
December 2010

**REASONS FOR DECISIONS BY THE DELEGATE OF THE
SECRETARY TO THE DEPARTMENT OF HEALTH AND AGEING
FOR AMENDMENTS TO THE CURRENT POISONS STANDARD (THE
POISONS STANDARD 2010)**

Amendments to the Poisons Standard 2010 to be incorporated into Amendment No. 1 to the Standard for the Uniform Scheduling of Medicines and Poisons 1 (“Poisons Standard Amendment No. 1 of 2011”)

Notice under subsection 52D(2) *Therapeutic Goods Act 1989* (the Act)

The Delegate of the Secretary to the Department of Health and Ageing for the purposes of subsection 52D(2) of the Act hereby gives notice of the Delegate's decision to amend the Poisons Standard 2010. These amendments will form part of a legislative instrument (Poisons Standard Amendment No. 1 of 2011) that will be registered in the Federal Register of Legislative Instruments and will commence on 1 January 2011. The Poisons Standard 2010 consists of the Standard for the Uniform Scheduling of Medicines and Poisons 1 (the SUSMP 1).

This notice provides the decisions of the Delegate, the reasons for those decisions, and the date of effect of the decisions. This notice provides reasons for those scheduling decisions that have not yet been implemented in the Poisons Standard 2010 or included in a previous notice.

The amendments set out in this notice will be incorporated into the SUSMP 1, Amendment No. 1 effective **1 January 2011**. Amendment No.1 to the SUSMP 1 will be available for purchase from National Mailing and Marketing Pty Ltd, telephone (02) 6269 1035.

Please also note that the Poisons Standard Amendment No. 1 of 2011 will be available electronically at the ComLaw website by 1 January 2011. A link to the current Poisons Standard consisting of the SUSMP 1 can be found at
<http://www.tga.gov.au/industry/scheduling-poisons-standard.htm>.

Please note that 'XXXXX' designates Commercial-in-Confidence or private information which has been removed.

TABLE OF CONTENTS

GLOSSARY.....III**FINAL DECISIONS ON SUBSTANCES NOT REFERRED TO AN ADVISORY COMMITTEE
ESTABLISHED UNDER SECTION 52B OR 52C OF THE THERAPEUTIC GOODS ACT 19891**

| | |
|---|----|
| 1. AFAMELANOTIDE AND MELANOCYTE STIMULATING HORMONE | 1 |
| 2. ASENAPINE..... | 2 |
| 3. BELIMUMAB | 4 |
| 4. LINAGLITPIN | 5 |
| 5. NITISINONE | 5 |
| 6. NOMEGESTROL..... | 7 |
| 7. ROFLUMILAST | 8 |
| 8. RUPATADINE | 9 |
| 9. SAPROPTERIN | 10 |
| 10. TAFLUPROST..... | 11 |
| 11. TAPENTADOL..... | 12 |
| 12. TUBERCULIN..... | 13 |
| 13. EDITORIALS AND ERRATA | 14 |

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]) |
| ACNPM | Advisory Committee on Non-Prescription Medicines (formerly Medicines Evaluation Committee [MEC]) |
| ACPM | Advisory Committee on Prescription Medicines (formerly Australian Drug Evaluation Committee [ADEC]) |
| ACSM | 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 [ACSM]) |
| 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 | Council Of Australian Governments |
| CRC | Child-Resistant Closure |
| CTFAA | Cosmetic, Toiletry & Fragrance Association of Australia |
| ECRP | Existing Chemicals Review Program |
| EPA | Environment Protection Authority |
| ERMA | Environmental Risk Management Authority (NZ) |
| FAISD | First Aid Instructions and Safety Directions |
| FDA | Food and Drug Administration (US) |
| FSANZ | Food Standards Australia New Zealand |
| GHS | Globally Harmonised System for Classification and Labelling of Chemicals |
| GIT | Gastro-intestinal tract |
| GP | General Practitioner |
| INN | International Non-proprietary Name |
| ISO | International Standards Organization |
| LC ₅₀ | The concentration of a substance that produces death in 50% of a population of |

