Australian Government
Department of Health
Therapeutic Goods Administration

Publication of final decisions amending, or not amending, the current Poisons Standard, May 2018

19 June 2018

Publication of decisions pursuant to regulation 42ZCZX of the *Therapeutic Goods Regulations 1990*

In accordance with regulation 42ZCZX, this notice gives effect to the Secretary's obligation to publish the final decisions, the reasons for those decisions and the date of effect of decisions made pursuant to regulations 42ZCZU or 42ZCZW of the *Therapeutic Goods Regulations 1990*.

The final decisions to which this notice relates include decisions made with respect to new therapeutic Prescription Only medicines known as New Chemical Entities (NCEs) which were not referred to an expert advisory committee.

Contents

New Chemical Entities – medicines for human therapeutic use

1.1. Atezolizumab

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include atezolizumab in Schedule 4 as follows:

Schedule 4 – New Entry

ATEZOLIZUMAB.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- Atezolizumab is an active chemical substance which has significant risks. The risk-benefit balance for an individual patient, including explanation of the risks in order for the balance to be understood, requires the input of a medical practitioner.

c) the toxicity of a substance

- Atezolizumab can cause significant, potentially fatal toxicity.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to atezolizumab.

Scheduling status

Atezolizumab is not specifically scheduled in the Poisons Standard, but as a monoclonal antibody, it is captured by the Schedule 4 entry for monoclonal antibodies as follows:

Schedule 4

MONOCLONAL ANTIBODIES for therapeutic use **except**:

a) in diagnostic test kits; or

b) when separately specified in these Schedules.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; and (c) the toxicity of a substance.

1.2. Avelumab

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include avelumab in Schedule 4 as follows:

Schedule 4 – New Entry

AVELUMAB.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- Avelumab is an active chemical substance which has significant risks. The risk-benefit balance for an individual patient, including explanation of the risks in order for the balance to be understood, requires the input of a medical practitioner.

c) the toxicity of a substance

- Avelumab can cause significant, potentially fatal toxicity

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to avelumab.

Scheduling status

Avelumab is not specifically scheduled in the Poisons Standard, but as a monoclonal antibody, it is captured by the Schedule 4 entry for monoclonal antibodies as follows:

Schedule 4

MONOCLONAL ANTIBODIES for therapeutic use **except**:

a) in diagnostic test kits; or

b) when separately specified in these Schedules.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; and (c) the toxicity of a substance.

1.3. Blinatumomab

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include blinatumomab in Schedule 4 as follows:

Schedule 4 – New Entry

BLINATUMOMAB.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- The benefits are considered to outweigh risks at a population level when blinatumomab is used for the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL).

b) the purposes for which a substance is to be used and the extent of use of a substance

- The use of blinatumomab as a treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL is approved based on phase II, non-randomised evidence. An improvement in clinical outcomes by direct prospective comparison in a randomised setting relative to other standard-of-care salvage therapies has not been established.

c) the toxicity of a substance

- The toxicity of blinatumomab includes tumour lysis syndrome, infusion reactions, neutropaenia and febrile neutropaenia, thrombocytopaenia, sepsis, fungal bacterial & viral infections, elevated liver enzymes, pancreatitis, leukoencephalopathy.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- Blinatumomab has a significantly complex preparation and administration schedule – a prescriber/administrator education program must be completed prior to use.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to blinatumomab.

Scheduling status

Blinatumomab is not specifically scheduled in the Poisons Standard, but as a monoclonal antibody, it is captured by the Schedule 4 entry for monoclonal antibodies as follows:

Schedule 4

MONOCLONAL ANTIBODIES for therapeutic use **except**:

a) in diagnostic test kits; or

b) when separately specified in these Schedules.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Advice on the place in therapy of this medicine;
- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation of a substance.

