

FINAL DECISIONS & REASONS FOR DECISIONS BY DELEGATES OF THE SECRETARY TO THE DEPARTMENT OF HEALTH AND AGEING

MAY 2012

The following delegates' final decisions and reasons on scheduling matters relate to applications considered as delegate-only decisions. These applications were not referred to an expert advisory committee.

Notice under subsections 42ZXZS and 42ZCZX of the Therapeutic Goods Regulations 1990 (the Regulations)

A delegate of the Secretary to the Department of Health and Ageing hereby gives notice of delegates' final decisions for amending the Poisons Standard (commonly referred to as the *Standard for the Uniform Scheduling of Medicines and Poisons* – SUSMP) under subsections 42ZCZS and 42ZCZX of the Regulations. This notice also provides the reasons for each decision and the date of effect of the decision.

Matters not referred to an advisory committee

A delegate may decide not to refer a scheduling application to an expert advisory committee for advice and instead may make a delegate-only decision. When deciding not to refer an application to an expert advisory committee for advice, the delegate considers the scheduling guidelines as set out in the Scheduling Policy Framework (SPF) accessible at www.tga.gov.au/industry/scheduling-spf.htm.

Implementation

The SUSMP and its amendments are available electronically at the ComLaw website, a link to which can be found at www.tga.gov.au/industry/scheduling-poisons-standard.htm.

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GLOSSARY

<i>ABBREVIATION</i>	<i>NAME</i>
AAN	Australian Approved Name
AC	Active constituent
ACCC	Australian Competition and Consumer Commission
ACCM	Advisory Committee on Complementary Medicines (formerly Complementary Medicine Evaluation Committee [CMEC])
ACNM	Advisory Committee on Non-prescription Medicines (formerly Medicines Evaluation Committee [MEC])
ACPM	Advisory Committee on Prescription Medicines (formerly Australian Drug Evaluation Committee [ADEC])
ACSOM	Advisory Committee on the Safety of Medicines (formerly Adverse Drug Reactions Advisory Committee [ADRAC])
ADEC	Australian Drug Evaluation Committee (now Advisory Committee on Prescription Medicines [ACPM])
ADI	Acceptable daily intake
ADRAC	Adverse Drug Reactions Advisory Committee (now Advisory Committee on the Safety of Medicines [ACSOM])
AHMAC	Australian Health Ministers' Advisory Council
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
ARfD	Acute reference dose
ASCC	Australian Safety and Compensation Council
ASMI	Australian Self-Medication Industry
ARTG	Australian Register of Therapeutic Goods
CAS	Chemical Abstract Service

CHC	Complementary Healthcare Council of Australia
CMEC	Complementary Medicine Evaluation Committee (now Advisory Committee on Complementary Medicines [ACCM])
CMI	Consumer Medicine Information
COAG	Councils of Australian Governments
CRC	Child-resistant closure
CTFAA	Cosmetic, Toiletry & Fragrance Association of Australia
CWP	Codeine Working Party
DAP	Drafting Advisory Panel
ECRP	Existing Chemicals Review Program
EPA	Environmental Protection Authority
ERMA	Environmental Risk Management Authority (New Zealand)
FAISD	First Aid Instructions and Safety Directions
FDA	Food and Drug Administration (United States)
FOI	<i>Freedom of Information Act 1982</i>
FSANZ	Food Standards Australia New Zealand
GHS	Globally Harmonised System for Classification and Labelling of Chemicals.
GIT	Gastro-intestinal tract
GP	General practitioner
HCN	Health Communication Network
INN	International Non-proprietary Name
ISO	International Standards Organization

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LC ₅₀	The concentration of a substance that produces death in 50% of a population of experimental organisms. Usually expressed as mg per litre (mg/L) as a concentration in air.
LD ₅₀	The concentration of a substance that produces death in 50% of a population of experimental organisms. Usually expressed as milligrams per kilogram (mg/kg) of body weight
LOAEL	Lowest observed adverse effect level
LOEL	Lowest observed effect level
MCC	Medicines Classification Committee (New Zealand)
MEC	Medicines Evaluation Committee (now Advisory Committee on Non-prescription Medicines [ACNM])
MOH	Ministry of Health (New Zealand)
NCCTG	National Coordinating Committee on Therapeutic Goods
NDPSC	National Drugs and Poisons Schedule Committee
NHMRC	National Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification & Assessment Scheme
NOAEL	No observed adverse effect level
NOEL	No observable effect level
NOHSC	National Occupational Health & Safety Commission
OCM	Office of Complementary Medicines
OCSEH	Office of Chemical Safety and Environmental Health (now Office of Chemical Safety [OCS])
OCS	Office of Chemical Safety (formerly Office of Chemical Safety and Environmental Health [OCSEH])
ODA	Office of Devices Authorisation
OMA	Office of Medicines Authorisation (formerly Office of Prescription and Non-prescription Medicines)

OOS	Out of session
OTC	Over-the-counter
PACIA	Plastics and Chemicals Industries Association
PAR	Prescription animal remedy
PBAC	Pharmaceutical Benefits Advisory Committee
PEC	Priority existing chemical
PGA	Pharmaceutical Guild of Australia
PHARM	Pharmaceutical Health and Rational Use of Medicines
PI	Product Information
PIC	Poisons Information Centre
PSA	Pharmaceutical Society of Australia
QCPP	Quality Care Pharmacy Program
QUM	Quality Use of Medicines
RFI	Restricted flow insert
SCCNFP	Scientific Committee on Cosmetic and Non-Food Products
SCCP	Scientific Committee on Consumer Products
STANZHA	States and Territories and New Zealand Health Authorities
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
SVT	First aid for the solvent prevails
TCM	Traditional chinese medicine
TGA	Therapeutic Goods Administration
TGC	Therapeutic Goods Committee

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TGO	Therapeutic Goods Order
TTHWP	Trans-Tasman Harmonisation Working Party
TTMRA	Trans-Tasman Mutual Recognition Agreement
WHO	World Health Organization
WP	Working party
WS	Warning statement

FINAL DECISIONS ON MATTERS NOT REFERRED TO AN ADVISORY COMMITTEE

1. CHEMICALS

1.1 SEDAXANE

SCHEDULING PROPOSAL

The Office of Chemical Safety (OCS) has evaluated the data provided in support of an application for the approval of a new seed treatment fungicide, namely sedaxane. The OCS recommended that sedaxane be included in Schedule 5. The applicant was provided a copy of the evaluation report and agreed with the proposed schedule listing.

