Australian Government

Department of Health
Therapeutic Goods Administration

Notice of final decisions to amend (or not amend) the current Poisons Standard

Final decisions and reasons for New Chemical Entities

25 September 2019

Scheduling amendments not referred to expert advisory committee

Subdivision 3D.3 of the *Therapeutic Goods Regulations 1990* (the Regulations) sets out the procedure to be followed where the Secretary receives an application under section 52EAA of the *Therapeutic Goods Act 1989* (the Act) to amend the current Poisons Standard and decides not to refer the proposed amendment to an expert advisory committee. These include, under regulation 42ZCZU, that the Secretary decides to make a final decision in relation to the proposed amendment without an interim decision. If the final decision is to amend the current Poisons Standard, the Secretary must, in doing so, take into account the matters mentioned in subsection 52E(1) of the Act (including, for example, the risks and benefits of the use of a substance, and the potential for abuse of a substance) and the scheduling guidelines as set out in the Scheduling Policy Framework for Medicines and Chemicals.

In accordance with 42ZCZX of the Regulations, the Secretary publishes here the scheduling final decision, the reasons for that decision and the date of effect (for decisions to amend the current Poisons Standard, this will be the date when it is expected that the current Poisons Standard will be amended to give effect to the decision). These Secretary's final decisions and reasons related to new therapeutic prescription only medicines known as New Chemical Entities.

Contents

Final decisions on matters not referred to an expert advisory committee

1. New Chemical Entities – medicines for human therapeutic use

1.1 Lorlatinib

Delegate's final decision

The delegate's final decision under regulation 42ZCZU of the *Therapeutic Goods Regulations 1990* is to include lorlatinib in Schedule 4 of the Poisons Standard as follows:

Schedule 4 – New Entry

LORLATINIB.

Index – New Entry

LORLATINIB

Schedule 4

Implementation date

1 October 2019

Reasons

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

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

– The risks and benefits of this medicine require medical diagnosis and ongoing clinical review and monitoring by medical practitioners with expertise in the condition.

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

– Medical diagnosis and ongoing clinical review and monitoring are essential for the appropriate use of this medicine.

(c) the toxicity of a substance:

– The toxicity of this substance requires ongoing medical review and monitoring.

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

– Nil.

(e) the potential for abuse of a substance:

– Nil.

(f) any other matters that the Secretary considers necessary to protect public health:

– Nil.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to lorlatinib, a new chemical entity (NCE) for a human therapeutic medicine.

Scheduling status

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

Delegate's considerations

- Advice on the place in therapy of this NCE;
- 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; and (c) the toxicity of a substance.

1.2 Niraparib

Delegate's final decision

The delegate's final decision under regulation 42ZCZU of the *Therapeutic Goods Regulations 1990* is to include niraparib in Schedule 4 of the Poisons Standard as follows:

Schedule 4 – New Entry

NIRAPARIB.

Index – New Entry

NIRAPARIB

Schedule 4

Implementation date

1 October 2019

Reasons

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

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

– The use of this medicine requires medical diagnosis and ongoing medical supervision and monitoring.

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

– The indication for use requires medical diagnosis and ongoing clinical review and monitoring.

(c) the toxicity of a substance:

– The toxicity of this substance requires ongoing clinical review and monitoring.

– This is a new chemical entity with no post market experience in Australia.

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

– Nil.

(e) the potential for abuse of a substance:

– Nil.

(f) any other matters that the Secretary considers necessary to protect public health:

– Nil.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to niraparib, a new chemical entity (NCE) for a human therapeutic medicine.

Scheduling status

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

Delegate's considerations

- Advice on the place in therapy of this NCE;
- 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; and (c) the toxicity of a substance.

1.3 Risankizumab

Delegate's final decision

The delegate's final decision under regulation 42ZCZU of the *Therapeutic Goods Regulations 1990* is to include risankizumab in Schedule 4 and Appendix K of the Poisons Standard as follows:

Schedule 4 – New Entry

RISANKIZUMAB.

Appendix K – New Entry

RISANKIZUMAB

Index – New Entry

RISANKIZUMAB

Schedule 4
Appendix K

Implementation date

1 October 2019

Reasons

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

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

– It 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:

– Moderate to severe plaque psoriasis.

(c) the toxicity of a substance:

– Potential toxicity is unknown.