1.4. Daratumumab

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include daratumumab in Schedule 4 as follows:

Schedule 4 – New Entry

DARATUMUMAB.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- The risks and benefits have been considered, with the view reached that benefits outweighed risks at a population level in the proposed indication.

b) the purposes for which a substance is to be used and the extent of use of a substance

- The extent of use of daratumumab is relatively limited, it is to be used:
  - in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.
  - as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are refractory to both a PI and an immunomodulatory agent.

c) the toxicity of a substance

- While daratumumab has distinct toxicities, these are well characterised and (given the benefits conferred in the target population) are consistent with scheduling as a Schedule 4 medicine.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- The dosage, formulation, labelling, packaging and presentation of daratumumab have been considered, and none of these aspects precludes scheduling as a Schedule 4 medicine.

e) the potential for abuse of a substance

- There is low potential for abuse of daratumumab.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to daratumumab.

Scheduling status

Daratumumab is not specifically scheduled in Poisons Standard, but as a monoclonal antibody, it is captured by the Schedule 4 entry for monoclonal antibodies as follows:

> **Schedule 4**
>
> MONOCLONAL ANTIBODIES for therapeutic use **except**:
>
> a) in diagnostic test kits; or
>
> b) when separately specified in these Schedules.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (e) the potential for abuse of a substance.

1.5. Durvalumab

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include durvalumab in Schedule 4 as follows:

Schedule 4 – New Entry

DURVALUMAB.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- Durvalumab is an active chemical substance which has significant risks. The risk-benefit balance for an individual patient, including explanation of the risks in order for the balance to be understood, requires the input of a medical practitioner.

c) the toxicity of a substance

- Durvalumab can cause significant, potentially fatal toxicity.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to durvalumab.

Scheduling status

Durvalumab is not specifically scheduled in the Poisons Standard, but as a monoclonal antibody, it is captured by the Schedule 4 entry for monoclonal antibodies as follows:

Schedule 4

MONOCLONAL ANTIBODIES for therapeutic use **except**:

a) in diagnostic test kits; or

b) when separately specified in these Schedules.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; and (c) the toxicity of a substance.

1.6. Idebenone

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include idebenone in Schedule 4 as follows:

Schedule 4– New Entry

IDEBENONE.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- Idebenone is a new chemical entity with no marketing experience in Australia.

b) the purposes for which a substance is to be used and the extent of use of a substance

- The diagnosis, treatment and monitoring of patients with Duchenne Muscular Dystrophy condition should be supervised by a medical practitioner experienced in managing this condition.

c) the toxicity of a substance

- Idebenone has a potential for adverse effects, requiring monitoring by a medical practitioner.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- Labelling needs to comply with the requirements for a Prescription-Only Medicine.

e) the potential for abuse of a substance

- Idebenone has a low potential for abuse.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to idebenone.

Scheduling status

Idebenone is not specifically scheduled and is not captured by any entry in the Poisons Standard.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (e) the potential for abuse of a substance.

1.7. Inotuzumab Ozogamicin

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include inotuzumab ozogamicin in Schedule 4 as follows:

Schedule 4 – New Entry

INOTUZUMAB OZOGAMICIN.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- Inotuzumab ozogamicin is a new chemical entity with no marketing experience in Australia. The risk-benefit balance at a population level has been considered, with the overall balance of benefits considered to outweigh the risks. The risk-benefit balance for an individual patient, including explanation of the risks in order for the balance to be understood, requires the input of a medical practitioner.

b) the purposes for which a substance is to be used and the extent of use of a substance

- The extent of use of inotuzumab ozogamicin is considered to be relatively more limited compared to other therapeutic products. The intended purpose for use is in the treatment of adults with relapsed or refractory CD22-positive B-Cell precursor lymphoblastic leukaemia.

c) the toxicity of a substance

- There are known risks and toxicities associated with the use of inotuzumab ozogamicin. The risk-benefit balance for an individual patient, including explanation of the risks in order for the balance to be understood, requires the input of a medical practitioner.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- The dosage, formulation, labelling, packaging and presentation have been considered and none of these aspects precludes scheduling as a Schedule 4 medicine.

e) the potential for abuse of a substance

- The potential for abuse of inotuzumab ozogamicin is considered to be low.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to inotuzumab ozogamicin.

Scheduling status

Inotuzumab ozogamicin is not specifically scheduled in the Poisons Standard, but as it is composed of a monoclonal antibody, it is captured by the Schedule 4 entry for monoclonal antibodies as follows:

> **Schedule 4**
>
> MONOCLONAL ANTIBODIES for therapeutic use except:
>
> a) in diagnostic test kits; or
>
> b) when separately specified in these Schedules.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Advice on the place in therapy of this medicine;
- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (e) the potential for abuse of a substance.