Delegate's reasons for amendments to the Poisons Standard

Amendments to be listed in the SUSMP 1, Amendment 1

iv

| | |
|------------------|--|
| | 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 (NZ) |
| MEC | Medicines Evaluation Committee (now Advisory Committee on Non-Prescription Medicines [ACNPM]) |
| MOH | Ministry of Health (NZ) |
| NCCTG | National Coordinating Committee of 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 |
| OCSEH | Office of Chemical Safety and Environmental Health |
| OOS | Out of Session |
| OTC | Over-the-Counter |
| PACIA | Plastics And Chemicals Industries Association |
| PAR | Prescription Animal Remedy |
| 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 |
| 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 |
| TGO | Therapeutic Goods Order |
| TTHWP | Trans-Tasman Harmonisation Working Party |
| TTMRA | Trans-Tasman Mutual Recognition Agreement |
| WHO | World Health Organization |
| WS | Warning Statement |

**FINAL DECISIONS ON SUBSTANCES NOT REFERRED TO AN
ADVISORY COMMITTEE ESTABLISHED UNDER
SECTION 52B OR 52C OF THE THERAPEUTIC GOODS
ACT 1989**

**1. AFAMELANOTIDE AND MELANOCYTE STIMULATING
HORMONE**

SUBSTANCE DETAILS

- Melanocyte stimulating hormone (MSH) is a polypeptide isolated from the pars intermedia of the pituitary of fish and amphibia which causes dispersal of melanin granules in the skin of fish and amphibia and allows adaptation to the environment.
- In adult humans, the pituitary gland lacks a distinct intermediate lobe, and the pituitary is not thought to secrete MSH directly. However, the precursor molecule, pro-opiomelanocortin, is cleaved in the pituitary into corticotrophin, the glycoprotein β -lipotrophin and an amino-terminal peptide. Subsequent processing in other tissues (i.e. the brain and gastrointestinal tract) may yield three forms of MSH: α -MSH, β -MSH, and γ -MSH.
- Afamelanotide (4-L-norleucine-7-D-phenylalanine- α -MSH, also known as Melanotan-1) is a synthetic analog of the naturally occurring melanocortin peptide hormone α -MSH. Afamelanotide should not be confused with a similar substance commonly known as Melanotan-II, which is a cyclic lactam synthetic analog of α -MSH.
- The Therapeutic Goods Administration (TGA) received inquiries on the status of afamelanotide and Melanotan-II following reports of the importation into Australia of products claiming to contain MSH from online suppliers.

SCHEUDLING CONSIDERATION

In making the decision and on the basis of available information, the Delegate took the following relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* into account: (a) risks and benefits of the substance; (b) purpose for which the substance is to be used; and (e) potential for abuse of a substance.

The Delegate noted that:

- This is a Delegate initiated consideration.
- Neither MSH nor afamelanotide are specifically scheduled in Australia.
- In accordance with paragraph 2(c) of Part 1 of the Standard for the Uniform Scheduling of Medicines and Poisons 1 (SUSMP 1), MSH (including afamelanotide and melanotan-II) is captured in Schedule 4 as a derivative of adrenocorticotrophic hormone and corticotrophin.

- Neither MSH nor afamelanotide are specifically scheduled in New Zealand.
- A specific entry for afamelanotide in Schedule 4 with a cross reference to MSH would provide clarity in the interpretation of the scheduling status of these substances.
- According to the Martindale monograph, α -MSH is under investigation in the prevention and treatment of ischaemic intrinsic acute renal failure. Afamelanotide is under investigation as a photoprotective agent in skin conditions such as erythropoietic protoporphyria, phototoxicity associated with photodynamic therapy, polymorphous light eruptions, actinic keratosis, and solar urticaria. Melanotan-II was under investigation for treating sexual dysfunction, although this has been abandoned due to side effects associated with the immune and cardiovascular systems. Its metabolite, bremelanotide, is under investigation for treating haemorrhagic shock.
- There are reports of widespread abuse of afemelanotide and Melanotan II as lifestyle drugs. Endogenous α -MSH has a wide range of regulatory functions in humans and therefore use of exogenous α -MSH analogues could adversely affect several physiological systems, especially as there is the potential for long-term use if abused for lifestyle reasons. Illicit use of α -MSH for tanning has also been associated with a change in size and pigmentation of pre-existing moles.
- No products containing afamelanotide or Melanotan II are registered for use in Australia. In September 2010, the TGA advised the media that these substances have not been assessed for safety or efficacy by the TGA and as a consequence consumers should be wary of using it.