The delegate considered this application and made a delegate-only decision. The Advisory Committee on Chemicals Scheduling (ACCS) was not consulted.

SUBSTANCE DETAILS

Sedaxane is a carboxamide fungicide belonging to the sub-class of the pyrazole-carboxamides. Sedaxane is a highly potent succinate dehydrogenase inhibitor of fungal pathogens. The proposed product, containing sedaxane, is intended for the control and/or suppression of seedling diseases in barley, oats, triticale and wheat.

SCHEDULING STATUS

Sedaxane is not currently specifically scheduled.

SCHEDULING CONSIDERATION

The delegate considered the following in regards to this application:

- the OCS Evaluation Report (not publicly available);
- scheduling history of other Schedule 5 carboxamide fungicides;
- section 52E of the *Therapeutic Goods Act 1989*; and
- scheduling factors for inclusion in Schedule 5¹.

DELEGATE'S FINAL DECISION

The delegate has made a delegate-only decision to include sedaxane in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons without a low exemption cut-off.

The implementation date for this decision is 1 September 2012

¹ Scheduling Policy Framework for Medicines and Chemicals <http://www.tga.gov.au/industry/scheduling-spf.htm>

The delegate decided that the relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* include (c) toxicity.

The decision to include sedaxane in Schedule 5 included the following reason:

- the toxicity profile of sedaxane is consistent with that of a substance in Schedule 5, as outlined in the scheduling policy framework. A low concentration cut-off to exempt sedaxane from Schedule 5 listing was not considered appropriate at this time.

SCHEDULE ENTRY

Schedule 5 – New Entry

SEDAXANE

1.2 BISTRIFLURON

SCHEDULING PROPOSAL

- The Office of Chemical Safety (OCS) has evaluated the data provided in support of an application for the approval of a new insecticide, namely bistrifluron. The OCS recommended that bistrifluron be included in Appendix B. The applicant was provided a copy of the evaluation report and agreed with the proposed schedule listing.

The delegate has considered this application and made a delegate-only decision. The Advisory Committee on Chemicals Scheduling was not consulted.

SUBSTANCE DETAILS

Bistrifluron is a benzoylurea compound, acts as an inhibitor of insect development and interferes with the cuticle formation of insects. The product is formulated into tablets and used as baits in in-ground and above-ground bait stations for the control of subterranean termite species.

SCHEDULING STATUS

- Bistrifluron is not currently specifically scheduled.

SCHEDULING CONSIDERATION

The delegate considered the following in regards to this application:

- the OCS Evaluation Report (not publicly available);
- scheduling history of other benzoylurea fungicides; and
- section 52E of the Therapeutic Goods Act 1989.

DELEGATE'S FINAL DECISION

The delegate has made a delegate only decision to include bistrifluron in Appendix B.

The implementation date for this decision is 1 September 2012.

The delegate decided that the relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* include (b) purpose and (c) toxicity.

The decision to include bistrifluron in Appendix B included the following reasons:

- bistrifluron's mode of action (an insect growth regulator that inhibits chitin synthesis) should be sufficiently species-specific for the product to be efficient in controlling termite infestations at the recommended level while not representing a toxicity hazard for humans. Moreover, another related insect growth regulator product containing chlorflurazuron, which is listed in Appendix B, also appears to be active against termites at a concentration of 1 per cent.
- The toxicity profile of bistrifluron is low, and under the guidelines provided in the scheduling policy framework¹, does not warrant listing in any of the poisons schedules.
- The delegate noted comments in the OCS evaluation report, that neurotoxicity studies had not been submitted with the application, but considered this is not a significant scheduling issue, since potential neurotoxicity had not been demonstrated in any of the studies submitted.

SCHEDULE ENTRY

Appendix B – New Entry

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
BISTRIFLURON	Sep 2012	a	1.1.2

2. MEDICINES

2.1 ETHYL ALCOHOL

SCHEDULING PROPOSAL

An applicant has requested rescheduling of ethyl alcohol from Appendix B to Schedule 2 and Schedule 9 with the proposed scheduling wording:

Schedule 2 – Proposed New entry

ETHYL ALCOHOL for human therapeutic use, **except:**

- (a) in preparations for use as a recreational drug
- (b) in herbal and mineral medicinal tinctures

Schedule 9 – Proposed New entry

ETHYL ALCOHOL **except** when included in schedule 2.

The delegate has considered this matter as a delegate-only decision. The Advisory Committee on Medicines Scheduling was not consulted.

SUBSTANCE DETAILS

Ethyl alcohol (ethanol) has a wide range of uses and presentations including alcoholic beverages and pharmaceutical applications such as, but not limited to, disinfection of skin, as a solvent, as a neurolytic, and as a sclerosant used for a variety of conditions including aldosterone-producing adenoma, parathyroid adenomas and gallbladder obstruction².

SCHEDULING STATUS

Ethyl alcohol currently listed in Appendix B - 'Substances considered not to require control by scheduling' of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). This exemption is for any use.

SCHEDULING HISTORY

The May 1974 Poisons Schedule Sub-Committee (PSSC) meeting was of the opinion that ethanol (ethyl alcohol) should be exempted from scheduling based on its toxicity data.

