Australian Government
Department of Health
Therapeutic Goods Administration

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

24 August 2020

TGA Health Safety Regulation

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

This web publication constitutes a notice for the purposes of regulation 42ZCZS and regulation 42ZCZX of the *Therapeutic Goods Regulations 1990* (the **Regulations**). In accordance with regulations 42ZCZS and 42CZX, this notice publishes:

- the decisions made by a delegate of the Secretary pursuant to regulations 42ZCZR and 42ZCZU;
- the reasons for those final decisions; and
- the date of effect of those decisions.

2 Deferral of the final decision in relation to melatonin

The delegate has made a decision to defer their final decision on melatonin. In accordance with regulations 42ZCZP of the *Therapeutic Goods Regulations 1990* (Cth) (Regulations) the delegate made a call for further submission specifically in relation to the 1 October 2020 implementation date set out in their interim decision. The closing date for submissions is 28 August 2020.

3 Final decisions on proposed amendments to the current Poisons Standard under regulation 42ZCZR

3.1 Final decisions on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #29, March 2020)

Final decision in relation to rizatriptan

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to rizatriptan as follows:

Schedule 4 – Amend Entry

RIZATRIPTAN **except** when included in Schedule 3.

Schedule 3 – New Entry

RIZATRIPTAN when in divided oral preparations containing 5 milligrams or less per dosage unit and when sold in a pack containing not more than 2 dosage units for the acute relief of migraine in patients who have a stable, well-established pattern of migraine symptoms.

Appendix H – New Entry

RIZATRIPTAN

Index –Amend Entry

RIZATRIPTAN

Schedule 4
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Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to rizatriptan;
- The five public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Advisory Committee on Medicines Scheduling (ACMS #29);
- The one public submission received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 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; and (f) any other matters considered necessary to protect public health;

- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm both my interim decision and the reasons published in my interim decision, to amend the current Poisons Standard to down-schedule rizatriptan from Schedule 4 to Schedule 3. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the public submission received before the second closing date in response to the call for further submissions published on 10 June 2020 under regulation 42ZCZP of the Regulations. I note the public submission was in support of my interim decision.

Date of effect of the decision

1 February 2021

Final decision in relation to ondansetron

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and not amend the current Poisons Standard in relation to ondansetron.

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to ondansetron;
- The five public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Advisory Committee on Medicines Scheduling (ACMS #29);
- The one public submission received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 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 (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision not to amend the current Poisons Standard with respect to ondansetron. Specifically, I confirm my interim decision not to down-schedule ondansetron from Schedule 4 to Schedule 3. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the public submission received before the second closing date in response to the call for further submissions published on 10 June 2020

under regulation 42ZCZP of the Regulations. I note the public submission was in support of my interim decision.

Date of effect of the decision

24 August 2020

Final decision in relation to adapalene

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to adapalene as follows:

Schedule 4 – Amend Entry

ADAPALENE **except** when included in Schedule 3.

Schedule 3 – New Entry

ADAPALENE in topical preparations containing 0.1 per cent or less of adapalene for the treatment of *acne vulgaris* in adults and in children over 12 years of age.

Appendix H – New Entry

ADAPALENE

Index – Amend Entry

ADAPALENE

Schedule 4
Schedule 3
Appendix H

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to adapalene;
- The six public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Advisory Committee on Medicines Scheduling (ACMS #29);
- The one public submission received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Section 52E of the *Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purpose for which a substance is to be used and the and 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;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision to amend the current Poisons Standard to down-schedule adapalene to Schedule 3 with restrictions on the preparation and indication. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the public submission received before the second closing date in response to the call for further submissions published on 10 June 2020 under regulation 42ZCZP of the Regulations. I note the public submission was in support of my interim decision.

Date of effect of the decision

1 June 2021

Final decision in relation to Selective Serotonin Reuptake Inhibitors (SSRI)

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision not amend the current Poisons Standard in relation to a Selective Serotonin Reuptake Inhibitors (SSRI) group entry.

Materials considered

In making this final decision, the Delegate considered the following material:

- The proposal to amend the current Poisons Standard with respect to a Selective Serotonin Reuptake Inhibitors (SSRI) group entry;
- The three public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Advisory Committee on Medicines Scheduling (ACMS #29);
- The one public submission received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Section 52E of the *Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purpose for which a substance is to be used and the and extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision not to amend the current Poisons Standard with respect a Selective Serotonin Reuptake Inhibitors (SSRI) group entry. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the public submission received before the second closing date in response to the call for further submissions published on 10 June 2020 under regulation 42ZCZP of the Regulations. I note the public submission was in support of my interim decision.

Date of effect of the decision

24 August 2020

Final decision in relation to ranitidine

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision not to amend the current Poisons Standard in relation to ranitidine.

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to ranitidine;
- The four public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Advisory Committee on Medicines Scheduling (ACMS #29);
- The two public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Section 52E 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;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision not to amend the current Poisons Standard with respect to ranitidine. My view is that the current scheduling of ranitidine is appropriate. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the public submission received before the second closing date in response to the call for further submissions published on 10 June 2020 under regulation 42ZCZP of the Regulations. The public submission proposes to an alternate scheduling of ranitidine to increase the pack size availability of Schedule 3 ranitidine, which in my view, is a matter for a separate scheduling application. Hence, I have not relied on the material in public submission in making my final decision to retain the current scheduling of ranitidine.

