Standard, the term medicine should be taken to encompass a preparation that is used as or included in a formulated medical device, unless there is a specific exclusion or exemption.

The following is a general description of the Schedules (and Appendices) for medicines and poisons. For the legal definitions, however, it is necessary to check with the relevant Australian State or Territory or New Zealand legislation.

Schedule 1 of this Scheduling Standard is intentionally blank.

Medicines

Medicines (Australia and New Zealand)

Medicines are included in Schedules 2, 3, and 4 with progression through these Schedules signifying increasingly strict controls. These Schedules reflect the need for involvement from a healthcare professional in the supply of certain medicines in order to facilitate safe use. New Zealand has proposed only to recognise recommendations for scheduling of substances for human therapeutic use included in Schedules 2, 3 and 4 of the Scheduling Standard.

Often medicines available for human use are also used as veterinary chemicals and, where the scheduling entry for both purposes of use is the same, only a single entry is included. The following is a general description of these Schedules:

Schedule 2. Pharmacy Medicine – Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.

Schedule 3. Pharmacist Only Medicine – Substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription.

Schedule 4. Prescription Only Medicine – Substances, the use or supply of which should be by or on the order of persons permitted by Australian State or Territory or New Zealand legislation to prescribe and should be available from a pharmacist on prescription.

Under certain circumstances a medicine may be exempt from scheduling requirements.

New Zealand-specific legislation will deal with situations where the schedule entries in New Zealand and Australia are not harmonised at the commencement of the ANZTPA, or where New Zealand has on public health grounds actively decided not to adopt recommendations from the Scheduling Standard. It is proposed that New Zealand will publish a list of these scheduling departures in the New Zealand Gazette on the Ministry of Health website.

Medicines (Australia)

Medicines included in Schedule 8 will continue to be recognised in Australia. In New Zealand the *Misuse of Drugs Act 1975* will continue to apply and product labelling in New Zealand will reflect the requirements of this legislation as well as relevant ANZTPA labelling requirements.

The following is a general description of Schedule 8:

Schedule 8. Controlled Drug – Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

Therapeutic products containing substances included in Schedules 5 and 6 of the Scheduling Standard are exempted from scheduling requirements under Section 1.02 of the Standard.

Poisons

Poisons – veterinary, agricultural, domestic or industrial chemicals (Australia only)

The poisons provisions in the Scheduling Standard apply only to Australia. Poisons are included in Schedules 2, 4, 5, 6, 7, 8 and 9.

Schedule 2 includes veterinary chemicals which should only be available through a pharmacy or through an authorised prescriber.

Schedule 4 and Schedule 8 contain veterinary chemicals which should be available only on prescription from a veterinarian.

For agricultural, veterinary, domestic and industrial chemicals, Schedules 5 and 6 represent increasingly strict container and labelling requirements with special regulatory controls over the availability of the agricultural, veterinary and industrial chemicals listed in Schedule 7.

The table below summarises how the requirements for labelling and container requirements in Schedules 5, 6 and 7 generally apply to the different categories of poisons.

Poison	Schedule	Requirements for Labelling/containers	Other controls
Agricultural or veterinary chemical	Schedule 5 or 6	Applied through <i>Agricultural and Veterinary Chemicals Code Act 1994</i> other than signal heading which is applied through State/Territory adoption of Part 2 of the Scheduling Standard	
	Schedule 7	Applied through <i>Agricultural and Veterinary Chemicals Code Act 1994</i> , other than signal heading which is applied through State/Territory adoption of Part 2 of the Scheduling Standard	Controls on possession, storage, availability and use applied through State/Territory adoption of Part 4 and Appendix J of the Scheduling Standard.
Chemical in a domestic end use product where any use in the workplace is only incidental	Schedule 5 or 6	Applied through State/Territory adoption of Parts 2 and 3 and Appendices E and F of the Scheduling Standard. Where products are incidentally used in the workplace, additional labelling information in accordance with the ASCC Code should be included.	Controls on paints applied through State/Territory adoption of Appendix I of the Scheduling Standard
	Schedule 7	n/a – domestic use is prohibited under State/Territory legislation by adoption of Part	n/a

4 of the Scheduling Standard

Chemical packed and sold solely for industrial purposes	Schedule 5 or 6	Must be labelled in accordance with ASCC Code.	
	Schedule 7	Must be labelled in accordance with ASCC Code. Where substances are also classed as dangerous goods by the Australian Dangerous Goods Code, the requirements of State and Territory dangerous goods legislation should be met.	Controls on possession, storage, availability and use applied through State/Territory adoption of Part 4 and Appendix J of the Scheduling Standard.

Schedule 9 contains substances that should be available only for medical or scientific research including clinical trials conducted with the approval of Australian Commonwealth and/or Australian State/Territory Health Authorities. Although appearing as a Schedule in this Scheduling Standard the method by which the use of these substances is permitted may vary between the States/Territories.

The following is a general description of these Schedules:

Schedule 2. Pharmacy Medicine – Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person or from an authorised prescriber.

Schedule 4. Prescription Animal Remedy – Substances, the use or supply of which should be by or on the prescription of persons permitted by Australian State or Territory legislation to prescribe.

Schedule 5. Caution – Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.

Schedule 6. Poison – Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.

Schedule 7. Dangerous Poison – Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.

Schedule 8. Controlled Drug – Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

Schedule 9. Prohibited Substance – Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth of Australia and/or Australian State or Territory Health Authorities.

Availability of medicines and poisons

The purpose of classification is to group medicines and poisons into Schedules that require similar regulatory controls over their availability.

The inclusion of a medicine or poison in a Schedule indicates the degree of control required. It does not indicate:

- that the medicine or poison is available; nor
- that it has been approved or is efficacious for any use that may be specified in a Schedule,

nor does it negate any obligation for licensing of a therapeutic product for human use or registration of an agricultural or veterinary chemical containing that medicine or poison.

Preparations containing medicines listed in two or more schedules

If a preparation contains two or more medicines, the provisions relating to each of the Schedules in which those medicines are included apply.

Where more than one Schedule applies to a preparation and there is conflict in the requirements of those different Schedules, the provision of the more restrictive Schedule applies, unless a contrary intention is indicated in the Schedules or relevant Australian State and Territory and New Zealand legislation.

The Schedules listed in order of greatest to least restriction are 8, 4, 3 and 2.

If a substance has a dual purpose as a medicine and a poison (eg an agricultural/veterinary chemical) and the scheduling entry is the same (irrespective of the purpose of use), the scheduling entry will be flagged in the electronic Scheduling Standard as having two or more uses.

Preparations containing poisons listed in two or more schedules

If a preparation contains two or more poisons, the provisions relating to each of the Schedules in which those poisons are included apply.

Where it is not possible to comply both with a provision relating to one of those Schedules and with a provision relating to another of those Schedules, the provision of the more restrictive Schedule applies, unless a contrary intention is indicated in the Schedules or relevant Australian State and Territory legislation.

The Schedules listed in order of greatest to least restriction are 9, 8, 4, 7, 2, 6 and 5.

PRINCIPLES OF SCHEDULING OF MEDICINES AND POISONS

Medicines and poisons are not scheduled on the basis of a universal scale of toxicity. Although toxicity is one of the factors considered, the decision to include a substance in a particular Schedule also takes into account many other factors such as the purpose of use, potential for abuse, safety in use and the need for the substance.

The matters which are required to be taken into account by expert committees in providing advice on scheduling matters and by the Authority or the Department in making scheduling decisions are included in the *Australia New Zealand Therapeutics Products Regulatory Scheme (Administration and Interpretation) Rule 2006* and [Australian poisons legislation].

The non-inclusion of, or exclusion of a substance from the Scheduling Standard should not be read as an indication that the substance is harmless or has no toxic effects.

Reading the Schedules

Schedule entries have been designed to be as simple as possible while retaining readability, legal integrity and as much freedom from ambiguity and contradiction as possible. As a result they are expressed in a number of ways, though this number has been kept to a minimum. It is necessary to keep this variety of expression in mind when searching or interpreting Schedule entries.

Firstly, medicines and poisons are scheduled individually using their approved names wherever practicable although exceptions are necessary in some cases. Some of those are mentioned overleaf. Older group entries have been revised and replaced by individual entries as time permits although in some of these cases a group term has also been retained to deal with any members of the group or class that may have escaped attention but should be scheduled.

Secondly, Schedule entries have been expressed in either positive or negative terms and care must be taken to distinguish between the two different forms of expression. Thus, terbutaline is in Schedule 3 only when one of the clauses in this Schedule entry applies, while chlorbutol is in Schedule 3 unless one of the exempting clauses applies.

Where exceptions are included in an entry these have been emphasised by printing the word “**except**” in bold type.

Where the Schedule entries for a medicine or poison make a specific exclusion or exemption, the requirements of the Scheduling Standard do not apply to that medicine or poison within the constraints of that exclusion or exemption although controls under other legislation may apply.

Where a medicine or poison has been included in more than one Schedule the principal entry, where practicable, has been included in the most restrictive Schedule with references to the other Schedule(s) involved.

A Schedule entry includes preparations containing the medicine or poison in any concentration and all salts and derivatives unless specifically stated otherwise. It should be noted that a scheduled substance included in any therapeutic product (including certain medical devices) in any agricultural or veterinary product means that product would also be subject to the labelling requirements and access controls specified for that substance. Further labelling and packaging requirements and access controls may be included under other relevant legislation.

The scheduling status of a medicine or poison can be determined by searching the Scheduling Standard. Some substances are also subject to exemptions or additional provisions as described in the Appendices to this Scheduling Standard.

In this process if the medicine or poison is not found under its “approved name” it may be shown under a group term such as:

Group

the parent acid of salts

the radical of a salt

the element

a chemical group with similar
toxicological or pharmacological
activity

a pharmacological group

Example

“oxalic acid” to find sodium oxalate

“chromates” to find potassium chromate

“arsenic” to find arsenic trioxide

“hydrocarbons, liquid” to find kerosene

“anabolic steroidal agents” to find
“androsterone”

DRAFT

PART 1 Interpretation

Any changes to the current definitions are primarily due to the need to be consistent (in as much as possible) with the definitions in the relevant legislation.

1.01 Definitions

In this Scheduling Standard, unless the contrary intention appears —

“Agricultural chemical” means a substance that is represented, imported, manufactured, supplied or used as a means of directly or indirectly:

- (a) destroying, stupefying, repelling, inhibiting the feeding of, or preventing infestation by or attacks of, any pest in relation to a plant, a place or a thing; or
- (b) destroying a plant; or
- (c) modifying the physiology of a plant or pest so as to alter its natural development, productivity, quality or reproductive capacity; or
- (d) modifying an effect of another agricultural chemical product; or
- (e) attracting a pest for the purpose of destroying it.

but does not include a veterinary chemical product.

“Animal” means any animal (other than a human being), whether vertebrate or not, and whether a food-producing species or not, and includes mammals, birds, bees, reptiles, amphibians, fish, crustaceans and molluscs.