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

– Substance requires subcutaneous injection.

(e) the potential for abuse of a substance:

– Nil.

(f) any other matters that the Secretary considers necessary to protect public health:

– Nil.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to risankizumab, a new chemical entity (NCE) for a human therapeutic medicine.

Scheduling status

Risankizumab 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 considerations

- Advice on the place in therapy of this NCE;
- 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 Darolutamide

Delegate's final decision

The delegate's final decision under regulation 42ZCZU of the *Therapeutic Goods Regulations 1990* is to include darolutamide in Schedule 4 of the Poisons Standard as follows:

Schedule 4 – New Entry

DAROLUTAMIDE.

Index – New Entry

DAROLUTAMIDE

Schedule 4

Implementation date

1 October 2019

Reasons

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

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

– The risks and benefits of darolutamide require the involvement of a medical practitioner experienced in the diagnosis and treatment of the condition.

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

– The use of darolutamide should be managed by a medical practitioner experienced in the diagnosis and treatment of the condition.

(c) the toxicity of a substance:

– The toxicity of darolutamide requires ongoing clinical review by a medical practitioner.

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

– Ongoing clinical monitoring is required to determine whether dose interruptions and/or reductions are required.

(e) the potential for abuse of a substance:

– Nil.

(f) any other matters that the Secretary considers necessary to protect public health:

– Nil.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to darolutamide, a new chemical entity (NCE) for a human therapeutic medicine.

Scheduling status

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

Delegate's considerations

- Advice on the place in therapy of this NCE;
- 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.

1.5 Alpelisib

Delegate's final decision

The delegate's final decision under regulation 42ZCZU of the *Therapeutic Goods Regulations 1990* is to include alpelisib in the Poisons Standard as follows:

Schedule 4 – New Entry

ALPELISIB.

Index – New Entry

ALPELISIB

Schedule 4

Implementation date

1 October 2019

Reasons

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

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

– The risks and benefits of treatment with alpelisib should be considered in consultation with a medical practitioner experienced in the diagnosis and treatment of the condition.

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

– The use of alpelisib requires clinical diagnosis and ongoing clinical monitoring by a medical practitioner experienced in the diagnosis and treatment of the condition.

(c) the toxicity of a substance:

– The toxicity of alpelisib requires regular monitoring and clinical review.

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

– Dose interruptions and/or reductions may be required to manage toxicity.

(e) the potential for abuse of a substance:

– Nil.

(f) any other matters that the Secretary considers necessary to protect public health:

– Nil.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to alpelisib, a new chemical entity (NCE) for a human therapeutic medicine.

Scheduling status

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

Delegate's considerations

- Advice on the place in therapy of this NCE;
- 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.

1.6 Linaclotide

Delegate's final decision

The delegate's final decision under regulation 42ZCZU of the *Therapeutic Goods Regulations 1990* is to include linaclotide in the Poisons Standard as follows:

Schedule 4 – New Entry

LINACLOTIDE.

Index – New Entry

LINACLOTIDE

Schedule 4

Implementation date

1 October 2019

Reasons

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

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

- It is a new chemical entity with no clinical or marketing experience in Australia.
- The benefits outweigh the risks.

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

- For the management of chronic idiopathic constipation [CIC] and irritable bowel syndrome with constipation[IBS-C].

(c) the toxicity of a substance:

- Minimal.

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

- Irritable Bowel Syndrome with Constipation.
  - The recommended dosage of linaclotide is 290 mcg orally once daily.
- Chronic Idiopathic Constipation
  - The recommended dosage of linaclotide is 145 mcg orally once daily. A dosage of 72 mcg once daily may be used based on individual presentation or tolerability.
- Strength/Dose Form
  - 72 µg, 145 µg and 290 µg as hard capsules for oral administration.

(e) the potential for abuse of a substance:

- Nil.

(f) any other matters that the Secretary considers necessary to protect public health:

- Nil.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to linaclotide, a new chemical entity (NCE) for a human therapeutic medicine.

Scheduling status

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

Delegate's considerations

- Subsection 52E(1) of the *Therapeutic Goods Act 1989*;
- The Scheduling Policy Framework (SPF 2018);
- The TGA evaluation report;
- The advice of the Advisory Committee Medicines; and
- The new drug application.