DECISION

The Delegate decided to list afamelanotide in Schedule 4 with a cross-reference to melanocyte stimulating hormone for inclusion into the current Poisons Standard (in particular in Amendment No.1 to the Standard for the Uniform Scheduling of Medicines and Poisons 1), effective 1 January 2011.

Schedule 4 – New Entry

AFAMELANOTIDE.

XXXXX

2. ASENAPINE**SUBSTANCE DETAILS**

- Asenapine is a novel atypical antipsychotic medication. It has been shown to have activity on dopamine (D)-2 and serotonin (5-HT)-2A receptors as well as on 5-HT_{1A}, 5-HT_{1B}, 5-HT_{2C}, 5-HT₆, 5-HT₇, D₃ and alpha-2 adrenergic receptors. It has highest affinity for blocking serotonin receptors, followed by dopamine and alpha-adrenergic receptors with minimal affinity for muscarinic receptors.

Proposed Indications:

- Treatment of schizophrenia including prevention of relapse and maintenance of clinical improvement during continuation therapy.
- Treatment of acute mania or mixed episodes associated with bipolar disorder.

SCEDULING CONSIDERATION

In making the decision and on the basis of available information, the Delegate took the following relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* into account: (a) risks and benefits of the substance; (b) purpose for which the substance is to be used; and (c) toxicity of a substance.

The Delegate noted that:

- As asenapine is not specifically scheduled in Australia, this is a consideration of scheduling of a new chemical entity as outlined in section 4.2 of the Scheduling Policy Framework.
- Asenapine is not currently scheduled in New Zealand.
- The seriousness of the indication mandates interaction with a medical professional.
- There is limited experience in the use of asenapine in the Australian environment.
- Despite being a psychotropic substance, currently available data do not indicate potential for misuse or illicit use. Asenapine is not currently listed as a psychotropic substance under international control.
- Asenapine has been approved by the US Food and Drug Administration and the European Medicines Agency as a prescription medicine.
- According to the Martindale monograph, asenapine is not recommended for use in patients with severe hepatic impairment.
- Common adverse effects of asenapine use include somnolence which may warrant an Appendix K entry.
- Although there is some evidence of maternal and embryo toxic effects, given the proposed indication, treatment would always occur under the direction of a medical specialist and an Appendix D entry would not be required.

DECISION

The Delegate decided to list asenapine in Schedule 4, for inclusion into the Poisons Standard 2010 (in particular in Amendment No.1 to the Standard for the Uniform Scheduling of Medicines and Poisons 1), effective 1 January 2011. The Delegate also decided to refer a proposed Appendix K entry for advice from the Advisory Committee for Medicines Scheduling.

Schedule 4 – New Entry

ASENAPINE.

3. BELIMUMAB**SUBSTANCE DETAILS**

- Belimumab is a humanised monoclonal antibody that inhibits B-lymphocyte stimulator (a naturally occurring protein required for B lymphocyte development).

Indication:

- Under investigation for the treatment of auto-immune diseases.

SCHEDULING CONSIDERATION

In making the decision and on the basis of available information, the Delegate took the following relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* into account: (a) risks and benefits of the substance; (b) purpose for which the substance is to be used; (c) toxicity; and (d) dosage, formulation and presentation of the substance.

The Delegate noted that:

- As belimumab is not specifically scheduled in Australia, this is a consideration of scheduling of a new chemical entity as outlined in section 4.2 of the Scheduling Policy Framework.
- Belimumab is captured under the Schedule 4 class entry for monoclonal antibodies for therapeutic use.
- Belimumab is not currently scheduled in New Zealand.
- The seriousness of the indication mandates interaction with a medical professional.
- There is limited experience in the use of belimumab in the Australian environment.
- There was no evidence of effects in pregnancy or sedation which would warrant an Appendix D or Appendix K entry.
- A specific Schedule 4 entry for belimumab would ensure clarity in interpretation.