“Animal feed premix” means a concentrated preparation, containing one or more poisons, for mixing with food ingredients to produce a bulk feed for a group of animals, but does not include a preparation for mixing with an individual animal’s food.

“Appropriate authority” means:

- (a) in the Australian Capital Territory, ACT Health;
- (b) in New South Wales, the Director-General of NSW Health;
- (c) in Northern Territory, the Chief Health Officer of the Department of Health and Community Services;
- (d) in Queensland, the Chief Executive of Queensland Health;
- (e) in South Australia, the Therapeutic Goods, Drug Programs and Population Strategies Branch of the Department of Health;
- (f) in Tasmania, the Secretary of the Department of Health and Human Services;
- (g) in Victoria, Secretary to the Department of Human Services;
- (h) in Western Australia, the Chief Executive Officer, Department of Health;

where there is no longer any such agency or Department, the appropriate authority is the relevant State/Territory agency or Department which administers the medicines and poisons legislation or person holding the appropriate delegation;

- (i) the Australian Pesticides and Veterinary Medicines Authority;

- (j) the New Zealand Ministry of Health; and
- (k) the Australia New Zealand Therapeutic Products Authority.

“Approved name” means:

Definition has been reorganised to reflect current practice but may require updating for medicines after the ANZTPA approved name guidelines are finalised

- (a) in relation to a medicine or veterinary chemical for therapeutic use-
 - (i) the international non-proprietary name recommended for the medicine or veterinary chemical by the World Health Organisation; or, if no such name is recommended,
 - (ii) the English name, not including synonyms, by which the medicine/veterinary chemical is described in the British Pharmacopoeia, the British Pharmaceutical Codex, the Australian Pharmaceutical Formulary and Handbook or the British Pharmacopoeia (Veterinary); or, if the medicine or veterinary chemical is not described in any of those publications,
 - (iii) the Australian Approved Name for the medicine or veterinary chemical, not including synonyms, as listed in the publication entitled *ANZTPA Approved Names*, or its successor, published by the Authority, Canberra; or, if the medicine or veterinary chemical is not listed in that publication,
 - (iv) the approved name given to the medicine or veterinary chemical by the Medicines Commission of Great Britain; or, if no such name is given,
 - (v) the accepted scientific name or the name descriptive of the true nature and origin of the medicine or veterinary chemical;
- (b) in relation to a poison excluding a veterinary chemical for therapeutic use –
 - (i) the English name recommended by the Standards Association of Australia as the common name for the poison; or, if no such name is recommended,
 - (ii) the English name given to the poison by the International Organisation for Standardisation; or, if no such name is given,
 - (iii) the English name given to the poison by the British Standards Institution; or, if no such name is given,
 - (iv) the Australian Approved Name for the poison, not including synonyms, as listed in the publication entitled {new name}, or its successor, published by the Australian Government Publishing Service; or, if the poison is not listed in that publication,
 - (v) the English name, not including synonyms, by which the poison is described in the British Pharmacopoeia, the British Pharmaceutical Codex, the Australian Pharmaceutical Formulary and Handbook or the British Pharmacopoeia (Veterinary); or, if the poison is not described in any of those publications,
 - (vi) the approved name given to the poison by the Medicines Commission of Great Britain; or, if no such name is given,

- (vii) the international non-proprietary name recommended for the poison by the World Health Organisation; or, if no such name is recommended,
- (viii) the accepted scientific name or the name descriptive of the true nature and origin of the poison.

“**Authorised prescriber**” means a registered medical, dental or veterinary practitioner or such other person authorised by the appropriate authority in Australia or New Zealand.

“**Authority**” means the Australia New Zealand Therapeutic Products Authority.

“**Blood**” means whole blood extracted from human donors.

“**Blood components**” means therapeutic components that have been manufactured from blood (including red cells, white cells, stem cells, platelets and plasma), except for products derived through fractionation of plasma.

“**Child-resistant closure**” means

- (a) a closure that complies with the requirements for a child-resistant closure in the Australian Standard AS1928-2001 entitled *Child-resistant packages* as specified or amended from time to time;
- (b) a closure approved by any order made under the therapeutic products legislation administered by the Australia New Zealand Therapeutic Products Authority; or
- (c) in the case of a can fitted with a press-on lid, a lid of the design known as “double tight” or “triple tight”.

“**Child-resistant packaging**” means packaging that is designed to be resistant to opening by children and that complies with:

- (a) complies with the requirements for a child-resistant closure in the Australian Standard AS1928-2001 entitled *Child-resistant packages* as specified or amended from time to time;
- (b) is reclosable and complies with the requirements of at least one of the following standards as specified or amended from time to time;
 - (i.) the international Organisation for Standardization Standard ISO 8317:1989 entitled *Child-resistant packaging – Requirements and testing procedures for reclosable packages*;
 - (ii.) the British Standards Institution Standard BS EN 28317:1993 entitled *Child-resistant packaging - Requirements and testing procedures for reclosable packages*;
 - (iii.) the Canadian Standards Association Standard CSA Z76.1-99 entitled *Reclosable Child-resistant Packages*;
 - (iv.) the United States Code of Federal Regulations, Title 16, Section 1700.15, entitled *Poison prevention packaging standards* and Section 1700.20 entitled *Testing procedure for special packaging*;
- (c) is approved as a child-resistant by any order made under the therapeutic products legislation administered by the Australia New Zealand Therapeutic Products Authority; or
- (d) is in the form of blister or strip packaging in which a unit of use is individually protected until the time of release and that complies with Section 3 (Requirements

for non-reclosable packages) of Australian Standard AS 1928-2001 *Child-resistant packages*.

“Compounded” in relation to a substance means combined with one or more other therapeutically active substances in such a way that it cannot be separated from them by simple dissolution or other simple physical means.

“Cosmetic” means a substance intended for placement in contact with any external part of the human body, including:

- (a) the mucous membranes of the oral cavity; and
- (b) the teeth;

with a view to:

- (c) altering the odours of the body; or
- (d) changing its appearance; or
- (e) cleansing it; or
- (f) maintaining it in good condition; or
- (g) perfuming it; or
- (h) protecting it.

“Debitterised neem seed oil” means highly purified oil from the neem seed containing only fatty acids and glycerides of fatty acids.

“Dermal use” means application to the skin primarily for localised effect.

“Designated solvent” means the following:

- a) acetone
- b) dimethylformamide
- c) N-(N-dodecyl)-2-pyrrolidone
- d) hydrocarbons, liquid
- e) methanol when included in Schedule 5
- f) methyl ethyl ketone
- g) methyl isoamyl ketone
- h) methyl isobutyl ketone
- i) N-methyl-2-pyrrolidone
- j) N-(N-octyl)-2-pyrrolidone
- k) phenyl methyl ketone
- l) styrene
- m) tetrachloroethylene
- n) 1,1,1-trichloroethane

“Dispensing label” means the label attached to the immediate container of a substance for therapeutic use at the time of dispensing.

“Distributor” means a person who imports, sells or otherwise supplies a medicine or poison.

“Divided preparation” means a preparation manufactured and packed as discrete pre-measured dosage units prior to sale or supply, and includes tablets, capsules, cachets, single dose powders or single dose sachets of powders or granules.

“Dosage unit” means an individual dose of a medicine or a veterinary chemical and includes a tablet, capsule, cachet, single dose powder or single dose sachet of powders or granules.

“Essential oils” means products obtained from natural raw materials either by distillation with water or steam or from the epicarp of citrus fruits by a mechanical process, or by dry distillation. For scheduling purposes it also means:

- (a) oils of equivalent composition derived through synthetic means; or
- (b) prepared mixtures of oils of equivalent composition comprising a mixture of synthetic and natural components.

“External” in relation to the use of a medicine or poison means application in the ears, eyes or nose or to a body surface other than in the mouth, rectum, vagina, urethra or other body orifice.

“First Schedule Paint” means a paint containing the specified proportion of any substance in the First Schedule to Appendix I of this Scheduling Standard.

“Graphic material” means the material which is to be deposited on another material by a graphic instrument during writing, drawing or marking and includes cores of pencils, school pastels or crayons, blackboard chinks, finger or showcard colours, poster paints and watercolour blocks.

“Height” in relation to letters used for words, expressions or statements on labels means the height of capital letters or lower case letters having an ascender or a descender.

“Hemp seed oil” means the oil obtained by cold expression from the ripened fruits (seeds) of Cannabis sativa.

“Immediate container” includes all forms of containers in which a medicine or poison is directly packed but does not include any such container intended for consumption or any immediate wrapper.

“Immediate wrapper” means metal foil, plastic foil, waxed paper, or any other such material not intended for consumption, when used as the first wrapper for a dosage unit or dressing.

“Internal use” means administration:

- (a) orally, except for topical effect in the mouth; or
- (b) for absorption and the production of a systemic effect,
 - (i) by way of a body orifice other than the mouth; or
 - (ii) parenterally, other than by application to unbroken skin.

“Label” means:

- (a) a written statement on a container of a poison; and
- (b) in relation to a therapeutic product, includes a display of printed information about the product:
 - (i) on, or attached to, the product; or
 - (ii) on, or attached to, a container or primary pack in which the product is supplied;
or
 - (iii) otherwise intended to be supplied to consumers with such a container or pack.

“Main label” means:

- (a) the part of a label that is most likely to be displayed, presented, shown, or examined under ordinary or customary conditions of display; and
- (b) where there are two or more labels or two or more portions of a single label – that label or portion of the label where the product name is more or most conspicuously shown; or
- (c) where the product name is equally conspicuous on two or more labels or portions of a label – each such label or portion.

“Manufacturer” means a person who manufactures, produces, or packs a medicine or poison.

“Medicine” means a substance when included in the Schedules that:

- (a) is presented as having properties for treating or preventing a disease, ailment, defect or injury in human beings; or
- (b) may be used in human beings with a view to making a medical diagnosis or to restoring, correcting, maintaining or modifying physiological functions.

“Measure pack” means a sealed container which contains a measured quantity of a poison for use on one occasion and one or more of which is enclosed in a primary pack.

“Medicine Label Statements for ANZTPA” (proposed) means the document of that name published by the Australia New Zealand Therapeutic Products Authority on [insert date] as in force from time to time.

“Name and address” in relation to a poison (other than an agricultural or veterinary chemical) means the name and address, in Australia, of the manufacturer or distributor of the poison but does not include a post office, cable, telegraphic or code address. Where such manufacturer or distributor is a company incorporated in accordance with the appropriate law of any State or Territory of the Commonwealth of Australia or a firm registered under the Business Names Act of any State or Territory, the inclusion in the label of the registered name of the corporation or firm or its branch or its division and the city or town in which a registered office is situated shall be deemed to comply with the requirements.

“Non-access packaging” is packaging that complies with the requirements of Australian Standard AS4710-2001 entitled *Packages for chemicals not intended for access or contact with their contents by humans*, in relation to products that are not intended for human therapeutic use.

“Non-volatile content” in relation to a paint or tint means that portion of a paint or tint determined to be the non-volatile content by Method 301.1 of Australian Standard AS 1580.