At the February 2003 meeting, the National Drugs and Poisons Schedule Committee (NDPSC) amended the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) to include Appendix B, replacing the previous 'Lists of Exemptions – Part 2' in the SUSDP. The NDPSC

² Parfitt K (ed) 1999, Martindale: The Complete Drug Reference 32nd Edition

concluded that 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.³

SCHEDULING CONSIDERATION

The delegate considered the following in regards to this application:

- the scheduling history of ethyl alcohol;
- the March 2011 final decisions for a 2010 application requesting ethyl alcohol be rescheduled from Appendix B to Schedule 9⁴;
- section 52E of the *Therapeutic Goods Act 1989*; and
- scheduling factors for inclusion in Schedule 2 and Schedule 9⁵.

DELEGATE'S INTERIM DECISION

The delegate made an interim decision that the current scheduling exemption of ethyl alcohol through listing in Appendix B remains appropriate.

The delegate decided that the relevant matters under section 52E(1) of the *Therapeutic Goods Act 1989* include (a) risks and benefits of the substance, (b) purpose for which the substance is to be used, (c) toxicity, (d) presentation of the substance, (e) potential for abuse and (f) other matters considered necessary to protect public health.

The delegate's reasons for this interim decision included:

- the submitted application did not address matters under section 52E of the Act including the lack of sufficient and relevant evidence to support a rescheduling proposal from Appendix B to Schedule 2 and Schedule 9.
- Restrictions on substances for human consumption such as food or beverages were sufficiently regulated through separate legislation. Commonwealth and State and Territory regulatory bodies enforce such restrictions to ensure the protection of public health, therefore imposing additional controls through scheduling is not warranted.
- Additional controls through scheduling for human consumption were not considered appropriate within the current regulatory system.

This reflected the March 2011 decision.

³ NDPS record of reasons, 37th meeting, 25-26 February 2003 <<http://www.tga.gov.au/archive/committees-ndpsc-record-37.htm>>

⁴ <http://www.tga.gov.au/industry/scheduling-decisions-1103-final.htm>

⁵ Scheduling Policy Framework for Medicines and Chemicals <http://www.tga.gov.au/industry/scheduling-spf.htm>

SUBMISSIONS ON INTERIM DECISION

As the delegate's interim decision was different to the applicant's proposal, the applicant was provided the opportunity to comment on the delegate's interim decision. The applicant's comments are not publicly available.

FURTHER SCHEDULING CONSIDERATION

The delegate considered the applicant's comments on the interim decision as well as advice sought from State and Territories in regards to this proposal.

DELEGATE'S FINAL DECISION

The delegate has made a final decision that the current scheduling exemption of ethyl alcohol through listing in Appendix B remains appropriate.

The delegate decided that the relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* include (a) risks and benefits of the substance, (b) purpose for which the substance is to be used, (c) toxicity, (d) presentation of the substance, (e) potential for abuse and (f) other matters considered necessary to protect public health.

The final decision to not reschedule ethyl alcohol included the following reasons:

- comments submitted by the applicant did not address matters under section 52E of the Act nor provide sufficient or relevant evidence to support the rescheduling proposal.
- There are existing controls on the access, labelling and packing of ethyl alcohol under separate legislation.
- Additional controls through scheduling for ethyl alcohol would be inappropriate due to the potential for duplication and conflicts in an already complex area of the regulatory system.

2.2 AXITINIB

SCHEDULING PROPOSAL

The Therapeutic Goods Administration (TGA) has evaluated a new chemical entity (NCE) for a human therapeutic medicine namely axitinib.

The delegate has therefore made a delegate-only decision. The Advisory Committee on Medicines Scheduling was not consulted⁶.

⁶ A new substance evaluated by the TGA is not routinely referred to a scheduling committee for advice - Scheduling Policy Framework for Medicines and Chemicals <http://www.tga.gov.au/industry/scheduling-spf.htm>

SUBSTANCE DETAILS

Axitinib is an antineoplastic agent and inhibits the activity of tyrosine kinase including members of the vascular endothelial cell growth factor receptors (VEGF)-1, (VEGF)-2 and (VEGF)-3⁷.

Axitinib is indicated for the treatment of renal cell carcinoma UK and US. Proposed indication in Australia is for the treatment of patients with advanced renal cell carcinoma.

SCHEDULING STATUS

Axitinib is not specifically scheduled in Australia.

SCHEDULING HISTORY

- In January 2012, the US FDA approved axitinib for use in patients with renal cell carcinoma that had failed to respond to a previous treatment.
- In February 2011, orphan designation was granted by the European Commission for axitinib for the treatment of cell carcinoma.
- Axitinib has not been classified (scheduled) in New Zealand.

SCHEDULING CONSIDERATION

The delegate noted the following in regards to this application:

- the scheduling history of other Schedule 4 substances that are in the same class as axitinib;
- section 52E of the *Therapeutic Goods Act 1989*;
- scheduling factors for inclusion in Schedule 4⁸;
- there are no known issues that require additional controls and/or requirements other than Schedule 4;

DELEGATE'S FINAL DECISION

The delegate has made a delegate-only decision to include axitinib in Schedule 4.

The implementation date for this decision is 1 September 2012.

The delegate decided that the relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* include (a) risks and benefits, (b) purpose and (c) toxicity.

⁷ US Product Information

⁸ Scheduling Policy Framework for Medicines and Chemicals <http://www.tga.gov.au/industry/scheduling-spf.htm>

The decision to include axitinib in Schedule 4 comprised the following reasons:

- axitinib is used for the treatment of advanced renal cell carcinoma, a condition that requires diagnosis and management by a medical professional;
- Axitinib's various toxicities are considered to be significant. The decision to prescribe the drug requires a careful assessment of the potential benefits and potential risks for each individual patient. A medical professional is needed to manage these toxicities.