DECISION

The Delegate decided to list belimumab in Schedule 4, for inclusion into the Poisons Standard 2010 (in particular in Amendment No.1 to the Standard for the Uniform Scheduling of Medicines and Poisons 1), effective 1 January 2011.

Schedule 4 – New Entry

BELIMUMAB.

4. LINAGLITPIN**SUBSTANCE DETAILS**

- Linagliptin is a DPP-4 inhibitor similar to saxagliptin, sitagliptin and vildagliptin.

Indication:

- Under investigation for treatment of adult patients with type 2 diabetes mellitus to improve glycaemic control in conjunction with diet and exercise, as monotherapy or as an add on to metformin, sulphonylureas, thiazolidinediones or metformin plus sulphonylureas.

SCHEDULING CONSIDERATION

In making the decision and on the basis of available information, the Delegate took the following relevant matters section 52E (1) of the *Therapeutic Goods Act 1989* into account: (a) risks and benefits of the substance; (b) purpose for which the substance is to be used; and (d) dosage, formulation and presentation of the substance.

The Delegate noted that:

- As linagliptin is not scheduled in Australia, this is a consideration of scheduling of a new chemical entity as outlined in section 4.2 of the Scheduling Policy Framework.
- Linagliptin is not currently scheduled in New Zealand.
- Similar substances (saxagliptin, sitagliptin and vildagliptin) are listed in Schedule 4.
- The seriousness of the indication mandates interaction with a medical professional.
- There is limited experience in the use of linagliptin in the Australian environment.
- There was no evidence of effects in pregnancy or sedation which would warrant an Appendix D or Appendix K entry.

DECISION

The Delegate decided to list linagliptin in Schedule 4, for inclusion into the Poisons Standard 2010 (in particular in Amendment No.1 to the Standard for the Uniform Scheduling of Medicines and Poisons 1), effective 1 January 2011.

Schedule 4 – New Entry

LINAGLIPTIN.

5. NITISINONE

SUBSTANCE DETAILS

- Nitisinone is a 4-hydroxyphenylpyruvate dioxygenase inhibitor.
- XXXXX

Indication:

- For the treatment of patients with hereditary tyrosinaemia type 1, in combination with dietary restriction of tyrosine and phenylalanine.

SCEDULING CONSIDERATION

In making the decision and on the basis of available information, the Delegate took the following relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* into account; (a) risks and benefits of the substance; and (b) purpose for which the substance is to be used.

The Delegate noted that:

- As nitisinone is not scheduled in Australia, this is a consideration of scheduling of a new chemical entity as outlined in section 4.2 of the Scheduling Policy Framework.
- Nitisinone is not currently scheduled in New Zealand.
- The seriousness of the indication mandates interaction with a medical professional.
- Experience of the use of nitisinone in the Australian marketplace is limited.
- According to the Martindale monograph for nitisinone and the XXXXX, associated adverse effects include granulocytopenia, leucopenia, thrombocytopenia and eye disorders due to increases in plasma tyrosine (conjunctivitis, corneal opacity, keratitis, photophobia, and eye pain). Effects on cognitive function have been observed. Although it is not known if nitisinone is excreted into human milk, breast feeding is contra-indicated because of the potential effects on a breast feeding child.
- Neither the XXXXX nor the Martindale monograph specified any effects in sedation which would warrant an Appendix K entry. Although nitisinone shows some evidence of teratogenicity, given the proposed indication, treatment would always occur under the direction of a medical specialist and an Appendix D entry would not be required.
- Nitisinone is not a narcotic, does not produce dependency and has no propensity for illicit use.
- Although nitisinone was originally developed for use as a herbicide, there is no evidence of any products registered for this purpose in Australia.
- Nitisinone is approved in Europe, the UK and the USA.

DECISION

The Delegate decided to list nitisinone in Schedule 4, for inclusion into the Poisons Standard 2010 (in particular in Amendment No.1 to the Standard for the Uniform Scheduling of Medicines and Poisons 1), effective 1 January 2011.