“Paint”, without limiting the ordinary meaning, includes any substance used or intended to be used for application as a colouring or protective coating to any surface but does not include graphic material.

“Pesticide” has the same meaning as agricultural or veterinary chemical.

“Poison” means any substance or preparation which is included in a Schedule to this Scheduling Standard which is not intended to be used as a medicine.

“Primary pack” means the pack in which a medicine or poison and its immediate container or immediate wrapper or measure pack are presented for sale or supply.

“Restricted flow insert” means a restriction fitted, or moulded, in the neck of a container which:

- (a) cannot readily be removed from the container by manual force; and
- (b) limits the delivery of the contents to drops each of which is not more than 200 microlitres.

“Scheduling”, in relation to a substance, means determining, for the purpose of facilitating the application to the substance of a system of access controls:

- (a) the schedule or schedules in the Scheduling Standard in which the name or a description of the substance is to be included; and
- (b) the application of other parts of the Scheduling Standard to the substance.

“Second Schedule Paint” means a paint containing the specified proportion of any substance in the Second Schedule to Appendix I of this Scheduling Standard.

“Selected container” means:

- (a) an injection vial having a nominal capacity of ten millilitres or less;
- (b) a single use syringe; or
- (c) any other container for substances for therapeutic use having a nominal capacity of ten millilitres or less.

“Solid” is considered to include “powder” for the purposes of scheduling.

“Substance” has the meaning given by section 1.02 of the Scheduling Standard.

“Therapeutic use”: means use in or in connection with:

- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in humans or animals;
- (b) influencing, inhibiting or modifying a physiological process in humans or animals;
- (c) testing the susceptibility of humans or animals to a disease or ailment;
- (d) influencing, controlling or preventing conception in humans or animals;

“Third Schedule Paint” means a paint containing the specified proportion of any substance in the Third Schedule to Appendix I of this Scheduling Standard.

“Tinter” means any pigment or admixture of pigment with other substances, in powder, semi-solid or liquid form, sold or supplied for the purpose of adding to paint in order to change the colour of the paint.

“Topical use” means application of a medicine or poison for the purpose of producing a localised effect on the surface of the organ or within the tissue to which it is applied.

“Toy” means an object or number of objects manufactured, designed, labelled or marketed as a plaything for a child or children up to the age of fourteen years.

“Transdermal use” means application to the skin primarily for systemic effect.

“Veterinary chemical” means a substance that is represented as being suitable for, or is manufactured, supplied or used for, administration or application to an animal by any means, or consumption by an animal, as a way of directly or indirectly:

- (a) preventing, diagnosing, curing or alleviating a disease or condition in the animal or an infestation of the animal by a pest; or
- (b) curing or alleviating an injury suffered by the animal; or
- (c) modifying the physiology of the animal:
 - (i) so as to alter its natural development, productivity, quality or reproductive capacity; or
 - (ii) so as to make it more manageable; or
- (d) modifying the effect of another veterinary chemical product.

“Writing” includes the visible representation or reproduction of words or figures in any form, and “to write” and “written” have corresponding meanings.

1.02 References to substances

Unless the contrary intention appears a reference to a substance in a schedule or an appendix to this Scheduling Standard includes:

- (a) that substance prepared from natural sources or artificially; and
- (b) where the substance is a plant (other than a plant included in Schedule 8 or 9), that plant or any part of that plant when packed or prepared for therapeutic use; and
- (c) every salt, active principle or derivative of the substance, including esters and ethers, and every salt of such an active principle or derivative; and
- (d) every alkaloid of the substance and every salt of such an alkaloid; and
- (e) except where the substance is levomethorphan or levorphanol, every stereoisomer of the substance and every salt of such a stereoisomer; and
- (f) every recombinant form of the substance; and
- (g) a preparation or admixture containing any proportion of the substance, but does not include:
 - (h) a preparation or product included in Appendix A, or a substance and the reason for its entry in Appendix B; or
 - (i) any other substance included in Schedules 1 to 6, at a concentration not exceeding 10 mg per litre or 10 mg per kilogram, unless that substance is also included in Schedule 7 or 8 or a lower concentration cut-off is specified in the entry for that substance; or
 - (k) any substance present as an impurity in a pesticide or veterinary chemical, at a concentration at or below the maximum content for that substance, specified for the pesticide in the current version of the *Minimum Compositional Standards (MCS) for Active Constituents* or its successor, as published by the Australian Pesticides and Veterinary Medicines Authority.
- (l) a substance in Schedule 5 or 6 when included in a human therapeutic product:
 - (i) for which a therapeutic product licence has been issued by the Australia New Zealand Therapeutic Products Regulatory Authority and that licence is in force³; or
 - (ii) meeting the conditions for exemption from product licensing for medicines, specified in Parts 1 or 2 of Schedule 4 of the *Australia New Zealand Therapeutic Product Regulatory Scheme (Medicines) Rule 2006*; or
 - (iii) meeting the criteria specified in Part 6 (Exemption from Principle, Procedures and Licensing) for exemption from the requirements of Part 4 (Product Licenses) of the *Australia New Zealand Therapeutic Product Regulatory Scheme (Medical Devices) Rule 2007*; or
 - (iv) meeting the conditions for exemption for medical devices specified in Schedule 5 of the *Australia New Zealand Therapeutic Product Regulatory Scheme (Medical Devices) Rule 2007*.

³ To avoid doubt, a licence continues to be in force during a period in which a licence is suspended.

Provision 1(2)(i) of the SUSDP is no longer required – requirements for dilute preparations will be transferred to each individual substance entry see APPENDIX G.

Additional clauses may be necessary to accommodate other therapeutic products outside the scope of the joint regulatory scheme. These clauses may need to be reviewed as the regulatory approach to these products matures.

1.03 Specification of concentration, strength or quantity

Unless the contrary intention appears where references to a concentration, strength or quantity is specified in a schedule or an appendix to this Scheduling Standard in respect of a substance:

- (a) if the substance is present as a salt, active principle or derivative (including an ester or ether), the concentration, strength or quantity is calculated as the equivalent amount of the substance that is listed in the Schedule or Appendix; and
- (b) the expression “one per cent” means:
 - (i) in the case of a liquid preparation, 1 gram of the substance per 100 millilitres of the preparation; or
 - (ii) in the case of a solid or semi-solid preparation, 1 gram of the substance per 100 grams of the preparation; and
 - (iii) any expression of greater or lesser percentages shall have a corresponding meaning; and
- (c) in the case of codeine such concentration, strength or quantity is calculated as anhydrous codeine.

1.04 References to temperatures

A reference to a boiling or distillation temperature in the schedules means that temperature at an atmospheric pressure of 101.325 kPa (760 millimetres of mercury).

PART 2 Labelling requirements for medicines and poisons

Medicines and poisons

2.01 General

- (1) Any word, expression or statement required by this Scheduling Standard to be written on a label or container must be clearly visible and not obscured and written:
 - (a) on the outside face of the label or container; and
 - (b) in the English language; and
 - (c) in durable and legible characters; and
 - (d) in a colour or colours contrasting strongly with the statement's background; and
 - (e) in letters at least 1.5 millimetres in height.
- (2) Paragraph 2.01(1)(e) does not apply to a word, expression or statement on a container which has a capacity of 20 millilitres or less, or on the label of such a container if:
 - (a) an appropriate authority approves the use of smaller letters; and
 - (b) the letters are at least 1 millimetre in height.
- (3) The label must be printed on, or securely attached to:
 - (a) the outside of the immediate container; and
 - (b) if the immediate container is enclosed in a primary pack, the outside of that primary pack.
- (4) The primary pack and immediate container of a medicine or poison must be labelled with the approved name of the medicine or poison and a statement of the quantity or strength of the medicine or poison as required in:
 - (a) for medicines – the Order for the labelling requirements for medicines made under the therapeutic products legislation;
 - (b) for agricultural and veterinary chemicals – the *Agricultural and Veterinary Chemicals Code 1994* as contained in the Schedule to the Commonwealth *Agricultural and Veterinary Chemicals Code Act 1994*.; and
 - (c) for other poisons - Sections 2.09 and 2.10 of this Scheduling Standard.
- (5) A Class label as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail* may be placed anywhere on the label that does not obscure any other statement or information required to be written on the label by this Standard.

2.02 Signal headings for medicines

The related SUSDP provisions have been reformatted to take account of the separation of requirements for medicines and poisons – see KEY CHANGE 2 at Attachment 1.

Note: The signal heading for a medicine is to be displayed prominently on the label as per the following provision to indicate the restrictions on consumer access to the medicine.

- (1) The primary pack and immediate container of a medicine must be labelled as follows:
- (a) where the medicine is included in a Schedule specified in Column 1 of the following table, with the signal words for that Schedule included opposite in Column 2 of the table:

Column 1 Schedule	Column 2 Signal words required
2	PHARMACY MEDICINE KEEP OUT OF REACH OF CHILDREN
3	PHARMACIST ONLY MEDICINE KEEP OUT OF REACH OF CHILDREN
4	PRESCRIPTION ONLY MEDICINE KEEP OUT OF REACH OF CHILDREN
8	CONTROLLED DRUG POSSESSION WITHOUT AUTHORITY ILLEGAL KEEP OUT OF REACH OF CHILDREN

and

(b) written:

- (i) commencing on the first line of the main label; and
- (ii) in bold-face sans-serif capital letters of uniform thickness; and
- (iii) with the first line of the signal words written in letters at least half the height of the largest letter or numeral on the label but need not be larger than:
- (A) 6 millimetres on labels for packages having a nominal capacity of 2 litres or less; or
- (B) 15 millimetres on labels for packages having a nominal capacity of more than 2 litres; and
- (iv) with the remaining lines of the signal words written in the order shown in column 2, on the second and subsequent lines of the main label, in letters at least four tenths the height of the letters used for the first line; and

- (v) with no other statement written on the same lines as the signal words;
- (2) For the purposes of subparagraph (1) (b)(iii) the term “largest letter or numeral” does not include:
- a) a single letter or numeral which is larger than other lettering on the label; or
 - b) an affix forming part of the trade name; or
 - c) numerals used to distinguish the strength of a preparation from the strengths of other preparations of the same medicine.

2.03 Exemptions for signal heading for medicines

New provisions - see KEY CHANGE 5 at Attachment 1

- (1) The labelling requirements for signal headings do not apply to a specified medicine which:
- (a) meets the criteria for exemption from product licensing in Schedule 4 Part 1 or Schedule 4 Part 2 of the *Australia New Zealand Therapeutic Products Regulatory Scheme (Medicines) Rule 2006*; or
 - (b) has been granted an exemption from the need for product licensing under Part 5 of the *Australia New Zealand Therapeutic Products Regulatory Scheme (Medicines) Rule 2006*; or
 - (c) where an appropriate authority has granted a labelling exemption for a specified medicine.
- (2) The labelling exemption from an appropriate authority referred to in subsection (1) must be limited to no more than 12 months from the effective date of the decision for retail supply of the specified medicine.