SCHEDULE ENTRY

Schedule 4 – New entry

AXITINIB

2.3 COBICISTAT

SCHEDULING PROPOSAL

The Therapeutic Goods Administration (TGA) has evaluated a new chemical entity (NCE) for a human therapeutic medicine namely cobicistat.

The delegate has made a delegate-only decision to include cobicistat in Schedule 4. The Advisory Committee on Medicines Scheduling was not consulted⁹.

SUBSTANCE DETAILS

Cobicistat is a new potent and selective inhibitor of human cytochrome P450 3A (CYP3A) enzyme. It is suitable for use in boosting anti-HIV drugs without risking selection of potential drug-resistant HIV variants.

Cobicistat is intended to be used in fixed dose combination tablet of elvitegravir/emtricitabine/tenofovir for the treatment of HIV-1 infection in adults who are antiretroviral naïve or have no known substitutions associated with resistance to the individual components.

SCHEDULING STATUS

Cobicistat is not specifically scheduled in Australia.

SCHEDULING HISTORY

- Cobicistat has not been classified (scheduled) in New Zealand.
- Applications for licensing of fixed combination medicinal product (elvitegravir/cobicistat/emtricitabine/tenofovir) are under review in the US, Canada and EU.

⁹ A new substance evaluated by the TGA is not routinely referred to a scheduling committee for advice - Scheduling Policy Framework for Medicines and Chemicals <http://www.tga.gov.au/industry/scheduling-spf.htm>

SCHEDULING CONSIDERATION

The delegate noted the following in regards to this application:

- scheduling history of other Schedule 4 substances that are in the same class as cobicistat;
- section 52E of the *Therapeutic Goods Act 1989*;
- scheduling factors for inclusion in Schedule 4¹⁰; and
- there are no known issues that require additional controls and/or requirements other than Schedule 4.

DELEGATE'S FINAL DECISION

The delegate has made a delegate only decision to include cobicistat in Schedule 4.

The implementation date for this decision is 1 September 2012.

The delegate decided that the relevant matters under section 52E(1) of the *Therapeutic Goods Act 1989* include (a) risks and benefits; (b) purpose and extent of use, (c) toxicity; and (d) dosage, formulation, labeling, packaging and presentation.

The decision to include cobicistat in Schedule 4 comprised of the following reasons:

- cobicistat is a new medicine without clinical experience in Australia.
- Cobicistat has not been studied in patients with severe hepatic impairment;
- Cobicistat decreases creatinine clearance and may increase the potential for nephrotoxicity associated with tenofovir;
- Co-administration of cobicistat with specified other medicines is contraindicated because of potential for life-threatening adverse events or loss of virological response;
- Cobicistat is to be used concomitantly with anti-HIV drugs and in conditions that require diagnosis and management by a medical professional; and
- Cobicistat is presented in a fixed combination tablet with current Schedule 4 medicines.

¹⁰ Scheduling Policy Framework for Medicines and Chemicals <http://www.tga.gov.au/industry/scheduling-spf.htm>

NEW SCHEDULE ENTRY

Schedule 4 – New entry

COBICISTAT

2.4 ELVITEGRAVIR

SCHEDULING PROPOSAL

The Therapeutic Goods Administration (TGA) has evaluated a new chemical entity (NCE) for a human therapeutic medicine namely elvitegravir.

The delegate has made a delegate-only decision to include elvitegravir in Schedule 4. The Advisory Committee on Medicines Scheduling was not consulted¹¹.

SUBSTANCE DETAILS

Elvitegravir is an integrase inhibitor. Integrase is one of three enzymes like protease and reverse transcriptase, essential for viral replication. Integrase inhibitors interfere with HIV replication by blocking the ability of the virus to integrate into the genetic material of human cells.

Elvitegravir is intended to be used in fixed dose combination tablet of cobicistat/emtricitabine/tenofovir for the treatment of HIV-1 infection in adults.

SCHEDULING STATUS

Elvitegravir is not specifically scheduled in Australia.

SCHEDULING HISTORY

- Elvitegravir has not been classified (scheduled) in New Zealand.
- A license application has been submitted to the European Medicines Agency (EMA) for a fixed combination medicine which contains elvitegravir (an integrase inhibitor)/cobicistat (a 'boosting' agent that enables once-daily dosing of elvitegravir)/emtricitabine for the treatment of HIV-1 infection in adults.
- A new drug application has also been submitted to the United States Food and Drugs Administration (USFDA).

SCHEDULING CONSIDERATION

The delegate noted the following in regards to this application:

¹¹ A new substance evaluated by the TGA is not routinely referred to a scheduling committee for advice - Scheduling Policy Framework for Medicines and Chemicals <http://www.tga.gov.au/industry/scheduling-spf.htm>

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- scheduling history of other Schedule 4 substances that are in the same class as elvitegravir;
 - section 52E of the *Therapeutic Goods Act 1989*;
 - scheduling factors for inclusion in Schedule 4¹²; and
 - there are no known issues that require additional controls and/or requirements other than Schedule 4.

DELEGATE'S FINAL DECISION

The delegate has made a delegate only decision to include elvitegravir in Schedule 4.

The implementation date for this decision is 1 September 2012.

The delegate decided that the relevant matters under section 52E(1) of the *Therapeutic Goods Act 1989* include (a) risks and benefits; (b) purpose, (c) toxicity and (d) dosage, formulation, labeling, packaging and presentation.

The decision to include elvitegravir in Schedule 4 comprised of the following reasons:

- elvitegravir is a new medicine without clinical experience in Australia.
- Elvitegravir has not been studied in patients with severe hepatic impairment.
- Elvitegravir is metabolized primarily by human cytochrome of human cytochrome P450 3A (CYP3A) enzyme and plasma exposures may reduced by coadministration with other medicines that induce CYP3A, which may lead to loss of virological response.
- Elvitegravir is to be used concomitantly with anti-HIV drugs and in conditions that require diagnosis and management by a medical professional.
- Elvitegravir is presented in a fixed combination tablet with current Schedule 4 medicines.