Schedule 4 – New Entry

NITISINONE.

6. NOMEGESTROL**SUBSTANCE DETAILS**

- Nomegestrol is a progestogen structurally related to progesterone used in the treatment of menstrual disorders and as the progestogen component of menopausal Hormone Replacement Therapy.

Indication:

- Oral contraception in fertile women including post-menarcheal adolescents from the age of 12 years.

SCHEDULING CONSIDERATION

In making the decision and on the basis of available information, the Delegate took the following relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* into account: (a) risks and benefits of the substance; (b) purpose for which the substance is to be used; and (d) dosage, formulation, labelling and presentation of the substance.

The Delegate noted that:

- As nomegestrol is not specifically scheduled in Australia, this is a consideration of scheduling of a new chemical entity as outlined in section 4.2 of the Scheduling Policy Framework.
- Nomegestrol is captured under the Schedule 4 class entry for sex hormones.
- Nomegestrol is not currently scheduled in New Zealand.
- The seriousness of the indication mandates interaction with a medical professional.
- There is limited experience in the use of nomegestrol in the Australian environment.
- There is no evidence to indicate drug dependency or potential for misuse / abuse.
- A specific Schedule 4 entry for nomegestrol would ensure clarity in interpretation.

DECISION

The Delegate decided to list nomegestrol in Schedule 4, for inclusion into the Poisons Standard 2010 (in particular in Amendment No.1 to the Standard for the Uniform Scheduling of Medicines and Poisons 1), effective 1 January 2011.

Schedule 4 – New Entry

NOMEGESTROL.

7. ROFLUMILAST**SUBSTANCE DETAILS**

- Roflumilast is a phosphodiesterase type-4 inhibitor.

Indication:

- For the maintenance treatment of chronic obstructive pulmonary disease associated with chronic bronchitis in patients at risk of exacerbations.

SCHEUDLING CONSIDERATION

In making the decision and on the basis of available information, the Delegate took the following relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* into account: (a) risks and benefits of the substance; and (b) purpose for which the substance is to be used.

The Delegate noted that:

- As roflumilast is not scheduled in Australia, this is a consideration of scheduling of a new chemical entity as outlined in section 4.2 of the Scheduling Policy Framework.
- Roflumilast is not currently scheduled in New Zealand.
- The seriousness of the indication mandates interaction with a medical professional.
- There is limited experience in the use of roflumilast in the Australian environment.
- There is no evidence to indicate potential for abuse / misuse.
- There is no evidence of effects in pregnancy or sedation which would warrant an Appendix D or Appendix K entry.

DECISION

The Delegate decided to list roflumilast in Schedule 4, for inclusion into the Poisons Standard 2010 (in particular in Amendment No.1 to the Standard for the Uniform Scheduling of Medicines and Poisons 1), effective 1 January 2011.

Schedule 4 – New Entry

ROFLUMILAST.

8. RUPATADINE**SUBSTANCE DETAILS**

- Rupatadine is an antihistamine with platelet-activating factor antagonist activity.

Indication:

- Under investigation for symptomatic treatment of seasonal allergic rhinitis, perennial allergic rhinitis and chronic idiopathic urticaria (CIU) in adults and adolescents (over 12 years of age).

SCHEUDLING CONSIDERATION

In making the decision and on the basis of available information, the Delegate took the following relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* into account: (b) purpose for which the substance is to be used.

The Delegate noted that:

- As rupatadine is not specifically scheduled in Australia, this is a consideration of scheduling of a new chemical entity as outlined in section 4.2 of the Scheduling Policy Framework.
- Rupatadine is captured by the Schedule 4 class entry for antihistamines.
- Rupatadine is not currently scheduled in New Zealand.
- The seriousness of the indication (CIU) mandates interaction with a medical professional.
- There is limited experience in the use of rupatadine in the Australian environment.
- There is no evidence to indicate drug dependency or potential for misuse / abuse.
- According to the Martindale monograph, rupatadine should be used with caution in patients with known prolongation of the QT interval, uncorrected hypokalaemia, or conditions such as bradycardia or acute myocardial ischaemia. Associated adverse effects included heart rhythm disturbances such as palpitations, tachycardia and torsade de pointes.
- Rupatadine shows some evidence of sedation which may warrant an Appendix K entry.
- A specific Schedule 4 entry for rupatadine would ensure clarity in interpretation.