2.04 Signal headings for poisons

The related SUSDP provisions have been reformatted to take account of the separation of requirements for medicines and poisons – see KEY CHANGE 2 at Attachment 1.

Note: the signal heading for a poison is to be displayed prominently on the label as per the following provision to indicate the relative degree of severity of the risk of harm to a person using or handling the substance, or in the case of veterinary chemicals for therapeutic use, the level of consumer access to the product.

- (1) The primary pack and immediate container of a poison must be labelled as follows:
- (a) where the poison is included in a Schedule set out in Column 1 of the following table, with the signal words for that Schedule included opposite in Column 2 of the table:

Column 1 Schedule	Column 2 Signal words required
2	PHARMACY MEDICINE KEEP OUT OF REACH OF CHILDREN
4	PRESCRIPTION ANIMAL REMEDY KEEP OUT OF REACH OF CHILDREN
5	CAUTION KEEP OUT OF REACH OF CHILDREN
6	POISON KEEP OUT OF REACH OF CHILDREN
7	DANGEROUS POISON KEEP OUT OF REACH OF CHILDREN
8	CONTROLLED DRUG POSSESSION WITHOUT AUTHORITY ILLEGAL KEEP OUT OF REACH OF CHILDREN

and

(b) written:

- (i) commencing on the first line of the main label; and
- (ii) in bold-face sanserif capital letters of uniform thickness; and
- (iii) with the first line of the signal words written in letters at least half the height of the largest letter or numeral on the label but need not be larger than:
 - (A) 6 millimetres on labels for packages having a nominal capacity of 2 litres or less; or
 - (B) 15 millimetres on labels for packages having a nominal capacity of more than 2 litres; and
- (iv) with the remaining lines of the signal words written in the order shown in column 2, on the second and subsequent lines of the main label, in letters at least four tenths the height of the letters used for the first line; and
- (v) with no other statement written on the same lines as the signal words other than, if the poison is a Schedule 5 poison, a statement of the principal hazard of the poison written on the first line.

(2) For the purposes of subparagraph (1) (b)(iii) the term "largest letter or numeral" does not include:

- a) a single letter or numeral which is larger than other lettering on the label; or
- b) an affix forming part of the trade name; or
- c) in the case of a veterinary chemical, numerals used to distinguish the strength of a preparation from the strengths of other preparations of the same product.

2.05 Application and exemptions

These provisions now use the term ‘authorised prescriber’, rather than list specific healthcare practitioners. ‘Authorised prescriber’ has been defined in the Interpretation Section.

- (1) A person must not sell or supply a medicine or poison unless it is labelled in accordance with sections 2.01 to 2.10.
- (2) Subsection (1) does not apply to a medicine or veterinary chemical that:
 - (a) is supplied by an authorised prescriber in the course of treating a patient or animal in the lawful practice of their profession; or
 - (b) is supplied on and in accordance with a prescription written by an authorised prescriber; or
 - (c) is prepared and supplied by a pharmacist for an individual patient.
- (3) Subsection (1) does not apply to a medicine or poison that:
 - (a) is packed and sold solely for dispensary, industrial, laboratory or manufacturing purposes; and
 - (b) is labelled in accordance with the Australian Safety and Compensation Council *National Code of Practice for the Labelling of Workplace Substances* [NOHSC: 2012 (1994)] or its successors.
- (4) Subsection (1) does not apply to a transparent cover, or to any wrapper, hamper, packing case, crate or other cover used solely for the purposes of transport or delivery.

2.06 Prohibitions

- (1) A label used in connection with any medicine or poison must not include:
 - (a) any reference to this Scheduling Standard, or any comment on, reference to, or explanation of any expression required by this Scheduling Standard that directly or by implication contradicts, qualifies or modifies such expression; or
 - (b) any expression or device suggesting or implying that a medicine or poison is safe, harmless, non-toxic, non-poisonous, or is recommended or approved by the Government or any government authority unless required by legislation; or
 - (c) any expression or device which is false or misleading in any particular concerning the safety of the medicine or poison or any of its ingredients; or

- (d) any trade name or description that:
 - (i) represents any single constituent of a compound preparation;
 - (ii) misrepresents the composition or any property or quality of the medicine or poison; or
 - (iii) gives any false or misleading indication of origin or place of manufacture of the medicine or poison.
- (2) A label must not be attached to the immediate container or primary pack used in connection with any medicine or poison in such a manner as to obscure:
 - (a) any expression required by this Scheduling Standard to be written or embossed on the container or pack; or
 - (b) any of the ribs or embossed or printed words required by sections 3.03 and 3.04 as appropriate.

Additional requirements for labelling of poisons other than agricultural and veterinary chemicals

Note: The additional requirements at 2.07 - 2.10 only apply to poisons other than agricultural or veterinary chemicals as equivalent requirements for labelling are included in the {name of labelling order for medicines} for medicines and the Agvet Code for agricultural and veterinary chemicals.

2.07 Identification Information – immediate wrapper

This provision has been reworded – see KEY CHANGE 2 at Attachment 1.

A poison, other than an agricultural or veterinary chemical, enclosed in an immediate wrapper must be contained in a primary pack labelled in accordance with this scheduling standard; and

- (a) the immediate wrapper must be conspicuously labelled with:
 - (i) the name of the manufacturer or distributor or the brand name or trade name used exclusively by the manufacturer or distributor for that poison; and
 - (ii) the approved name of the poison; and
 - (iii) a statement of the quantity or strength of the poison in accordance with section 2.10.

2.08 Primary packs and immediate containers

These provisions have been reformatted to take account of the separation of requirements for medicines and poisons – see KEY CHANGE 2 at Attachment 1.

- (1) The primary pack and immediate container of a poison, other than an agricultural or veterinary chemical, must be labelled:
 - (a) with the name and address of the manufacturer and distributor of the poison;

- (b) with the approved name of the poison in accordance with section 2.09;
- (c) with a statement of the quantity, proportion and strength of the poison in accordance with section 2.10; and
- (d) in accordance with the any applicable requirements of the table immediately following this section.

(2) Where the condition or conditions as set out in Column 1 of the table apply, the label must contain the statement or statements included in Column 2 of the table, written as specified in Column 3 of the following table.

SUSDP provisions 7(1)(f), 7(1)(i), 7(1)(k)(i), and 7(1)(l) have been transferred to other legislation – see KEY CHANGE 1 at Attachment 1.

Column 1 Condition/s	Column 2 Statement/s required	Column 3 Written
(a) The poison is a dry chlorinating compound containing more than 10 percent of available chlorine, except for preparations certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5.1 (oxidising substances)	FIRE AND EXPLOSION HAZARD	(i) on a separate line or lines immediately below the signal words “KEEP OUT OF REACH OF CHILDREN” as required by paragraph 2.04(1)(a); and (ii) in bold-face sanserif capital letters of uniform thickness; and (iii) in letters at least four tenths the height of the letters used for the
(b)The poison is an alkaline salt in a dishwashing machine product	BURNS SKIN AND THROAT	signal word or words; and (iv) with nothing else written on the same line.
(c) The poison may be harmful to the user and requires safety directions specified by paragraph 2.08(2)(f)	READ SAFETY DIRECTIONS BEFORE OPENING OR USING or READ SAFETY DIRECTIONS	(i) on a separate line or lines; (A) immediately below the signal words “KEEP OUT OF REACH OF CHILDREN” as required by paragraph 2.04(1)(a); or (B) if one or more other cautionary statements is required to be on the line immediately below “KEEP OUT OF REACH OF CHILDREN”, immediately below that statement or those statements;

Column 1 Condition/s	Column 2 Statement/s required	Column 3 Written
		<p>(ii) in bold-face sanserif capital letters of uniform thickness; and</p> <p>(iii) in letters at least four tenths the height of the letters used for the signal word or words; and</p> <p>(iii) with nothing else written on the same line.</p>
(d) The poison meets the criteria for a 'flammable liquid' in the <i>Australian Code for the Transport of Dangerous Goods by Road or Rail</i> , as in force at The commencement of this Scheduling Standard and as amended from time to time	FLAMMABLE	on the main label in bold-face sanserif capital letters of uniform thickness, unless already present in accordance with the requirements of the <i>Australian Code for the Transport of Dangerous Goods by Road or Rail</i> ;
(e) The poison is a Schedule 5 poison	DO NOT SWALLOW	in bold-face sanserif capital letters on the main label or as part of the directions for use;
(f) The poison is included in Appendix F of this Scheduling Standard	Safety directions as required by Appendix F, prefaced by the words: SAFETY DIRECTIONS	written in bold-face sanserif capital letters with the appropriate safety directions grouped together as a distinct section of the label;
	Warning statements as required by Appendix F	grouped together; (i) if safety directions are included on the label, immediately after the words "SAFETY DIRECTIONS"; or (ii) if there are no safety directions, immediately preceding the directions for use;
(g) The poison is included in Appendix E of this Scheduling Standard	First aid directions as required by Appendix E, prefaced by the words:	written in bold-face sanserif capital letters with the appropriate first aid instructions grouped together;

Column 1 Condition/s	Column 2 Statement/s required	Column 3 Written
	FIRST AID	<p>(i) if a primary pack contains two or more immediate containers of poisons each requiring different first aid instructions:</p> <p>(A) written on each immediate container as specified in Columns 2 and 3; and</p> <p>(B) replaced on the primary pack with the statement –</p> <p>FIRST AID: See inner packs;</p>
(h)The poison is prepared, packed or sold for a specific purpose	<p>Directions for use unless it is impractical to include such directions on the label and:</p> <p>(i) the primary pack and the immediate container are labelled with the statement “DIRECTIONS FOR USE: See package insert”; and</p> <p>(ii) an appropriate authority has authorised the directions for use to be written on a package insert instead of the label; and</p> <p>(iii) the insert is enclosed in the primary pack.</p>	clearly and adequately

2.09 Approved name

The related SUSDP provisions have been reformatted to improve usability.

- (1) The approved name of the poison and a statement of the quantity proportion or strength of the poison as stated in 2.10 must be written in bold-face sanserif capital letters on the main label, unless:

- (a) a list of approved names is required; and
 - (b) it is impractical to include the list on the main label; and
 - (c) an appropriate authority has authorised its inclusion on another part of the label.
- (2) If the poison is a Schedule 5 poison referred to in Column 1 of the following table the name opposite thereto in Column 2 may be used as the approved name:

Column 1	Column 2
Alkaline Salts	Alkaline Salts
Amines for use as curing agents for epoxy resins (unless separately specified in the Schedules)	Aliphatic amines or aromatic amines
Epoxy resins, liquid	Liquid epoxy resins
Hydrocarbons, liquid	Liquid hydrocarbons
Quaternary ammonium compounds	Quaternary ammonium compound(s)

- (3) If a poison contains a mixture of designated solvents in excess of 25 per cent of the total volume of the poison but the proportion of one or more individual designated solvents in the mixture is equal to or less than 25 per cent, the approved names of those solvents may be expressed as follows:
- (a) where the designated solvent is a liquid hydrocarbon as "liquid hydrocarbons"; or
 - (b) where the designated solvent is a ketone as "ketones"; or
 - (c) in any other case as "solvents" or "other solvents".

