# Final decisions and reasons for decisions by delegates of the Secretary to the Department of Health

# December 2013

## Notice under subsections 42ZCZS 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 the 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 Therapeutic Goods Regulations 1990 (the Regulations). This notice also provides the reasons for each decision and the date of effect (implementation date) of the decision.

The delegates' final decisions and reasons relate to:

- scheduling proposals considered as delegate-only matters, i.e. not referred to an expert advisory committee.

## Matters not referred to an advisory committee

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

## Publishing of the amendments to the Poisons Standard

The amendments to the Schedules, Appendices or other parts of the Poisons Standard are published electronically on ComLaw and in a hardcopy Amendment to the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) prior to the date of effect (implementation date) of the final decisions. Further information, including links to the Poisons Standard on ComLaw, is available at http:www.tga.gov.au/industry/scheduling-poisons-standard.htm.

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# Glossary

| Abbreviation | Name |
|---|---|
| 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 |

| Abbreviation | Name |
|---|---|
| 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 | Freedom of Information Act 1982 |
| 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 |

| Abbreviation | Name |
|---|---|
| INN | International Non-proprietary Name |
| ISO | International Standards Organization |
| LC50 | 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. |
| LD50 | 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]) |

| Abbreviation | Name |
|---|---|
| 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 |

| Abbreviation | Name |
|---|---|
| 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 |
| 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 expert advisory committee

## 1. New chemical entities – medicines for human therapeutic use

### 1.1 Lurasidone

***Scheduling proposal***

The delegate considered an application from the Therapeutic Goods Administration (TGA) for the scheduling of lurasidone, a new chemical entity for a human therapeutic medicine.

Lurasidone is an atypical antipsychotic agent.

Lurasidone is indicated for treatment of schizophrenia.

The delegate decided to make a delegate-only decision for the substance. The Advisory Committee on Medicines Scheduling (ACMS) was consulted on the requirement for a sedation warning. The delegate has considered the committee's recommendation and lurasidone is to be included in Appendix K (see Final Decisions on Matters referred to the ACMS #9 [http://www.tga.gov.au/industry/scheduling-decisions-1311-final-03-parta-acms.htm]).

***Scheduling status***

Lurasidone is not specifically scheduled and is not captured by any entry in the *Standard for the Uniform Scheduling of Medicines and Poisons*.

Lurasidone is not classified in New Zealand.

***Delegate's consideration***

The delegate considered the following in regards to this application for scheduling.

- The new drug application.
- The TGA evaluation report.
- The advice of the Advisory Committee on Prescription Medicines.
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.

***Delegates' final decision***

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include lurasidone in Schedule 4, with an implementation date of 1 Feb 2014.

The delegate decided that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits; (b) purpose and the extent of use and (f) any other matters that the Secretary considers necessary to protect public health.

The delegate decided that the reasons for the final decision comprise of the following.

- Lurasidone is a new chemical entity with no clinical/marketing experience in Australia.
- It is a treatment for schizophrenia, a condition requiring medical diagnosis and management.
- This substance has similar side-effects to other atypical antipsychotic agents and should have similar scheduling requirements.

***Schedule 4 – New Entry***

LURASIDONE.

**1.2 Vedolizumab**

***Scheduling proposal***

The delegate considered an application from the Therapeutic Goods Administration (TGA) for the scheduling of vedolizumab, a new chemical entity for a human therapeutic medicine.

Vedolizumab is immunoglobulin G1-kappa, anti-[*Homo sapiens* alpha4beta7 integrin (lymphocyte Peyer's patch adhesion molecule 1, LPAM-1), humanized monoclonal antibody.

Vedolizumab is indicated for treatment of:

- adult patients with moderate to severe ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist.
- adult patients with moderate to severe Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist.

The delegate decided to make a delegate-only decision. The Advisory Committee on Medicines Scheduling was not consulted.

***Scheduling status***

Vedolizumab is not specifically scheduled in the *Standard for the Uniform Scheduling of Medicines and Poisons* but may be captured by a group/class entry for monoclonal antibodies:

**SCHEDULE 4**

MONOCLONAL ANTIBODIES for therapeutic use **except**:

(a) in diagnostic test kits; or

(b) when separately specified in these Schedules.

Vedolizumab is not classified in New Zealand.

***Delegate's consideration***

The delegate considered the following in regards to this application for scheduling.

- The new drug application.
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.

The delegate noted that currently there are no issues of concern that require additional control other than by inclusion in Schedule 4.

***Delegate's final decision***

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include vedolizumab in Schedule 4, with an implementation date of 1 Feb 2014.

The delegate decided that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits; (b) purpose and the extent of use and (c) toxicity, d) dosage, formulation, labelling, packaging and presentation, and (e) the potential for abuse of vedolizumab.

The delegate decided that the reasons for the final decision comprise of the following.

- Vedolizumab is a new chemical entity with no clinical and marketing experience in Australia.
- Vedolizumab is intended for the treatment of life-threatening conditions.
- Vedolizumab has side effects that also require close monitoring.

***Schedule 4 – New Entry***

VEDOLIZUMAB.

**1.3 Vortioxetine**

***Scheduling proposal***

The delegate considered an application from the Therapeutic Goods Administration (TGA) for the scheduling of vortioxetine, a new chemical entity for a human therapeutic medicine.

Vortioxetine is an antidepressant with a novel mechanism of action that belongs to a group of selective serotonine reuptake inhibitors (SSRIs).

Vortioxetine is indicated for the treatment of major depressive disorder including prevention of relapse.

The delegate decided to make a delegate-only decision on the scheduling of the substance. The Advisory Committee on Medicines Scheduling (ACMS) were consulted on recommendation of inclusion in Appendix L. The ACMS recommendation was not to include vortioxetine in Appendix L (see Final Decisions on Matters referred to the ACMS #9 [http://www.tga.gov.au/industry/scheduling-decisions-1311-final-03-parta-acms.htm]).

***Scheduling status***

Vortioxetine is not specifically scheduled and is not captured by any entry in the *Standard for the Uniform Scheduling of Medicines and Poisons*.

Vortioxetine is not classified in New Zealand.

***Delegate's consideration***

The delegate considered the following in regards to this application for scheduling.

- The new drug application.
- The TGA evaluation report.
- The advice of the Advisory Committee on Prescription Medicines.

- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.

The delegate noted that currently there are no issues of concern that require additional control other than by inclusion in Schedule 4.

### *Delegates' final decision*

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include VORTIOXETINE in Schedule 4, with an implementation date of 1 Feb 2014.

The delegate decided that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits; (b) purpose and the extent of use and (c) toxicity, d) dosage, formulation, labelling, packaging and presentation, and (e) the potential for abuse of vortioxetine.

The delegate decided that the reasons for the final decision comprise of the following.

- Vortioxetine is a new chemical entity with no clinical/marketing experience in Australia.
- Vortioxetine affects multiple CNS receptors, particularly serotonin receptors. Other antidepressants acting at serotonin receptors (e.g. SSRIs) have been associated with pulmonary hypertension and with withdrawal syndrome in newborns.
- Vortioxetine is an antidepressant with a novel mechanism of action, inhibiting serotonin transport and direct agonist action on serotonin receptors. It also has effects on many other CNS receptors.
- The toxicity of vortioxetine is similar to that of other already scheduled SSRIs.
- 5, 10, 15 and 20 mg film coated tablets.
- The potential for abuse of this substance is limited.

### *Schedule 4 – New Entry*

VORTIOXETINE.