DECISION

The Delegate decided to list rupatadine in Schedule 4, for inclusion into the Poisons Standard 2010 (in particular in Amendment No.1 to the Standard for the Uniform Scheduling of Medicines and Poisons 1), effective 1 January 2011. The Delegate also decided to refer a proposed Appendix K entry for advice from the Advisory Committee for Medicines Scheduling.

Schedule 4 – New Entry

RUPATADINE.

9. SAPROPTERIN**SUBSTANCE DETAILS**

- Sapropterin is the synthetic form of tetrahydrobiopterin, an endogenous cofactor for phenylalanine hydroxylase.
- XXXXX.

Indication:

- Proposed for the treatment of hyperphenylalaninaemia in sapropterin-responsive adult and paediatric patients, with phenylketonuria or tetrahydrobiopterin deficiency.

SCHEUDLING CONSIDERATION

In making the decision and on the basis of available information, the Delegate took the following relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* into account: (a) risks and benefits of the substance; and (b) purpose for which the substance is to be used.

The Delegate noted that:

- As sapropterin is not scheduled in Australia, this is a consideration of scheduling of a new chemical entity as outlined in section 4.2 of the Scheduling Policy Framework.
- Sapropterin is not currently scheduled in New Zealand.
- The seriousness of the indication mandates interaction with a medical professional.
- Experience in the use of sapropterin in the Australian marketplace is limited.
- Sapropterin is not a narcotic, does not produce dependency and has no propensity for illicit use.
- According to the XXXXX, associated adverse effects include headache and rhinorrhoea, diarrhoea, vomiting, abdominal pain, hypophenylalaninaemia, pharyngolaryngeal pain, nasal congestion and cough. In addition, rebound of blood

phenylalanine levels to above pre-treatment levels may occur with cessation of treatment with sapropterin dihydrochloride.

- Neither the XXXXX nor the Martindale monograph specified any effects in pregnancy or sedation which would warrant an Appendix D or Appendix K entry.
- Sapropterin has been approved for marketing by the US Food and Drug Administration (2007) and by the European Medicines Agency (2008).

DECISION

The Delegate decided to list sapropterin in Schedule 4, for inclusion into the Poisons Standard 2010 (in particular in Amendment No.1 to the Standard for the Uniform Scheduling of Medicines and Poisons 1), effective 1 January 2011.

Schedule 4 – New Entry

SAPROPTERIN.

10. TAFLUPROST

SUBSTANCE DETAILS

- Tafluprost is a synthetic analogue of dinoprost (a prostaglandin F2 α).

Indication:

- The reduction of elevated intraocular pressure in open-angle glaucoma or ocular hypertension.

SCEDULING CONSIDERATION

In making the decision and on the basis of available information, the Delegate took the following relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* into account: (a) risks and benefits of the substance; and (b) purpose for which the substance is to be used.

The Delegate noted that:

- As tafluprost is not specifically scheduled in Australia, this is a consideration of scheduling of a new chemical entity as outlined in section 4.2 of the Scheduling Policy Framework.
- As a prostaglandins analogue, tafluprost is captured by the Schedule 4 class entry for prostaglandins.
- The related substance, dinoprost, is listed in Schedule 4 and Appendix D.
- Tafluprost is not currently scheduled in New Zealand.
- The seriousness of the indication mandates interaction with a medical professional.

- There is limited experience in the use of tafluprost in the Australian environment.
- Tafluprost has been approved for marketing in UK, Denmark, Germany, Finland, Norway and Sweden.
- A specific Schedule 4 entry for tafluprost would ensure clarity in interpretation.
- Reproductive toxicity studies showing embryofetal lethality, teratogenicity and other effects raise concerns with regard to use of tafluprost in pregnancy. This also suggests that tafluprost may have a low risk of being an abortifacient which may warrant entries in Appendix D and Appendix L.