2.10 Statements of quantity, proportion or strength

The statement of the quantity, proportion or strength of a poison must be expressed in the most appropriate of the following forms:

- (a) if the poison is a liquid in a liquid preparation, as the mass or volume of the poison per stated volume of the preparation;
- (b) if the poison is a liquid in a solid or semi-solid preparation, as the mass or volume of the poison per stated mass of the preparation;
- (c) if the poison is a solid or semi-solid in a liquid preparation, as the mass of the poison per stated volume of the preparation;
- (d) if the poison is a solid or semi-solid in a solid or semi-solid preparation, as the mass of the poison per stated mass of the preparation;
- (e) if the poison is a gas in a liquid preparation, as the mass of the poison per stated volume of the preparation;

- (f) if the poison is a gas in a solid or semi-solid preparation, as the mass of the poison per stated mass of the preparation;
- (g) if the poison is a gas in a gaseous preparation, as the mass of the poison per stated mass of the preparation;
- (h) if the poison is a solution of a mineral acid, the proportion of the acid may be expressed as the mass of the acid per stated mass of the preparation;
- (i) if the poison is an inorganic pigment, the proportion may be expressed as a percentage of the metal present using one of the following expressions as appropriate:
 - contains not more than 10 per cent (*name of the metal*); or
 - contains not more than 30 per cent (*name of the metal*); or
 - contains more than 30 per cent of (*name of the metal*);
- (j) if the poison is included in a paint, other than a paint for therapeutic or cosmetic use, the proportion may be expressed as a range provided that the limits of the range do not differ by more than 5 per cent of the product;
- (k) if the poison is a lead-based pigment included in automotive paint, the proportion may be expressed as the maximum content of the lead that may be present in the non-volatile content of the paint;
- (l) if a preparation contains more than one derivative of a poison, the quantity or proportion of the poison may be expressed as the equivalent quantity or proportion of one of the derivatives present which it would contain if all of the derivatives were that derivative;
- (m) for the purposes of subsection 2.10(l) "derivative" includes alkaloid.

Note: the Agricultural/veterinary Code requires the approved name of an agricultural or veterinary chemical and a statement of quantity, proportion and strength of the agricultural/veterinary chemical to also be included on the label and specifies related requirements.

2.11 Exemptions from additional labelling requirements for certain poisons

Gas cylinders

(1) The requirements of subparagraph 2.04(1)(b)(v) do not apply to a cylinder containing a poison that is a compressed gas.

Paints and Tinters

(2) The requirements of sections 2.04 and 2.08 do not apply to a poison which is a paint (other than a paint which is for cosmetic use) or tinter which meet the conditions set out in Column 1 of the table immediately following this subsection, provided that any statements as specified opposite in Column 2 of that table are included on the label.

Column 1	Column 2
Condition	Label statement required
(a) The paint/tinter contains only Schedule 5 poisons	
(b) The paint / tinter is a First Schedule, Second Schedule	The name and proportion of the First Schedule, Second Schedule or Third Schedule poisons it contains, provided that

Column 1 Condition	Column 2 Label statement required
or Third Schedule poison in Appendix I	where the substance is a metal or metal salt the proportion is expressed as the metallic element present calculated on the non-volatile content” or “in the dried film” of the paint.
(c)The paint/tinter is: (i) a paint which is a First Schedule, Second Schedule or Third Schedule poison in Appendix I; or (ii) a tinter which is or contains a First Schedule, Second Schedule or Third Schedule poison in Appendix I and it contains more than 0.1 percent of lead in the non-volatile content of the tinter.	(i) The word WARNING written in bold-face sanserif capital letters, the height of which is not less than 5 mm, on the first line of the main label with no other words written on that line; and (ii) the expression “KEEP OUT OF REACH OF CHILDREN”, written in bold-face sanserif capital letters, the height of which is not less than 2.5 mm, on a separate line immediately below the word “WARNING”; and (iii) the appropriate warnings specified for the paint in Appendix F, written immediately below the expression “KEEP OUT OF REACH OF CHILDREN”.

Camphor and naphthalene

- (3) The labelling requirements of paragraph 2.01(1)(d) and sections 2.04 and 2.08 of this Scheduling Standard do not apply to a device that contains camphor or naphthalene in block, ball, disc or pellet form if the device:
- (a) complies with subsection 3.06(3); and
 - (b) is sold or supplied in a primary pack labelled in accordance with subsection 2.01(1) and sections 2.04 and 2.08.

2.12 Exemptions from additional labelling requirements for certain containers

The requirements of section 2.04 do not apply to an immediate container that is a measure pack or selected container when:

- (1) packed in a primary pack labelled in accordance with section 2.04; and
- (2) labelled with:
 - (a) the signal word or words, relating to the Schedule in which the poison is included and the purpose for which it is to be used, as shown in the table to paragraph 2.04(1)(a); and
 - (b) the approved name of the poison and the quantity, proportion or strength of the poison in accordance with section 2.10; and
 - (c) the name of the manufacturer or distributor or the brand name or trade name used exclusively by the manufacturer or distributor for the poison.

SUSDP Provision 9(2)(d) has been transferred to other legislation – see KEY CHANGE 1 at Attachment 1.

DRAFT

PART 3 Container requirements for poisons other than agricultural and veterinary chemicals

This part has been reformatted to take account of KEY CHANGES 1 and 2 at Attachment 1.

3.01 Application and exemptions

- (1) A person must not sell or supply a poison, other than an agricultural or veterinary chemical unless the immediate container complies with all the provisions of this Part.
- (2) Subsection (1) does not apply to a poison that is packed and sold solely for industrial, laboratory, dispensary or manufacturing purposes.

Note: Equivalent requirements for containers are included in the {name of order for containers for medicines} for medicines and the Agvet Code for agricultural and veterinary chemicals.

3.02 Child-resistant closures

- (1) If a poison listed in Column 1 of the following table is sold or supplied in a container having a nominal capacity specified opposite for that poison in Column 2, the container must be closed with a child-resistant closure.

Column 1 Name of the poison	Column 2 Nominal Capacity
Alkaline salts included in Schedule 5, when packed and labelled as dishwashing machine tablets.	All sizes
Alkaline salts included in Schedule 5, when packed and labelled as dishwashing machine liquids or gels.	5 litres/kilograms or less
Alkaline salts included in Schedule 5, when packed and labelled as a food additive.	2.5 litres or less
Anise oil when included in Schedule 5.	200 millilitres or less
Basil oil when included in Schedule 5.	200 millilitres or less
Bay oil when included in Schedule 6.	200 millilitres or less
Cajuput oil when included in Schedule 6.	200 millilitres or less
Cassia oil when included in Schedule 5.	200 millilitres or less
Cineole when included in Schedule 6.	2 litres or less
Cinnamon bark oil when included in Schedule	200 millilitres or less

Column 1 Name of the poison	Column 2 Nominal Capacity
5.	
Cinnamon leaf oil when included in Schedule 6.	200 millilitres or less
Clove oil when included in Schedule 6.	200 millilitres or less
Essential oils when included in Schedule 6 because of their natural camphor component.	200 millilitres or less
Ethylene glycol when included in Schedule 6.	5 litres or less
Ethylene glycol when included in Schedule 5 in preparations containing more than 50per cent of ethylene glycol.	5 litres or less
Eucalyptus oil when included in Schedule 6	2 litres or less
Eugenol when included in Schedule 6.	200 millilitres or less
Hydrocarbons, liquid, when packed as kerosene, lamp oil, mineral turpentine, thinners, reducers, white petroleum spirit or dry cleaning fluid.	5 litres or less
Hydrochloric acid when included in Schedule 6.	5 litres or less
Marjoram oil when included in Schedule 5.	200 millilitres or less
Melaleuca oil (tea-tree oil) when included in Schedule 6.	200 millilitres or less
Methylated spirit excluding preparations or admixtures.	5 litres or less
Methyl salicylate and preparations containing more than 50 per cent of methyl salicylate.	200 millilitres or less
Nutmeg oil when included in Schedule 5.	200 millilitres or less
Oil of turpentine.	5 litres or less
Pennyroyal oil when included in Schedule 6.	200 millilitres or less
Potassium hydroxide as such.	2.5 litres or less
Potassium hydroxide in oven, hotplate or drain cleaners when included in Schedule 6 except when in pressurised spray packs.	5 litres or less
d-Pulegone when included in Schedule 6.	200 millilitres or less
Sage oil (Dalmatian) when included in Schedule 6.	200 millilitres or less
Sodium hydroxide as such.	2.5 litres or less

Column 1 Name of the poison	Column 2 Nominal Capacity
Sodium hydroxide in oven, hotplate or drain cleaners when included in Schedule 6 except when in pressurised spray packs.	5 litres or less
Thujone when included in Schedule 6	200 millilitres or less
Thyme oil when included in Schedule 5.	200 millilitres or less

- (2) The manufacturer or packer of a poison listed in the table must ensure that the child-resistant closure is appropriate for the container and the poison and that it retains its child-resistant properties for the expected life of the poison.

SUSDP Provision 25A Schedule 8 poisons has been transferred to other legislation – see KEY CHANGE 4 at Attachment 1.

3.03 Containers for poisons other than Schedule 5 poisons

- (1) If a poison, other than a Schedule 5 poison, is sold or supplied in a container with a nominal capacity of 2 litres or less, the container must comply with Australian Standard AS 2216 – 1997, *Packaging for Poisonous Substances* (ISBN 0 7337 1176 6) as published by Standards Australia.
- (2) If a poison, other than a Schedule 5 poison, is sold or supplied in a container with a nominal capacity of more than 2 litres, the container must:
- (a) comply with subsection 1.4 (General Requirements) of Australian Standard AS 2216 – 1997; and
 - (b) have the word "POISON" on the side or shoulder of the container:
 - (i) embossed; or
 - (ii) indelibly written in a colour in distinct contrast to the background colour;

in sanserif capital letters the height of which is at least one thirty second part of the length, height or width of the container, whichever is the greatest.

3.04 Containers for Schedule 5 poisons

- (1) The container in which any Schedule 5 poison is sold or supplied must:
- (a) comply with the container requirements of subsection 3.03(1) or subsection 3.03(2); or
 - (b) be readily distinguishable from a container in which food, wine or other beverage is sold; and
 - (i) comply with subsection 1.4 (General Requirements) of Australian Standard AS 2216 – 1997 excluding paragraph 1.4.3;

- (ii) be securely closed and, except when containing a preparation for use on one occasion only, be capable of being re-closed to prevent spillage of its contents; and
- (iii) have the expression "POISON", "NOT TO BE TAKEN" or "NOT TO BE USED AS A FOOD CONTAINER" embossed or indelibly written thereon, or printed on a permanent adhesive label designed to adhere to a substrate without lifting and which cannot be removed without damaging either the label or the substrate.