NEW SCHEDULE ENTRY

Schedule 4 – New entry

ELVITEGRAVIR.

¹² Scheduling Policy Framework for Medicines and Chemicals <http://www.tga.gov.au/industry/scheduling-spf.htm>

3. EDITORIALS AND ERRATA

3.1 POISONS STANDARD REFERENCE REVIEW

PROPOSAL

To amend the Poisons Standard to include up-to-date references.

BACKGROUND

New editions of, and amendments to, the Poisons Standard (currently entitled the *Standard for the Uniform Scheduling of Medicines and Poisons* [SUSMP]) are legislative instruments and are required to be registered on the Federal Register of Legislative Instruments (FRLI). Section 52D of the *Therapeutic Goods Act 1989* sets out the requirements for validation of the Poisons Standard, including disallowance under the *Legislative Instruments Act 2003*.

References in a legislative instrument must be up-to-date and, in regard to references to quasi-legal publications, must be specific to a particular version before it is registered on FRLI. Wording to the effect “as specified or amended from time to time” is deemed inappropriate for references in a legislative instrument and is to be excluded. This wording is only appropriate for use in an Act, with all subordinate legislation and quasi legal documents (such as the Poisons Standard) to include full titles, and publication dates where available, when referencing.

DELEGATES' CONSIDERATION

The delegates noted that:

- the Medicines and Poisons Scheduling Secretariat had undertaken a review of the references contained in the *Poisons Standard 2011* (SUSMP No. 2), in preparation for the *Poisons Standard 2012*, being a consolidation of SUSMP No. 2 and its Amendments into SUSMP No. 3;
- a number of references required correcting, updating or deleting;
- a number of these entries also required editorial amendment for clarity and for consistency with other entries in the Poisons Standard.

Reference amendments

- Therapeutic Goods Order 65 – *Child resistant packaging for therapeutic goods* has been superseded by Therapeutic Goods Order 80 – *Child-Resistant Packaging Requirements for Medicines*. As both TGO 65 and TGO 80 are referenced only once in the Poisons Standard, and listed together in the Introduction, reference to TGO 65 is to be deleted from the paragraph 7 in the Introduction.
- References to “TGO 69” and “TGO 80” in paragraph 7 in the Introduction are to be amended to read “Therapeutic Goods Order” 69 – *General requirements for labels for*

medicines" and "Therapeutic Goods Order 80 – *Child-Resistant Packaging Requirements for Medicine*".

- The wording "as in force from time to time" is to be deleted from the Appendix A entry for medical devices and the wording "as amended from time to time" is to be deleted from the Appendix C entry for clioquinol.
- Where a reference is made to a subsection or subregulation of an Act or Regulation, the word "section" is to be amended to read "subsection" and the word "regulation" is to be amended to read "subregulation", as appropriate.
- Subregulation 12(1A) of the Therapeutic Goods Regulations 1990 is Schedule 5A to the same Regulations. For clarity, the reference to "subregulation 12(1A)" in paragraph (b) of the Appendix C entry for clioquinol is to be amended to read "Schedule 5A (subregulation 12(1A))".
- The appropriate authorities in the ACT, NSW and South Australia have changed their names. Under "Appropriate authority" in Part 1, Interpretation:
 - "ACT Health" in paragraph (a) is to be amended to read "the ACT Government Health Directorate";
 - "NSW Health" in paragraph (c) is to be amended to read "NSW Ministry of Health";
 - for South Australia, "Department of Health" in paragraph (f) is to be amended to read "Department for Health and Ageing".
- Spelling is to be corrected in a number of references under "Approved name" in Part 1, Interpretation:
 - "International Organisation for Standardisation" in subparagraph (c)(iii) is to be amended to read "International Organization for Standardization";
 - "International European Committee for Standardisation" in subparagraph (c)(vi) is to be amended to read "International European Committee for Standardization"; and
 - "World Health Organisation" in subparagraph (c)(vii) is to be amended to read "World Health Organization".
- The Cosmetic Toiletries and Fragrance Association has changed its name to Personal Care Products Council and the title of the *International Cosmetic Ingredient Dictionary* is incomplete. Subparagraph (c)(viii) under "Approved name" in Part 1, Interpretation, is to be amended to read "the International Nomenclature Cosmetic Ingredient name for the poison listed in the *International Cosmetic Ingredient Dictionary & Handbook* published by the Personal Care Products Council of America".
- A number of entries reference "Dangerous Good of Class 5, Division 5.1: Oxidising substances". The Department of Infrastructure and Transport (DIT), being the current publisher of the *Australian Code for the Transport of Dangerous Goods by Road and Rail*, has advised that dangerous goods are divided into nine (9) Classes with each Class divided into Divisions: Class 5 refers to oxidising substances and organic peroxides, Division 5.1 refers to oxidising substances and Division 5.2 refers to organic peroxides. DIT has advised that the more correct descriptor is "Class 5, Division 5.1: Oxidising substances". As such,

the references in subparagraph 7(1)(d) under Part 2, Labels and Containers, and in paragraphs (e) and (g) under chlorinating compounds and paragraphs (e), (h) and (j) under dichloroisocyanurates in Appendix F, Part 3, are to be amended to read “Dangerous Good of Class 5, Division 5.1: Oxidising substances, as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail*”

- References in paragraph 5 under Introduction, paragraph 13 under Part 2, Labels and Container, and paragraph (a) of the Schedule 6 entry for glycolic acid are to be amended to read “Safe Work Australia’s *National Code of Practice for the Labelling of Workplace Substances* [NOHSC:2012(1994)]”.
- Australia New Zealand Standard AS/NZS ISO 8124.3.2003 entitled *Safety of toys Part 3: Migration of certain elements* has been superseded. Paragraph 3 under Appendix I is to be amended to include the new Australia New Zealand Standard “AS/NZS ISO 8124.3.2012 entitled *Safety of toys Part 3: Migration of certain elements* (ISO 8124-3:2010, MOD)”.
- The word “entitled” is to be inserted between the reference number and the title of the Australian Standard in the Appendix A entry for chemistry sets.