1.8. Lifitegrast

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include lifitegrast in Schedule 4 as follows:

Schedule 4– New Entry

LIFITEGRAST.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- Lifitegrast is a new chemical entity with no previous clinical or marketing experience in Australia. There is clinical and marketing experience with Lifitegrast internationally.
- The medicine acts as an anti-inflammatory. It targets the interaction between lymphocyte function associated antigen and its cognate ligand intercellular adhesion molecule 1.

b) the purposes for which a substance is to be used and the extent of use of a substance

- Lifitegrast will be used in 5% solution for the topical treatment of dry eye disease.

c) the toxicity of a substance

- Low toxicity. There is sometimes mild eye irritation when the drops are installed. These effects are transient. As it is a topical medicine, reproductive effects are unlikely.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- 5% solution. The formulation for therapeutic use also contains sodium chloride, sodium phosphate dibasic anhydrous, sodium thiosulfate pentahydrate, sodium hydroxide and hydrochloric acid.
- The dose is one drop twice daily.
- The usual labelling for eye drops is appropriate.
- The medicine will be presented in 0.2ml single use containers, packaged in foil pouches (5 per pouch) in a box containing 60. This will be sufficient for a patient to use the medicine for 30 days.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to lifitegrast.

Scheduling status

Lifitegrast is not specifically scheduled and is not captured by any entry in the Poisons Standard.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation of a substance.

1.9. Lonoctocog alfa

Delegate's final decision

Final decision:

The delegate's final decision is that lonoctocog alfa is exempt from scheduling as it falls under Appendix A – General Exemptions under HUMAN BLOOD PRODUCTS.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- The risks and benefits have been considered with the view reached that benefits outweighed risks.

b) the purposes for which a substance is to be used and the extent of use of a substance

- Lonoctocog alfa is a recombinant single-chain coagulation Factor VIII for use in Haemophilia A

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to lonoctocog alfa.

Scheduling status

Lonoctocog alfa is exempt from scheduling as it is captured by the Appendix A entry for HUMAN BLOOD PRODUCTS, (iv) clotting factors as follows:

Appendix A - General exemptions

HUMAN BLOOD PRODUCTS including:

a) whole blood;

b) blood components including red cells, white cells, platelets and plasma (including cryoprecipitate); and

c) the following plasma-derived therapeutic proteins; and their equivalent recombinant alternatives:

i) albumin;

ii) anticoagulation complex;

iii) C1 esterase inhibitors;

iv) clotting factors;

v) fibrinogen;

vi) protein C;

vii) prothrombin complex concentrate (PCC); and

viii) thrombin.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Advice on the place in therapy of this medicine;
- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; and (b) the purposes for which a substance is to be used and the extent of use of a substance.

1.10. Midostaurin

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include midostaurin in Schedule 4 as follows:

Schedule 4 – New Entry

MIDOSTAURIN.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- Midostaurin is an active chemical substance which has significant risks. The risk-benefit balance for an individual patient, including explanation of the risks in order for the balance to be understood, requires the input of a medical practitioner.

c) the toxicity of a substance

- Midostaurin can cause significant, potentially fatal toxicity.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to midostaurin.

Scheduling status

Midostaurin is not specifically scheduled and is not captured by any entry in the Poisons Standard.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; and (c) the toxicity of a substance.

1.11. Neratinib

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include neratinib in Schedule 4 as follows:

Schedule 4 – New Entry

NERATINIB.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- Neratinib is an active chemical substance which has significant risks in terms of immunomodulation. The risk-benefit balance for an individual patient, including explanation of the risks in order for the balance to be understood, requires the input of a medical practitioner.

c) the toxicity of a substance

- Neratinib can cause significant, potentially fatal toxicity.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to neratinib.

Scheduling status

Neratinib is not specifically scheduled and is not captured by any entry in the Poisons Standard.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; and (c) the toxicity of a substance.