(2) Notwithstanding subsection (1), the following Schedule 5 poisons namely:

- (a) methylated spirit(s);
- (b) liquid hydrocarbons when packed as kerosene, lamp oil, mineral Turpentine, thinners, reducers, white petroleum spirit or dry cleaning fluid;
- (c) petrol;
- (d) toluene; or
- (e) xylene,

must not be sold or supplied in a bottle or jar having a nominal capacity of 2 litres or less, unless the immediate container complies with the container requirements specified in subsection 3.03(1).

3.05 Approved containers for poisons

- (1) Notwithstanding sections 3.03 and 3.04 a poison may be packed in a container that does not comply with the tactile identification requirements of the Australian Standard AS 2216 -1997 or the requirements of paragraph 3.03(2)(b) or subparagraph 3.04(1)(b)(iii) if:
 - (a) the other safety factors are not diminished;
 - (b) the container is for a specific purpose; and
 - (c) an appropriate authority has approved the use of the container for that purpose.
- (2) Notwithstanding subsection 3.03(1) a poison which is included in Schedule 6 and is an essential oil may be packed in an amber glass container which does not comply with the tactile identification requirements of the Australian Standard AS 2216 - 1997 if:
 - (a) the other safety factors are not diminished; and
 - (b) the container is fitted with a restricted flow insert and a child-resistant closure.

3.06 Exemptions from container requirements for certain poisons

Paints, small containers and poisons for use in automatic photographic or photocopy processing machines

- (1) Sections 3.03 and 3.04 do not apply to the immediate container of a poison prepared, packed and sold:
 - (a) as a paint, other than a paint which is for cosmetic use; or

- (b) in containers having a nominal capacity of 15 millilitres or less; or
- (c) for use in automatic photographic or photocopy processing machines if the container is specifically designed to fit into the machines.

Aerosol containers, collapsible tubes and flexible measure packs

- (2) The tactile identification or embossing required by sections 3.03 or 3.04 of this scheduling standard or Australian Standard AS 2216 – 1997 do not apply to a container that is an aerosol container, a collapsible tube, or a measure pack which is a flexible sachet.

Camphor and naphthalene

- (3) The container requirements of section 3.03 do not apply to a device that contains only camphor or naphthalene in block, ball, disc or pellet form for domestic use, if the device:

- (a) in normal use, prevents removal or ingestion of its contents; and
- (b) is incapable of reacting with the poison; and
- (c) is sufficiently strong to withstand the ordinary risks of handling, storage or transport; and
- (d) has the word "POISON" and the approved name of the poison embossed or indelibly printed on it.

3.07 Prohibitions

- (1) A person must not sell or supply:
- (a) camphor or naphthalene in ball, block, disc or pellet form for domestic use unless the balls, blocks, discs or pellets are enclosed in a device which, in normal use, prevents removal or ingestion of its contents ; or
 - (b) a poison in a container which has the name of another poison embossed or indelibly marked thereon; or
 - (c) any poison which is for internal use or any food, drink or condiment in a container prescribed by sections 3.03 or 3.04; or
 - (d) any poison, not including a food additive, in a food, drink or a condiment container.

SUSDP Provisions relating to Advertising have been transferred to other legislation – see KEY CHANGE 3 at Attachment 1.

PART 4 Advertising, sale, supply, possession, storage and dispensing of medicines and poisons

4.01 Advertising

- (1) A person must not include any reference to a substance included in Schedule 9 or Appendix C of this Scheduling Standard in any advertisement.

4.02 Sale or supply of Schedule 2 medicines

- (1) A person, other than a pharmacist (or an assistant under the direction of a pharmacist) or an authorised prescriber in the lawful practice of their profession, must not sell or supply a Schedule 2 medicine unless licensed to do so.
- (2) A person is not eligible to be granted a licence to sell a Schedule 2 medicine by way of retail sale unless:
 - (a) the person is carrying on the business of selling goods by retail; and
 - (b) the premises from which the medicine will be sold is more than 25 kilometres by the shortest practical route from the nearest pharmacy; and
 - (c) the person satisfies an appropriate authority that the person is fit and proper to be licensed under relevant State/Territory legislation.
- (3) Notwithstanding subsection (1), a person is not eligible to be granted a licence to sell any Schedule 2 substance included in Appendix L of this Scheduling Standard.

4.02(3) is a new provision, required as a result of the creation of the new Appendix L – see KEY CHANGE 7 at Attachment 1.

4.03 Sale or supply of Schedule 3 medicines

- (1) A person, other than a pharmacist, or authorised prescriber, in the lawful practice of his or her profession, must not sell or supply a Schedule 3 medicine.
- (2) The person who sells or supplies a Schedule 3 medicine must:
 - (a) provide adequate instructions for use, either written or verbal, at the time of supply or sale; and
 - (b) label the container with his or her name or the name of the professional practice and the address from which it was sold or supplied.

4.04 Supply of certain Schedule 3 medicines to be recorded

- (1) A pharmacist who supplies a Schedule 3 substance in Appendix H, whether on prescription or otherwise, must record details of the supply.

SUSDP Provision 37(3) has evolved into new provision 4.04, required as a result of the creation of new Appendix H – see KEY CHANGE 6 at Attachment 1.

4.05 Sale or supply of Schedule 4 medicines or veterinary chemicals

These provisions now use the term ‘authorised prescriber’, rather than list specific healthcare practitioners. ‘Authorised prescriber’ has been defined in the Interpretation Section.

- (1) A person, other than an authorised prescriber in the ordinary course of their professions or a pharmacist dispensing a legal prescription must not sell or supply a Schedule 4 medicine or veterinary chemical.
- (2) Subsection (1) does not apply to a pharmacist who sells or supplies a Schedule 4 medicine or veterinary chemical, other than a medicine or veterinary chemical excepted by regulation from this provision, without a prescription if:
 - (a) the patient is under medical treatment with the medicine or veterinary chemical and continuation of medication is essential; and
 - (b) the quantity sold or supplied does not exceed 3 days medication; and
 - (c) the pharmacist is satisfied that an emergency exists.
- (3) Section 4.03 and subsections 4.02(1) and 4.05(1) do not apply to sale by way of wholesale dealing to a pharmacist, an authorised prescriber or a person licensed or otherwise authorised to possess, sell or supply such medicines or veterinary chemicals.

4.06 Possession, use, sale and supply of Schedule 7 poisons

- (1) A person must not possess or use a Schedule 7 poison for domestic or domestic garden purposes.
- (2) A person must not sell or supply:
 - (a) a Schedule 7 poison for domestic or domestic garden purposes; or
 - (b) a Schedule 7 poison being a liquid preparation containing paraquat unless it is coloured blue or green and contains sufficient stenching agent to produce an offensive smell; or
 - (c) a Schedule 7 poison for which an authorisation to possess or use is required by subsection (3) unless the purchaser produces his or her authorisation.
- (3) A person must not possess or use any of the following Schedule 7 poisons unless he or she is authorised to do so by the appropriate authority:
 - (a) arsenic;
 - (b) cyanides;

- (c) fluoroacetic acid;
 - (d) fluoroacetamide;
 - (e) hydrocyanic acid;
 - (f) strychnine;
 - (g) thallium.
- (4) The appropriate authority may exempt a person or a class of persons from the requirement to hold an authorisation under subsection (3) and may vary or revoke the exemption by notice in writing.
- (5) For the purposes of this paragraph, “notice” means a notice issued by the appropriate authority under the relevant State/Territory legislation.

4.07 Prohibitions on sale, prescribing and possession of certain medicines and poisons

- (1) A person must not:
- (a) obtain, possess, administer, sell, supply or use a substance listed in Appendix C of this Scheduling Standard for the purpose or purposes indicated in relation to that medicine or poison in Appendix C; or
 - (b) sell or supply, other than by way of wholesale dealing, or prescribe a medicine or poison listed in Appendix D sections 1.02, 1.03, 1.04 or 1.05 except in accordance with the provisions indicated for that medicine or poison in Appendix D; or
 - (c) knowingly have in his or her possession a medicine or poison listed in Appendix D section 1.06 without authority; or
 - (d) obtain, possess, administer, prescribe, sell, supply, distribute or use a substance listed in Schedule 9 unless authorised in writing by the appropriate authority.

4.08 Storage of certain medicines and poisons

- (1) A person who sells or supplies Schedule 2 medicines must keep those medicines in such a way that public access to advice from a pharmacist is available if required.
- (2) A person who sells or supplies medicines or poisons in Schedule 3, Schedule 4 or Schedule 7 must keep those medicines or poisons in a part of the premises to which the public does not have access.

SUSDP Provision 45 (2) (Dispensed medicines) has been transferred to the new Appendix M – see KEY CHANGE 8 at Attachment 1.

4.09 Dispensed medicines

- (1) A person must not supply a dispensed medicine containing:
 - (a) a substance for internal use listed in Appendix K, unless the label of the container bears a sedation warning (being warning statement 39, 40 or 90 as specified in Appendix F, Part 1) which must be immediately preceded by a symbol in the form of an open equilateral triangle at least 4.5 millimetres high in bold print, coloured red; or
 - (b) a substance listed in Column 1 of the table at Appendix M, Part 2 (1) unless it is clearly labelled with a warning statement as specified in Column 2 of that table.

4.10 General requirements for dispensing labels

- (1) A person must not supply a dispensed medicine or veterinary chemical unless it is labelled in accordance with and the requirements of Appendix M, Part 1.

PART 5

THE SCHEDULES

For the purposes of consultation the schedules have been left blank. Scheduling decisions made by the National Drugs and Poisons Schedule Committee (NDPSC) under the Therapeutic Goods Act 1989 that take effect prior to the commencement of the joint regulatory scheme will be incorporated into the new Scheduling Standard. Transitional arrangements will apply for NDPSC decisions made prior to the commencement of the joint regulatory scheme which have not come into effect.

PART 6

APPENDICES

TO THE

SCHEDULING STANDARD

For the purposes of consultation individual entries in the Appendices have not been incorporated. Decisions made by the National Drugs and Poisons Schedule Committee (NDPSC) under the Therapeutic Goods Act 1989 that take effect prior to the commencement of the joint regulatory scheme will be incorporated into the new Scheduling Standard. Transitional arrangements will apply for NDPSC decisions made prior to the commencement of the joint regulatory scheme which have not come into effect.

APPENDIX A

GENERAL EXEMPTIONS FROM THIS SCHEDULING STANDARD FOR MEDICINES OR POISONS IN CERTAIN KINDS OF PRODUCTS (Subsection 1.02 (h))

This Scheduling Standard does not apply to a medicine or poison in any of the following products:

DRAFT

APPENDIX B

MEDICINES AND POISONS CONSIDERED NOT TO REQUIRE CONTROL BY SCHEDULING

(Subsection 1.02 (h))

[This Appendix should be read in conjunction with Appendix A]

INTRODUCTION

At various times, either the NDPSC (as the former decision making body for the purposes of entries in the SUSDP) or the Authority has considered substances for which the available information suggests that inclusion in the Schedules to the Scheduling Standard is not necessary or not the most appropriate means of controlling the risk to public health.