Editorial amendments

- Entries in the table of Appendices in the Introduction are to be amended for consistency of wording throughout the table.
- For clarity, the wording “sections 2-12” is to be amended to read “paragraphs 2 to 12” in paragraphs (b) and (h) under “Appropriate authority” in Part 1, Interpretation.
- For clarity and consistency with other entries in the Poisons Standard, the wording “(*name of the metal*)” in subparagraph 8(4) under Part 2, Labels and Containers, is to be amended to read “of (*insert name of the metal*)”;
- For clarity and consistency with other entries in the Poisons Standard, the wording “which are labelled” in paragraph (a) of the Schedule 6 entry for glycolic acid is to be amended to read “, when labelled”.

DELEGATE’S FINAL DECISION

The delegate has made a final decision to:

- amend the Poisons Standard to include up-to-date references;
- editorially amend the Poisons Standard; and
- include the reference and editorial amendments in the *Poisons Standard 2012*, expected to be published in June 2012.

Note: the reference and editorial amendments are underlined in the following amended entries.

INTRODUCTION - AMENDMENTS

PARAGRAPH 5 – Amend entry to read:

Poisons which are packed and sold solely for industrial, manufacturing, laboratory or dispensary use are exempt from all labelling requirements included in the SUSMP as they are covered by Safe Work Australia's National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012 (1994)]. Note, however, that this exemption does not extend to controls on supply of these poisons.

PARAGRAPH 7 – Amend entry to read:

The various Commonwealth legislative instruments which integrate with the SUSMP include:

- the Agricultural and Veterinary Chemicals Code Act 1994
- the Agricultural and Veterinary Chemicals Code Regulations 1995
- the Therapeutic Goods Act 1989
- Therapeutic Goods Order 69 – General requirements for labels for medicines
- Therapeutic Goods Order 80 – Child-Resistant Packaging Requirements for Medicines
- the Required Advisory Statements for Medicine Labels (RASML)

APPENDICES TO THE POISONS STANDARD (last page under Introduction) – Amend entry to read:

Some substances in certain circumstances are also subject to exemptions or additional restrictions as described in the Appendices to this Standard. The table below summarises the purpose of each of the Appendices and the controls imposed on substances included in them.

Appendix	Title	Purpose/ controls imposed
Appendix A	General exemptions.	List of classes of products or uses exempted from this <u>Standard</u> .
Appendix B	Substances considered not to require control by scheduling.	List of poisons exempted from scheduling.
Appendix C	Substances, other than those included in Schedule 9, of such danger to health as to warrant prohibition of sale, supply and use.	List of poisons prohibited from sale, supply or use because of their known potential for harm to human and/or animal health.
Appendix D	Additional controls on possession or supply of poisons included in Schedule 4 or 8	List of poisons included in Schedule 4 or 8 where additional <u>specified</u> controls apply <u>on possession or supply</u> .
Appendix E	First aid instructions for poisons.	First aid instructions for poisons (other than agricultural and veterinary chemicals and chemicals packed and sold solely for industrial, dispensary, manufacturing or laboratory use).

Appendix	Title	Purpose/ controls imposed
Appendix F	Warning statements and general safety directions for poisons.	Warning statements and general safety directions for poisons (other than human medicines, agricultural and veterinary chemicals and chemicals packed and sold solely for industrial, dispensary, manufacturing or laboratory use).
Appendix G	Dilute preparations.	Concentration cut-offs for specified poisons, below which the requirements of the Standard do not apply.
Appendix H	Schedule 3 medicines permitted to be advertised.	<u>List of medicines included in Schedule 3</u> that are permitted to be advertised to the public.
Appendix I	Uniform Paint Standard	Requirements <u>applying</u> to poisons included in paints or tinters.
Appendix J	Conditions for availability and use of Schedule 7 poisons.	<u>List of poisons included in Schedule 7</u> where additional specified conditions apply to their availability and use.
Appendix K	Human medicines required to be labelled with a sedation warning.	List of human medicines required to be labelled with a warning regarding their sedation potential.
Appendix L	Requirements for dispensing labels for medicines.	Requirements applying to labels attached to medicines at the time of dispensing.

PART 1, INTERPRETATION

SUBPARAGRAPH 1(1) - AMENDMENTS

“**Appropriate authority**” – Amend entry to read:

“**Appropriate authority**” means:

- (a) in the Australian Capital Territory, the ACT Government Health Directorate;
- (b) for the purpose of providing an exemption from all or part of paragraphs 2 to 12 of this Standard by the Australian Pesticides and Veterinary Medicines Authority, the Chief Executive Officer or their delegate;
- (c) in New South Wales, the Director-General of the NSW Ministry of Health;
- (d) in the Northern Territory, the Chief Health Officer of the Department of Health;
- (e) in Queensland, the Chief Executive of Queensland Health;

- (f) in South Australia, the Chief Executive of the Department for Health and Ageing;
- (g) in Tasmania, the Secretary of the Department of Health and Human Services;
- (h) for the purpose of providing an exemption from all or part of paragraphs 2 to 12 of this Standard by the Therapeutic Goods Administration, the National Manager or their delegate;
- (i) in Victoria, the Secretary to the Department of Health;
- (j) in Western Australia, the Chief Executive Officer of the Department of Health.