1.12. Nivolumab

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include nivolumab in Schedule 4 as follows:

Schedule 4 – New Entry

NIVOLUMAB.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- Nivolumab is an active chemical substance which has significant risks in terms of immunomodulation. The risk-benefit balance for an individual patient, including explanation of the risks in order for the balance to be understood, requires the input of a medical practitioner.

c) the toxicity of a substance

- Nivolumab can cause significant, potentially fatal toxicity.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to nivolumab.

Scheduling status

Nivolumab is not specifically scheduled in the Poisons Standard, but as a monoclonal antibody, it is captured by the Schedule 4 entry for monoclonal antibodies as follows:

Schedule 4

MONOCLONAL ANTIBODIES for therapeutic use except:

a) in diagnostic test kits; or

b) when separately specified in these Schedules.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Advice on the place in therapy of this medicine;
- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; and (c) the toxicity of a substance.

1.13. Obeticholic acid

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include obeticholic acid in Schedule 4 as follows:

Schedule 4 – New Entry

OBETICHOLIC ACID.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- Obeticholic acid is a new chemical entity with no clinical or marketing experience in Australia.

b) the purposes for which a substance is to be used and the extent of use of a substance

- Obeticholic acid is to be used to treat the serious medical condition of primary biliary cirrhosis.

c) the toxicity of a substance

- Obeticholic acid has potential for toxicity in overdose.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- The dose may require adjustment during the course of treatment.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to obeticholic acid.

Scheduling status

Obeticholic acid is not specifically scheduled in the Poisons Standard.

Obeticholic acid derivatives, chenodeoxycholic acid, cholic acid, deoxycholic acid and ursodeoxycholic acid are in Schedule 4 of the Poisons Standard.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Advice on the place in therapy of this medicine;
- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation of a substance.

1.14. Palbociclib

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include palbociclib in Schedule 4 as follows:

Schedule 4 – New Entry

PALBOCICLIB.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- The risks and benefits have been considered with the view reached that benefits outweighed risks at a population level in the proposed indication.

b) the purposes for which a substance is to be used and the extent of use of a substance

- Palbociclib is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with: an aromatase inhibitor as initial endocrine-based therapy; or Fulvestrant in patients who have received prior therapy. Therefore use is relatively limited.

c) the toxicity of a substance

- While palbociclib has distinct toxicities, these are well characterised and (given the benefits conferred in the target population) are consistent with scheduling as an Schedule 4 medicine.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- The dosage, formulation, labelling, packaging and presentation of palbociclib have been considered and none of these aspects precludes scheduling as a Schedule 4 medicine.

e) the potential for abuse of a substance

- The potential for abuse was considered low.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to palbociclib.

Scheduling status

Palbociclib is not specifically scheduled and is not captured by any entry in the Poisons Standard.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Advice on the place in therapy of this medicine;
- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (e) the potential for abuse of a substance.

1.15. Pegaspargase

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include pegaspargase in Schedule 4 as follows:

Schedule 4– New Entry

PEGASPARGASE.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- Pegaspargase is a new chemical entity with relatively little experience of use in Australia.
- The risks and benefits have been considered with the view reached that benefits outweighed risks at a population level in the proposed indication.

b) the purposes for which a substance is to be used and the extent of use of a substance

- Pegaspargase is used as a component of antineoplastic combination therapy in patients with acute lymphoblastic leukaemia, so use is relatively limited.

c) the toxicity of a substance

- While pegaspargase has distinct toxicities, these are well characterised and (given the benefits conferred in the target population) are consistent with scheduling as a Schedule 4 medicine.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- The dosage, formulation, labelling, packaging and presentation of pegaspargase have been considered and none of these aspects precludes scheduling as a Schedule 4 medicine.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to pegaspargase.

Scheduling status

Pegaspargase is not specifically scheduled and is not captured by any entry in the Poisons Standard.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Advice on the place in therapy of this medicine;
- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation of a substance.

1.16. Ramucirumab

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include ramucirumab in Schedule 4 as follows:

Schedule 4 – New Entry

RAMUCIRUMAB.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- Ramucirumab is an active chemical substance which has significant risks. The risk-benefit balance for an individual patient, including explanation of the risks in order for the balance to be understood, requires the input of a medical practitioner.

c) the toxicity of a substance

- Ramucirumab can cause significant, potentially fatal toxicity

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to ramucirumab.