Listing in Appendix B indicates that a decision has been taken not to list substances anywhere in the Schedules, either for a specific purpose, or generally. It is an inclusive, but not an exhaustive, list ie. there may be substances not included in the Schedules, and not included in Appendix B, which may be hazardous or non-hazardous, but have not been considered in relation to the need for scheduling.

Substances may be included in Appendix B because they have intrinsically low toxicity, or where other factors suggest that the potential public health risk would be minimal.

Factors which are considered when determining an Appendix B entry include:

- The toxicology profile was adequately characterised and not consistent with inclusion in any of the Schedules;
- The use, purpose or product presentation minimised any hazard to the public such as to not require scheduling; or
- The public access was limited such that scheduling was inappropriate or unnecessary.

The list has been developed from current scheduling files and historical records. For transparency, where the reason for entry and/or purpose or use for the substance was apparent in the consideration, this has been included in the columns "Reason for Entry" and "Area of Use".

Inclusion in Appendix B will not prevent reconsideration of the scheduling of a substance where adverse information becomes available about the Appendix B entry for that substance. The Authority considers applications for scheduling. Applications for entry into Appendix B will not be accepted.

PART 1

REASONS FOR ENTRY

PART 2

AREAS OF USE

PART 3

SUBSTANCES CONSIDERED NOT TO REQUIRE CONTROL BY SCHEDULING

SUBSTANCE	DATE	REASON	ENTRY FOR LISTING	AREA OF USE
------------------	-------------	---------------	--------------------------	--------------------

APPENDIX C

MEDICINES AND POISONS, THE SALE, SUPPLY OR USE OF WHICH SHOULD BE PROHIBITED BECAUSE OF THEIR KNOWN POTENTIAL HARM TO HUMAN AND/OR ANIMAL HEALTH

(Subsection 4.01(1), Paragraph 4.07(1)(a))

Substances listed in this Appendix will reflect the most recent version of the SUSDP, including any amendments agreed at the last meeting of the NDPSC before the commencement of the joint regulatory scheme.

DRAFT

APPENDIX D

ADDITIONAL CONTROLS ON POSSESSION OR SUPPLY OF MEDICINES AND VETERINARY CHEMICALS INCLUDED IN SCHEDULE 4 OR 8.

(Paragraphs 4.07(1)(b) and 4.07(1)(c))

Appendix D will be retained. However, the new Appendix D has been reformatted to allow States and Territories to adopt by reference. Flexibility has also been built in to enable States and Territories to further define those substances which can only be prescribed by a specialist physician.

1.00 General

For the purposes of this Appendix the terms “authorised prescriber” and “authorised medical practitioner” are taken to have the same meaning as provided for in the relevant State/Territory legislation which adopts this Appendix.

1.01 Application

This Appendix applies to medicines or veterinary chemicals which are included in Schedule 4 or Schedule 8 of the Scheduling Standard.

1.02. Medicines available only on prescription

The following medicines are available only from, or on the prescription or order of, an authorised medical practitioner:

Substances listed in this Appendix will reflect the most recent version of the SUSDP, including any amendments agreed at the last meeting of the NDPSC before the commencement of the joint regulatory scheme.

Note: Please refer to relevant State/Territory drug legislation for the definition of an “authorised medical practitioner” for the purposes of this section. In some States/Territories certain medicines listed in this section may only be prescribed by a specialist physician.

1.03 Prescribing certain medicine for patients of child-bearing age

(1) Where the medicine to be prescribed is a medicine specified in subsections 1.02 (k), (l), (m), (n), (o), (p) or (q) of this Schedule and the patient is a woman of child-bearing age, the prescriber must:

- (a) ensure that the possibility of pregnancy has been excluded prior to commencement of treatment; and
- (b) if the medicine is -
 - (i) acitretin or etretinate, advise the patient to avoid becoming pregnant during or for a period of 24 months after completion of treatment;
 - (ii) bexarotene, isotretinoin, tretinoin for oral use or thalidomide, advise the patient to avoid becoming pregnant during or for a period of 1 month after completion of treatment; or
 - (iii) bosentan, advise the patient to avoid becoming pregnant during or for a period of 3 months after completion of treatment.

1.04 Medicines which can only be prescribed by a specialist physician

Where the medicine to be prescribed is alefacept, the medicine must only be prescribed from, or on the prescription or order of, a dermatologist.

1.05 Medicines which require an authority from the Authority to prescribe

Where the medicine to be prescribed is dronabinol (delta-9-tetrahydrocannabinol), the medicine must only be available from, or on the prescription or order of, an authorised medical practitioner authorised by the Managing Director of the Authority under (*relevant part of Therapeutic Products legislation referring to special access scheme*).

1.06 Possession of medicines or veterinary chemicals without an authority

Possession of the following medicines or veterinary chemicals without an authority is illegal (e.g. possession other than in accordance with a legal prescription):

Substances listed in this Appendix will reflect the most recent version of the SUSDP, including any amendments agreed at the last meeting of the NDPSC before the commencement of the joint regulatory scheme.

APPENDIX E
FIRST AID INSTRUCTIONS FOR POISONS
(other than agricultural or veterinary chemicals or chemicals
packed and sold solely for industrial use)
(Subsection 2.08(2)(g))

*Appendix E will be retained for poisons only. The requirements for medicines will be removed from the Appendix accordingly and transferred to the ANZTPA 'Required Advisory Statements for Medicine Labels' (RASML).
The requirements for agricultural and veterinary chemicals are contained in the FAISD Handbook (Handbook of First Aid Instructions, Safety Directions and Warning Statements for Agricultural and Veterinary Chemicals) - see KEY CHANGE 4 at Attachment 1.*

INTRODUCTION

Directions for First Aid Attention

Under poisons legislation, scheduled substances and their preparations are required to be labelled with appropriate directions for first aid attention in case of poisoning. It is the responsibility of the manufacturer and supplier of a poison to ensure that the first aid instructions included on the label of a poison are appropriate for a specific product. The following code has been prepared as a guide for health authorities and manufacturers in drafting suitable first aid directions for this purpose. Standard statements specified in this Appendix may be varied provided that the intent is not changed.

The directions listed for any particular substance may require modification to take into account combination of that substance with other substances, both toxic and non toxic, in a formulation, as well as the physical form and presentation of the product. Any such modification should be concise and readily understood.

These First Aid Instructions include action to be taken in case of eye contamination from substances recognised as causing direct poisoning via the eye, causing severe eye damage or requiring prolonged flushing to free the absorbed substance from the eye tissue. However, it is recognised that many other substances or preparations will require a statement of varying nature depending on the detailed formulation. While the necessity to flush the eyes in case of accident will be so self-evident as not to justify label space in many instances, a statement such as "If in eyes rinse well with water" may be appropriate.

Modified First Aid Instruction on Primary Pack

Where a primary pack contains two or more immediate containers of poisons each requiring different first aid instructions:

- (a) each immediate container must be labelled with first aid instructions appropriate for its contents; and
- (b) the primary pack must be labelled with the statement:

FIRST AID: See inner packs.

Exempt Preparations

This Appendix applies only to scheduled poisons. The directions are for substances and their preparations at the concentrations at which the Schedules apply. If it is thought desirable to show first aid instructions for a substance exempted from the Schedules, it is the responsibility of the manufacturer to ensure they are appropriate.

Poisons Information Centre Telephone Numbers

Companies should use the poisons information centre telephone number(s) appropriate to the country(ies) of sale for the product, that is Australia or New Zealand or both. These are 13 1126 for Australia and 0800 764 766 for New Zealand.

Companies wishing to use a poisons information centre telephone number other than the national telephone numbers for Australia and New Zealand must meet the following criteria:

1. The poisons information service whose number is used must be attended by adequately trained staff for 24 hour emergency poisons information; and
2. Calls must be logged and submitted for incorporation into the official collection of poisoning data.

APPENDIX E

PART 1

STANDARD STATEMENTS

To be grouped together and prefaced with the words "FIRST AID" (refer paragraph 2.08(2)(g))

Standard Statements

APPENDIX E

PART 2

POISONS TO BE LABELLED WITH FIRST AID INSTRUCTIONS

(other than agricultural or veterinary chemicals or chemicals packed and sold solely for industrial use)

Labelling is not required at concentrations below scheduled levels (see the Introduction to this Appendix).

POISON

STANDARD STATEMENTS

Substances and standard statements listed in this Appendix will reflect the most recent version of the SUSDP, including any amendments agreed at the last meeting of the NDPSC before the commencement of the joint regulatory scheme.

APPENDIX F WARNING STATEMENTS AND GENERAL SAFETY DIRECTIONS FOR POISONS

(other than agricultural or veterinary chemicals
or chemicals packed and sold solely for industrial use)

(paragraphs 2.05(3)(b), 2.08(2)(f) and subparagraph 2.11(2)(c)(ii))

*Appendix F will be retained for poisons only (other than agricultural or veterinary chemicals or chemicals packed and sold solely for industrial use).
The requirements for medicines are to be removed from the Appendix accordingly and transferred to the ANZTPA 'Required Advisory Statements for Medicine Labels' (RASML) - see KEY CHANGE 4 at Attachment 1.*

INTRODUCTION

Warning Statements and Safety Directions

It is the responsibility of the manufacturer and supplier of a poison to ensure that the purchaser or user of a product is given sufficient information to be able to use it correctly and safely.

Under poisons legislation, scheduled substances, which may be harmful to the user, must be labelled with appropriate warning statements and/or safety directions. The selection of warning statements and safety directions will depend on the formulation of the product, and the use for which it is sold or supplied. The following code has been prepared as a guide for this purpose.

The wording of warning statements and safety directions specified in this Appendix may be varied provided that the intent is not changed. Additional statements also may be added to ensure that the user of a product is sufficiently advised of its harmful nature and how to avoid any deleterious effects.

Poisons Information Centre Telephone Numbers

Companies should use the poisons information centre telephone number appropriate to the country(ies) of sale for the product, that is Australia or New Zealand or both. These are 13 1126 for Australia and free-call number 0800 764 766 for New Zealand.

Companies wishing to use a poisons information centre telephone number other than the national telephone numbers for Australia and New Zealand in warning statement No. 99 in Part 1 of this Appendix must meet the following criteria:

1. The poisons information service whose number is used must be attended by adequately trained staff for 24 hour emergency poisons information; and
2. Calls must be logged and submitted for incorporation into the official collection of poisoning data.

APPENDIX F, Part 1 – Warning Statements

PART 1

WARNING STATEMENTS

APPENDIX F

PART 2

SAFETY DIRECTIONS – GENERAL

To be grouped together and prefaced with the words “SAFETY DIRECTIONS” - see paragraph 2.08(2)(f) to this Scheduling Standard.

APPENDIX F

PART 3

POISONS TO BE LABELLED WITH WARNING STATEMENTS OR SAFETY DIRECTIONS

(other than agricultural chemicals or veterinary chemicals or chemicals packed and sold solely for industrial use)

(Where more than one statement or direction is required they may be combined to form simple sentences where appropriate.)