DECISION

The Delegate decided to list tafluprost in Schedule 4, for inclusion into the Poisons Standard 2010 (in particular in Amendment No.1 to the Standard for the Uniform Scheduling of Medicines and Poisons 1), effective 1 January 2011. The Delegate also decided to refer proposed Appendix D and Appendix L entries for advice from the Advisory Committee for Medicines Scheduling.

Schedule 4 – New Entry

TAFLUPROST.

11. TAPENTADOL

SUBSTANCE DETAILS

- Tapentadol is a centrally acting analgesic that exerts its pharmacological effects primarily by binding to mu-opioid receptors. Its binding affinity is approximately 18 times less than that of morphine.
- Tapentadol also inhibits noradrenaline reuptake and binds to 5-HT_{2A}, β₁-adrenergic receptor, and the muscarinic receptor M₁. A pharmacology study demonstrated that tapentadol demonstrated abuse potential comparable to that of hydromorphone.

SCHEUDLING CONSIDERATION

In making the decision and on the basis of available information, the Delegate took the following relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* into account: (a) risks and benefits of the substance; (b) purpose for which the substance is to be used; and (e) potential for abuse.

The Delegate noted that:

- As tapentadol is not specifically scheduled in Australia, this is a consideration of scheduling of a new chemical entity as outlined in section 4.2 of the Scheduling Policy Framework.

- Tapentadol is not currently scheduled in New Zealand.
- The seriousness of the indication mandates interaction with a medical professional.
- The US Drug Enforcement Agency has placed tapentadol into Schedule II, the same category as the narcotics morphine, oxycodone and fentanyl. The Committee on Narcotics Drugs in Germany has listed tapentadol in SIII the same schedule as hydromorphone and morphine. Tapentadol has not yet been included in the Single Convention on Narcotic Drugs or in the list of controlled psychotropic drugs.
- A clinical study has indicated that the potential for abuse of tapentadol is similar to hydromorphone, which is listed in Appendix 8 and Appendix K.
- Tapentadol is associated with sedation effects (somnolence and lethargy) which may warrant an Appendix K entry.
- Tapentadol is classified by the US Food and Drug Administration as a Category C pregnancy drug (drugs which should be given only if the potential benefit justifies the potential risk to the foetus.). Pre-clinical studies have revealed teratogenic effects in animals, however no controlled teratogenicity studies in humans have been reported. These effects may warrant an Appendix D entry.

DECISION

The Delegate decided to list tapentadol in Schedule 8, for inclusion into the Poisons Standard 2010 (in particular in Amendment No.1 to the Standard for the Uniform Scheduling of Medicines and Poisons 1), effective 1 January 2011.. The Delegate noted that for entry in Appendix K and Appendix D the advice of the Advisory Committee for Medicines Scheduling would be required.

Schedule 8 – New Entry

TAPENTADOL.

12. TUBERCULIN**SUBSTANCE DETAILS**

- Tuberculin skin tests are used to detect tuberculoprotein hypersensitivity when *Bacillus Calmette-Guerin (BCG)* vaccination is being considered or as an aid to diagnosis of tuberculosis. Tuberculin for sensitivity testing is given by intradermal injection as in the Mantoux test.

SCHEDULING CONSIDERATION

In making the decision and on the basis of available information, the Delegate took the following relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* into account: (a) risks and benefits of the substance; and (b) purpose for which the substance is to be used.

The Delegate noted that:

- This was a Delegate initiated consideration.
- Although captured by the Schedule 4 antigens class entry, tuberculin is not specifically scheduled in Australia.
- Tuberculin is not specifically scheduled in New Zealand.
- A specific listing for tuberculin in Schedule 4 would ensure clarity in interpretation and enforcement.
- According to the Martindale monograph for tuberculins, associated adverse effects include pain and pruritus at the injection site, occasionally with vesiculation, ulceration, or necrosis in highly sensitive persons. Granuloma, nausea, headache, dizziness, malaise, rash, urticaria, oedema, and pyrexia have been reported occasionally; immediate systemic hypersensitivity, including anaphylaxis, has been reported rarely. There have also been rare reports of lymphangitis.
- The Martindale monograph does not specify any effects with respect to teratogenicity or sedation that would warrant an Appendix D or Appendix K entry.