Scheduling status

Ramucirumab is not specifically scheduled in the Poisons Standard, but as a monoclonal antibody, it is captured by the Schedule 4 entry for monoclonal antibodies as follows:

Schedule 4

MONOCLONAL ANTIBODIES for therapeutic use **except**:

a) in diagnostic test kits; or

b) when separately specified in these Schedules.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Advice on the place in therapy of this medicine;
- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; and (c) the toxicity of a substance.

1.17. Rufinamide

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include rufinamide in Schedule 4, Appendix K and Appendix L as follows:

Schedule 4 – New Entry

RUFINAMIDE.

Appendix K – New Entry

RUFINAMIDE

Appendix L, Part 2 – New Entry

RUFINAMIDE

Warning statement/s: 62 (Do not use if pregnant), 76 (Do not become pregnant during use or within (Insert number of months as per approved Product Information) month(s) of stopping treatment), 77 (WARNING - May cause birth defects)

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- Rufinamide is a new chemical entity with no clinical experience in Australia.

b) the purposes for which a substance is to be used and the extent of use of a substance

- Rufinamide is an anti-epileptic drug to be used widely.

c) the toxicity of a substance

- Satisfactory with pregnancy warning.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- Pregnancy label added.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to rufinamide.

Scheduling status

Rufinamide is not specifically scheduled and is not captured by any entry in the Poisons Standard.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Advice on the place in therapy of this medicine;
- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation of a substance.

1.18. Secukinumab

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include secukinumab in Schedule 4 as follows:

Schedule 4 – New Entry

SECUKINUMAB.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- Secukinumab is an antibody against interleukin-17A, initially approved for use in some psoriasis patients, with use subsequently expanded to some patients with psoriatic arthritis and ankylosing spondylitis. In these uses the benefits are considered to outweigh risks at a population level.

b) the purposes for which a substance is to be used and the extent of use of a substance

- Secukinumab was initially approved for use in some psoriasis patients (adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy), with use subsequently expanded to some patients with psoriatic arthritis and ankylosing spondylitis. Accordingly, the extent of use of the product is relatively limited.

c) the toxicity of a substance

- Secukinumab has its own distinct toxicities but these have been addressed within the benefit/risk consideration noted above.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- The dose regimen, formulation, labelling, packaging and presentation of secukinumab have been considered and none of these aspects precludes scheduling of Secukinumab as Schedule 4.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to secukinumab.

Scheduling status

Secukinumab is not specifically scheduled in the Poisons Standard, but as a monoclonal antibody, it is captured by the Schedule 4 entry for monoclonal antibodies as follows:

Schedule 4

MONOCLONAL ANTIBODIES for therapeutic use **except**:

a) in diagnostic test kits; or

b) when separately specified in these Schedules.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Advice on the place in therapy of this medicine;
- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation of a substance.

1.19. Siltuximab

Delegate's final decision

Final decision:

The delegate's final decision is to amend the Poisons Standard to include siltuximab in Schedule 4 as follows:

Schedule 4 – New Entry

SILTUXIMAB.

Implementation date: **1 June 2018**

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate include:

a) the risks and benefits of the use of a substance

- Siltuximab is indicated for use in some patients with Multicentric Castleman's disease. In this use the benefits are considered to outweigh risks at a population level.

b) the purposes for which a substance is to be used and the extent of use of a substance

- Siltuximab is indicated for the treatment of patients with Multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative. Accordingly, the extent of use is relatively very small.

c) the toxicity of a substance

- Siltuximab has its own distinct toxicities but these have been addressed within the benefit/risk consideration noted above.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- The dose regimen, formulation, labelling, packaging and presentation of siltuximab have been considered and none of these aspects precludes scheduling of Siltuximab as Schedule 4.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to siltuximab.

Scheduling status

Siltuximab is not specifically scheduled in the Poisons Standard, but as a monoclonal antibody, it is captured by the Schedule 4 entry for monoclonal antibodies as follows:

Schedule 4

MONOCLONAL ANTIBODIES for therapeutic use **except**:

a) in diagnostic test kits; or

b) when separately specified in these Schedules.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Advice on the place in therapy of this medicine;
- Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation of a substance.