POISON

SAFETY

WARNING

STATEMENTS

DIRECTIONS

Substances, warning statements and safety directions listed in this Appendix will reflect the most recent version of the SUSDP, including any amendments agreed at the last meeting of the NDPSC before the commencement of the joint regulatory scheme.

APPENDIX G

The requirements for dilute preparations will be transferred to each individual substance entry in the Schedules.

(blank)

DRAFT

APPENDIX H

SCHEDULE 3 MEDICINES SUBJECT TO MANDATORY RECORDING REQUIREMENTS

(Subsection 4.04(1))

The list of Schedule 3 substances permitted to be advertised in Australia, currently included in Appendix H of the SUSDP, will be transferred to a schedule to a Australia New Zealand Therapeutic Products Regulatory Scheme Rule or Australian legislation - see KEY CHANGE 3 at Attachment 1.

Appendix H will become a new appendix that will contain those Schedule 3 substances that should be subject to national mandatory recording - see KEY CHANGE 6 at Attachment 1.

Blank

APPENDIX I

UNIFORM PAINT STANDARD

(Subsections 2.11(2)(b) and (c))

Appendix I has been retained. However, the new Appendix has been reformatted to allow States and Territories to adopt by reference.

1.01 Definitions

In this Appendix –

“**First Schedule Paint**” means a paint which contains a substance listed in Column 1 of the following table where the substance is present in the proportion specified in Column 2 and the proportion of the substance is calculated as a percentage of the element present in the non-volatile content of the paint.

Column 1 Substance	Column 2 Proportion
antimony or antimony compounds	more than 5 per cent
other than antimony titanate pigments	
barium salts except barium sulfate or barium metaborate	more than 5 per cent
cadmium or cadmium compounds	more than 0.1 per cent
chromium as chromates of ammonia, barium, potassium, sodium, strontium or zinc	more than 5 per cent
selenium or selenium compounds	more than 0.1 per cent

“**Second Schedule Paint**” means a paint which contains a substance listed in Column 1 of the following table and the substance is present in the proportion specified in Column 2.

Column 1 Substance	Column 2 Proportion
dichloromethane (methylene chloride)	more than 5 per cent by wt.
ethylene glycol monoalkyl ethers and their acetates	more than 10 per cent by vol

toluene	more than 50 per cent by vol.
xylene	more than 50 per cent by vol.

“**Third Schedule Paint**” means a paint which contains a substance listed in Column 1 of the following table and the substance is present in the proportion specified in Column 2 and the proportion of the substance is calculated as a percentage of the element present in the non-volatile content of the paint.

Column 1	Column 2
Substance	Proportion
lead or lead compounds	more than 0.1 per cent
lead or lead compounds occurring as an impurity in zinc based paint	more than 0.2 per cent

1.02 Prohibitions – paints containing basic lead carbonate

(1) A person must not manufacture, sell, supply or use a paint containing basic lead carbonate (white lead) except for application as a mirror backing:

- (a) containing not more than 15 per cent of lead in the non-volatile content of the paint; and
- (b) applied not more than 40 microns thick; and
- (c) covered by a paint which does not contain lead.

1.03 Prohibitions – First and Third Schedule Paints

(1) A person must not manufacture, sell, supply or use a kind of paint specified in Column 1 of the following table for application to an item specified opposite in Column 2:

Column 1	Column 2
Kind of Paint	Prohibited Application
(a) a First Schedule Paint or a Third Schedule Paint	(i) a roof or for any surface to be used for the collection or storage of potable water; or (ii) furniture
(b) a First Schedule Paint	(i) any fence, wall, post, gate or building (interior or exterior) other than a building which is used exclusively for industrial

purposes or mining or any oil terminal; or

(ii) any premises used for the manufacture, processing, preparation, packing or serving of products intended for human or animal consumption

(c) a Third Schedule Paint

(i) any fence, wall, post, gate, building (interior or exterior), bridge, pylon, pipeline, storage tank or any similar structure; or

(ii) any premises, equipment or utensils used for the manufacture, processing, preparation, packing or serving of products intended for human or animal consumption.

1.04 Application to toys

A person must not manufacture, sell, supply or use a paint for application to toys unless the paint complies with the specification for coating materials contained in Australian/New Zealand Standard Safety of toys Part 3: Migration of certain elements AS/NZS ISO 8124.3:2003.

1.05 Paints containing pesticides

A person must not manufacture, sell, supply, or use a paint containing a pesticide except a fungicide, algicide, bactericide or antifouling agent.

**APPENDIX J
CONDITIONS FOR AVAILABILITY AND USE OF
SCHEDULE 7 POISONS**

PART 1

CONDITIONS FOR AVAILABILITY AND USE

(NOTE - the following controls are recommended for poisons only when included in Schedule 7. These conditions for availability and use may be implemented through poisons controls or other State or Territory legislation.)

**APPENDIX J
CONDITIONS FOR AVAILABILITY AND USE OF
SCHEDULE 7 POISONS**

PART 2

[Note: Appendix J is currently being reviewed and may require updating in the future dependent on outcome of NDPSC considerations.](#)

A poison listed in this Appendix is to be available only in accordance with the conditions specified beside it in the "Conditions" column. The conditions apply only when the poison is included in Schedule 7.

POISON

CONDITIONS

APPENDIX K

MEDICINES REQUIRED TO BE LABELLED WITH A SEDATION WARNING

(Paragraph 4.09 (1)(a))

Substances listed in this Appendix will reflect the most recent version of the SUSDP, including any amendments agreed at the last meeting of the NDPSC before the commencement of the joint regulatory scheme.

DRAFT

APPENDIX L

SCHEDULE 2 MEDICINES THAT CANNOT BE SOLD BY LICENSED POISON SELLERS

(Subsection 4.02(3))

This is a new appendix that will list substances that may not be sold by licensed poison sellers - see KEY CHANGE 7 at Attachment 1.

Blank

DRAFT

APPENDIX M

REQUIREMENTS FOR DISPENSING LABELS FOR MEDICINES AND VETERINARY CHEMICALS

(Section 4.10; Paragraph 4.09 (1)(b))

This is a new Appendix that lists requirements for dispensing labels.

PART 1 GENERAL REQUIREMENTS FOR DISPENSING LABELS

- (1) All details, words and other required information on a label on a container of a substance for therapeutic use must be in the English language in sanserif font of a letter height not less than 1.5mm.
- (2) All symbols, numbers and words on a label must be in durable characters.
- (3) The label on a container of a substance for therapeutic use must contain the following details:
 - (a) the name, address and telephone number of the dispenser supplying the substance;
 - (b) the approved name of the substance and / or its proprietary name (unless it is a preparation compounded in accordance with the dispenser's own formula);
 - (c) adequate directions for use;
 - (d) the strength and form of the substance;
 - (e) the total quantity of the goods in the container;
 - (f) the words "KEEP OUT OF REACH OF CHILDREN" in red on a white background;
 - (g) if the substance is intended for external use only, the word "POISON", or the words "FOR EXTERNAL USE ONLY", in red on a white background;
 - (h) if the substance is a medicine, the name of the person for whom it was dispensed; and
 - (i) if the substance is a veterinary chemical, the species of animal, the name of the animal's owner and the words "FOR ANIMAL TREATMENT ONLY".
- (4) The label on a container of a medicine or veterinary chemical that is supplied on prescription must also include:
 - (a) the prescription reference number;
 - (b) the date on which the prescription was supplied (unless that date is clear from the prescription reference number); and
 - (c) the directions for use set out in the prescription.

PART 2 ADDITIONAL LABELLING REQUIREMENTS FOR CERTAIN MEDICINES

Medicines required to be labelled with certain warning statements

A substance listed in Column 1 of the following table must be labelled with a warning statement in Appendix F, Part 1 as specified opposite in Column 2.

Column 1	Column 2
substance	Warning statement
levocabastine	62
acitretin or adapalene or bexarotene or etretinate isotretinoin or thalidomide or retinoin for oral use	7, 62 and 76
acitretin or adapalene or bexarotene or etretinate isotretinoin or thalidomide or retinoin for topical use	62 and 77
leflunomide	7, 62 and 87
misoprostol	53

DRAFT

KEY CHANGES:

1	As part of the implementation of Recommendation 22 of the Galbally Review, controls on advertising, labelling and packaging of agricultural and veterinary chemicals will be transferred from the SUSDP to relevant Agricultural and Veterinary Chemicals Legislation. It is anticipated that this will be achieved through: amendment of the <i>Agricultural and Veterinary Chemicals Code Act 1994</i> to include restrictions on advertising of Schedule 4 and Schedule 8 veterinary chemicals; and amendment to the <i>Agricultural and Veterinary Chemicals Code Regulations 1995</i> to include Ministerial Orders on labelling and packaging of agricultural and veterinary chemicals.
2	As decisions relating to the scheduling of poisons will not apply in New Zealand, requirements for medicines and poisons have been separated to assist New Zealand to adopt only the relevant aspects of the SUSMP
3	As part of the implementation of Recommendation 22 of the Galbally Review, controls on advertising of therapeutic products will be transferred from the SUSDP to the new legislation.
4	As part of the implementation of Recommendation 22 of the Galbally Review, controls on packaging and labelling of therapeutic products (except signal headings) will be transferred from the SUSDP to the new therapeutic products legislation. Draft Orders are currently being developed which will implement the transfer of these controls. Building on this recommendation, the NCCTG has also recommended that all packaging and labelling (including signal heading) controls on therapeutic products in Schedule 5 and 6 are transferred into Orders under the Australia New Zealand Therapeutic Products Authority. Substances in Schedules 5 and 6 in the new scheduling standard will therefore not include substances which are specifically used for human therapeutic use.
5	As part of the implementation of Recommendation 20 of the Galbally Review, criteria have been developed by the National Coordinating Committee on Therapeutic Goods (NCCTG) to allow mutual recognition of labelling exemptions granted by other jurisdictions.

6	As part of the implementation of Recommendation 16 of the Galbally Review, jurisdictions will adopt the new Appendix H of the SUSMP that will list substances which have been shown to pose a significant risk of diversion to the illicit market and the public health benefits of recording the supply of these substances has been established.
7	Recommendation 15 of the Galbally Review recommended that persons holding Poisons Licences which permit the retail sale of Schedule 2 products in remote areas where there is no pharmacy be allowed to sell the full range of products in Schedule 2 unless risk of diversion, poisoning or medical misadventure is such that the sale of that product should only be from a pharmacy. As part of the implementation of this Recommendation, the new Appendix L will list substances which licensed poison sellers are not allowed to sell.
8	New Appendix M will list all of the requirements for dispensing labels previously included in the body of the SUSDP.
9	Recommendation 7 of the Galbally Review proposed that the title of the <i>Standard for the Uniform Scheduling of Drugs and Poisons</i> be changed to the <i>Standard for the Uniform Scheduling of Medicines and Poisons</i> .