DECISION

The Delegate decided to list tuberculin in Schedule 4, for inclusion into the Poisons Standard 2010 (in particular in Amendment No.1 to the Standard for the Uniform Scheduling of Medicines and Poisons 1), effective 1 January 2011.

Schedule 4 – New Entry

TUBERCULIN.

13. EDITORIALS AND ERRATA

CONSIDERATIONS

Appropriate Authority

The Delegate noted that:

- The definition of “appropriate authority” in Part 1, Interpretation, of the Standard for the Uniform Scheduling of Medicines and Poisons 1 (SUSMP 1) states:

“Appropriate authority” means:

- (a) in the Australian Capital Territory, ACT Health;
- (b) for the purpose of providing an exemption from sections 2-12 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 New South Wales Health;
- (d) in the Northern Territory, the Chief Health Officer of the Department of Health & Families;
- (e) in Queensland, the Chief Executive of Queensland Health;
- (f) in South Australia, the Chief Executive of the Department of Health;
- (g) in Tasmania, the Secretary of the Department of Health and Human Services;
- (h) for the purpose of providing an exemption from sections 2-12 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.

· XXXXX advised that the current definition of “appropriate authority” may be misinterpreted and requested the following editorial amendment to paragraphs (b) and (h) of the entry:

- (b) for the purpose of providing an exemption from **all or part of** sections 2 **through** 12 of this Standard by the Australian Pesticides and Veterinary Medicines Authority, the Chief Executive Officer or their delegate;

...

- (h) for the purpose of providing an exemption from **all or part of** sections 2 **through** 12 of this Standard by the Therapeutic Goods Administration, the National Manager or their delegate;

Trifluoromethanesulfonic acid

The Delegate noted that:

- Trifluoromethanesulfonic acid is listed in Schedule 6, Appendix E and Appendix F of the SUSMP.
- Due to an oversight, the Appendix E entry listed the substance as trifluoromethane-sulphonic acid. The Scheduling Secretariat suggested that to avoid misinterpretation the spelling of the Appendix E entry be amended in line with the remaining listings.

- Recent scheduling convention indicates a preference for the use of 'f' instead of 'ph' in scheduling entries (ie. sulfonate vs. sulphonate).

The Delegate agreed that the relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989* included (f) other matters that the Secretary considers necessary to protect public health.

DECISIONS

The Delegate decided to editorially amend paragraphs (b) and (h) of the definition of "appropriate authority" to include the words "all or part of sections 2 through 12", for inclusion for inclusion into the Poisons Standard 2010 (in particular in Amendment No.1 to the Standard for the Uniform Scheduling of Medicines and Poisons 1), effective 1 January 2011. The Delegate also decided to editorially amend the spelling of the trifluoromethane-sulphonic acid Appendix E entry to "trifluoromethanesulfonic acid", for inclusion into the Poisons Standard 2010 (in particular in Amendment No.1 to the Standard for the Uniform Scheduling of Medicines and Poisons 1), effective 1 January 2011.

INTERPRETATION – Amendment

APPROPRIATE AUTHORITY – Amend entry to read:

"Appropriate authority" means:

- in the Australian Capital Territory, ACT Health;
- for the purpose of providing an exemption from all or part of sections 2 through 12 of this Standard by the Australian Pesticides and Veterinary Medicines Authority, the Chief Executive Officer or their delegate;
- in New South Wales, the Director-General of New South Wales Health;
- in the Northern Territory, the Chief Health Officer of the Department of Health & Families;
- in Queensland, the Chief Executive of Queensland Health;
- in South Australia, the Chief Executive of the Department of Health;
- 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 sections 2 through 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.

Appendix E – Amendment**TRIFLUOROMETHANE-SULPHONIC ACID – Amend entry to read:****POISON****STANDARD STATEMENTS**

Trifluoromethanesulfonic acid A,G3,E2