“Approved name” – Amend entry to read:

“Approved name” means:

- (a) in relation to a poison that is for human therapeutic use, the name approved for use by the Therapeutic Goods Administration;
- (b) in relation to a poison that is for animal or agricultural use, the name approved for use by the Australian Pesticides and Veterinary Medicines Authority;
- (c) in relation to all other poisons:
 - (i) the name used in an entry in these Schedules; or, if no such name is given,
 - (ii) the English name recommended by Standards Australia as the common name for the poison; or, if no such name is given,
 - (iii) the English name given to the poison by the International Organization for Standardization; or, if no such name is given,
 - (iv) the English name given to the poison by the British Standards Institution; or, if no such name is given,
 - (v) the name that would comply with the requirements of part (a) or (b) of this definition, or, if no such name is given,
 - (vi) the English name given to the poison by the European Committee for Standardization (CEN); or, if no such name is given,
 - (vii) the international non-proprietary name recommended for the poison by the World Health Organization; or, if no such name is given,
 - (viii) the International Nomenclature Cosmetic Ingredient name for the poison listed

in the *International Cosmetic Ingredient Dictionary & Handbook* published by the Personal Care Products Council of America ; or, if no such name is given,

- (ix) the accepted scientific name or the name descriptive of the true nature and origin of the poison.

“Child-resistant closure” – Amend entry to read:

“Child-resistant closure” means:

- (a) a closure that complies with the requirements for a child-resistant closure in the Australian Standard AS 1928-2007 entitled *Child-resistant packaging – Requirements and testing procedures for reclosable packages* (ISO 8317:2003, MOD);
- (b) a closure approved by an order made under subsection 10(3) of the Commonwealth *Therapeutic Goods Act 1989*; 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”.

See also "Non-access packaging".

“Child-resistant packaging” – Amend entry to read:

“Child-resistant packaging” means packaging that:

- (a) complies with the requirements of the Australian Standard AS 1928-2007 entitled *Child resistant packaging – Requirements and testing procedures for reclosable packages* (ISO 8317:2003, MOD);
- (b) is reclosable and complies with the requirements of at least one of the following Standards:
 - (i) the International Organization for Standardization Standard ISO 8317:2003 entitled *Child-resistant packaging – Requirements and testing procedures for reclosable packages*;
 - (ii) the British Standards Institution Standard BS EN ISO 8317:2004 entitled *Child-resistant packaging. Requirements and testing procedures for reclosable packages*;
 - (iii) the Canadian Standards Association Standard CSA Z76.1-06 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 child-resistant by any order made under subsection 10(3) of the Commonwealth *Therapeutic Goods Act 1989*; 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 entitled *Child-resistant packages*.

See also "Non-access packaging".

PART 2, LABELS AND CONTAINERS – AMENDMENTS

SUBPARAGRAPH 7(1)(d) – Amend entry to read:

- [7(1)] (d) if the poison is a dry chlorinating compound containing more than 10 per cent of available chlorine, **except** for preparations certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5, Division 5.1: Oxidising substances, as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail*, with the cautionary statement –

FIRE AND EXPLOSION HAZARD

written:

- (i) on a separate line or lines immediately below the cautionary statement “KEEP OUT OF REACH OF CHILDREN” as required by subparagraph 7(1)(c); and
- (ii) in bold-face sans serif capital letters of uniform thickness; and
- (iii) in letters at least four-tenths the height of the letters used for the signal word or words; and
- (iv) with nothing, other than a Class label as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail*, written on the same line;

SUBPARAGRAPH 7(1)(k)(i) – Amend entry to read:

- [7(1)(k)] (i) if the poison is for human therapeutic use, written in accordance with orders made under subsection 10(3) of the Commonwealth *Therapeutic*

Goods Act, 1989; or

SUBPARAGRAPH 8(1) – Amend entry to read:

- [8] (1) if the poison is for human therapeutic use, in the manner prescribed by orders made under subsection 10(3) of the Commonwealth *Therapeutic Goods Act 1989*;

SUBPARAGRAPH 8(4) – Amend entry to read:

- [8] (4) 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 of (insert name of the metal); or
- contains not more than 30 per cent of (insert name of the metal); or
- contains more than 30 per cent of (insert name of the metal);

SUBPARAGRAPH 9(1) – Amend entry to read:

- [9] (1) the immediate container is for a therapeutic good and is labelled in the manner prescribed by orders made under subsection 10(3) of the Commonwealth *Therapeutic Goods Act 1989*; or

SUBPARAGRAPH 10(1) – Amend entry to read:

- [10] (1) the selected container or ampoule is for a therapeutic good and is labelled in the manner prescribed by orders made under subsection 10(3) of the Commonwealth *Therapeutic Goods Act 1989*; or

SUBPARAGRAPH 11(1) – Amend entry to read:

- [11] (1) the selected container is a plastic ampoule that is continuous with a strip of the same material and opens as it is detached from the strip, is for a therapeutic good and is labelled in the manner prescribed by orders made under subsection 10(3) of the Commonwealth *Therapeutic Goods Act 1989*; or

SUBPARAGRAPH 13(2) – amend entry to read:

- [13] (2) is labelled in accordance with Safe Work Australia's *National Code of Practice for the Labelling of Workplace Substances* [NOHSC: 2012 (1994)].

PARAGRAPH 25(1) – Amend entry to read:

- [25] (1) If a poison, other than a poison included in a therapeutic good packaged in a manner compliant with orders made under subsection 10(3) of the Commonwealth

Therapeutic Goods Act 1989, listed in column 1 in the following table is sold or supplied in a container having a nominal capacity specified for that poison in column 2, it must be closed with a child-resistant closure.

PART 4, THE SCHEDULES

SCHEDULE 6 - AMENDMENTS

GLYCOLIC ACID - Amend entry to read:

GLYCOLIC ACID (including its salts and esters) in cosmetic products or when packed and labelled for use as an agricultural chemical **except:**

- (a) in cosmetic preparations for salon use only when labelled in accordance with the Work Safe Australia's National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012 (1994)];
- (b) in preparations containing 5 per cent or less of glycolic acid; or
- (c) in preparations containing 20 per cent or less of glycolic acid with a pH of 3.5 or greater.

PART 5 - THE APPENDICES

APPENDIX A - AMENDMENTS

CHEMISTRY SETS - Amend entry to read:

CHEMISTRY SETS for toy and educational use, when complying with the requirements of Australian Standard AS 8124.4-2003 entitled *Safety of toys Part 4: Experimental sets for chemistry and related activities*.

MEDICAL DEVICES - Amend entry to read:

MEDICAL DEVICES classified as Class III by the classification rules set out in Schedule 2 to the *Therapeutic Goods (Medical Devices) Regulation 2002* **except:**

- (a) injectable tissue reconstructive, augmentation and restoration materials, including collagen;
- (b) medical devices which include anticoagulants;
- (c) artificial tears;

(d) urinary catheters; or

(e) intra-articular fluids.

APPENDIX C - AMENDMENT

CLIOQUINOL- Amend entry to read:

CLIOQUINOL and other halogenated derivatives of 8-hydroxyquinoline for human internal use **except** when being used solely for experimental purposes in humans and such use:

- (a) is in accordance with an approval granted under paragraph 19(1)(b), and the requirements of subsection 19(4A), of the *Therapeutic Goods Act 1989* - otherwise known as the Clinical Trial Exemption (CTX) scheme; or
- (b) is in accordance with the requirements of subsection 18(1) of the *Therapeutic Goods Act 1989* and Schedule 5A (subregulation 12(1A)) of the *Therapeutic Goods Regulations 1990* - otherwise known as the Clinical Trial Notification (CTN) scheme.

APPENDIX F PART 3 - AMENDMENTS

POISON

WARNING STATEMENTS

SAFETY DIRECTION

Chlorinating compounds - Amend entry to read:

(a) in household cleaning or bleaching preparations.	20	
(b) in preparations containing less than 10 per cent of available chlorine.	11	1,4,10
(c) in liquid preparations containing 10 per cent or more of available chlorine.	3,18	1,4,6,8,10, 15,16,17,18, 19,20,22,26
(d) in dry preparations containing 10 per cent or more of available chlorine.	10,18,22,23	1,4,8,12,13, 14,15,16,17, 18,19,20,21,
(e) in dry preparations containing 10 per cent or more of available chlorine certified by a relevant	10,18,22	1,4,8,12,13, 14,15,16,17, 18,19,20,21,

	State or Territory authority as not being a Dangerous Good of <u>Class 5, Division 5.1: Oxidising substances, as specified in the Australian Code for the Transport of Dangerous Goods by Road and Rail.</u>		22,26
(f)	in compressed block or tablets containing 10 per cent or more of available chlorine except in preparations for use in toilet cisterns only, containing 15 g or less of trichloroisocyanuric acid.	10,22,23	12,13,14,15, 17,18,19,21
(g)	in other compressed blocks or tablets containing 10 per cent or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of <u>Class 5, Division 5.1: Oxidising substances, as specified in the Australian Code for the Transport of Dangerous Goods by Road and Rail</u> except in preparations for use in toilet cisterns only, containing 15 g or less of trichloroisocyanuric acid	10,22	12,13,14,15, 17,18,19,21

Dichloroisocyanurates - Amend entry to read:

(a)	in household cleaning or bleaching preparations.	20	
(b)	in preparations containing less than 10 per cent of available chlorine.	11	1,4,10
(c)	in liquid preparations containing 10 per cent or more of available chlorine.	3,18	1,4,6,8,10, 15,16,17,18, 19,20,22,26
(d)	in dry preparations containing 10 per cent or more of available chlorine.	10,18,22,23	1,4,8,12,13,14, 15,16,17,18,19,

		20,21,22,26
(e) in dry preparations containing 10 per cent or more of available Chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of <u>Class 5, Division 5.1: Oxidising substances</u> , as specified in the <i>Australian Code for the Transport of Dangerous Goods by Road and Rail</i> .	10,18,22	1,4,8,12,13,14,15,16,17,18,19,20,21,22,26
(f) in anti-bacterial tablets containing 2.5 g or less of sodium dichloroisocyanurate.	60	
(g) in other compressed blocks or tablets containing 10 per cent or more of available chlorine except in preparations containing 21 g or less of sodium dichloroisocyanurate for use in toilet cisterns only.	10,22,23	12,13,14,15,17,18,19,21
(h) in other compressed blocks or tablets containing 10 per cent or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of <u>Class 5, Division 5.1: Oxidising substances</u> , as specified in the <i>Australian Code for the Transport of Dangerous Goods by Road and Rail</i> except in preparations containing 21 g or less of sodium dichloroisocyanurate for use in toilet cisterns only.	10,22	12,13,14,15,17,18,19,21
(i) in other compressed blocks or tablets containing 10 per cent or more of available chlorine in preparations containing 5 g or less of sodium dichloroisocyanurate for use in toilet bowls only.		

(i) during storage	10,22,23	12,13,14,15,17, 18,21
(ii) during use	5	1,4,7,12
(j) in other compressed blocks or tablets containing 10 per cent or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of <u>Class 5, Division 5.1: Oxidising substances</u> , as specified in the <i>Australian Code for the Transport of Dangerous Goods by Road and Rail</i> in preparations containing 5 g or less of sodium dichloroisocyanurate for use in toilet bowls only.		
(i) during storage	10,22	12,13,14,15,17, 18,21
(ii) during use	5	1,4,7,12

APPENDIX I - AMENDMENT

PARAGRAPH 3 – Amend entry to read:

3. 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 AS/NZS ISO 8124.3:2012 entitled *Safety of toys Part 3:Migration of certain elements* (ISO 8124-3:2010, MOD).