Date of effect of the decision

24 August 2020

Final decision in relation to fexofenadine

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to fexofenadine as follows:

Schedule 4 – Amend Entry

FEXOFENADINE **except**:

a) when included in Schedule 2;

b) ~~or~~ in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

   i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and

   ii) labelled with a recommended daily dose not exceeding 120 mg of fexofenadine;

c) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

   i) in a primary pack containing 5 dosage units or less and not more than 5 days' supply; and

   ii) labelled with a recommended daily dose not exceeding 180 mg of fexofenadine; or

d) for the treatment of seasonal allergic rhinitis and children 6 years of age and over when:

   i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and

   ii) labelled with a recommended daily dose not exceeding 60 mg of fexofenadine.

Schedule 2 – Amend Entry

FEXOFENADINE in preparations for oral use **except** in divided preparations:

a) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

   i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and

   ii) labelled with a recommended daily dose not exceeding 120 mg of fexofenadine;

b) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

   i) in a primary pack containing 5 dosage units or less and not more than 5 days' supply; and

   ii) labelled with a recommended daily dose not exceeding 180 mg of fexofenadine; or

c) for the treatment of seasonal allergic rhinitis and children 6 years of age and over when:

   i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and

   ii) labelled with a recommended daily dose not exceeding 60 mg of fexofenadine.

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to fexofenadine;
- The four public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Advisory Committee on Medicines Scheduling (ACMS #29);
- The one public submission received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Section 52E of the *Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purpose for which a substance is to be used and the and extent of use of a substance; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation of a substance;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision to amend the Schedule 2 and Schedule 4 entries for fexofenadine in the current Poison Standard. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the public submission received before the second closing date in response to the call for further submissions published on 10 June 2020 under regulation 42ZCZP of the Regulations.

I have considered the public submission in opposition raising concern that broadening the availability of fexofenadine to the general sale level will reduce health professional consultation and may lead to inappropriate self-selection of products. In my view, seasonal allergic rhinitis is a common, easily identified condition that is appropriate for self-management where non-treatment can affect a patient's quality of life. Having considered that fexofenadine has an established safety profile and its limited propensity for overdose, as detailed in my reasons for my interim decision, I am satisfied that fexofenadine can be supplied at the general sales level, with reasonable safety, without any access to health professional advice.

Date of effect of the decision

1 October 2020

Final decision in relation to flurbiprofen

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision, with a minor editorial change to the wording, and amend the current Poisons Standard in relation to flurbiprofen as follows:

Schedule 4 – Amend Entry

FLURBIPROFEN **except** when included in or expressly excluded from Schedule 2.

Schedule 2 – Amend Entry

FLURBIPROFEN in preparations for topical oral use when:

a) in divided preparations containing 10 mg or less of flurbiprofen per dosage unit **except** when:

   i) in a primary pack containing not more than 16 dosage units; and

   ii) labelled only for the treatment of adults and children over 12 years.

b) in undivided preparations containing 0.25 percent or less or 10 mg or less per dose of flurbiprofen.

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to flurbiprofen;
- The five public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Advisory Committee on Medicines Scheduling (ACMS #29);
- The one public submission received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Section 52E of the *Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (a) the risks and benefits of the use of a substance; (b) the purpose for which a substance is to be used and the and extent of use of a substance; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation of a substance;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision, with a minor editorial change to the wording, to amend the Schedule 2 and Schedule 4 entries for flurbiprofen in the current Poison Standard. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the public submission received before the second closing date in response to the call for further submissions published on 10 June 2020 under regulation 42ZCZP of the Regulations.

Flurbiprofen lozenges are typically used to treat the inflammation and pain associated with a sore throat. I have considered the public submission in opposition, which claims that making flurbiprofen-containing products accessible outside of the pharmacy setting presents a greater risk of COVID-19 spread on the basis that it may delay consumer access to COVID-19 testing and health professional advice. I have not found, and the submitter has not provided, any compelling evidence to substantiate these claims or to establish that there is a net risk to public health in down-scheduling flurbiprofen as proposed in my interim decision.

Date of effect of the decision

1 October 2020

3.2 Final decisions on proposed amendments referred to the Advisory Committee on Chemicals Scheduling (ACCS #27, March 2020)

Final decision in relation to carbetamide

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to carbetamide as follows:

Schedule 6 – New Entry

CARBETAMIDE.

Appendix B – Delete Entry

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
~~CARBETAMIDE~~	~~Aug 1991~~	~~a~~	~~1~~
a = Low Toxicity 1 = Agriculture			

INDEX – Amend Entry

CARBETAMIDE

~~Appendix B, Part 3~~

Schedule 6

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to carbetamide;
- The advice received from the Meeting of the Advisory Committee on Chemicals Scheduling (ACCS#27);
- Subsection 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;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision to amend the current Poisons Standard, to remove carbetamide from Appendix B and add it to Schedule 6. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and have noted that no public submissions were received before the second closing date in response to the call for further submissions published on 10 June 2020 under regulation 42ZCZP of the Regulations.

Date of effect of the decision

1 October 2020

Final decision in relation to arbutin

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to vary the interim decision and amend the current Poisons Standard in relation to arbutin as follows:

Schedule 6 – New entries

ARBUTIN (ALPHA) **except**:

a) in preparations for application to the face containing 2 per cent or less alpha-arbutin with hydroquinone levels of 10mg/kg or less; or

b) in preparations for application to the body containing 0.5 per cent or less alpha-arbutin with hydroquinone levels of 10mg/kg or less.

ARBUTIN (BETA) **except**:

a) when included in Schedule 4; or

b) oral herbal preparations containing 500 mg or less beta-arbutin per recommended daily dose; or

c) in preparations for application to the face containing 7 per cent or less beta-arbutin with hydroquinone levels of 10mg/kg or less.

ARBUTIN (DEOXY OR OTHER DERIVATIVES).

Schedule 4 – New entry

ARBUTIN (BETA) in oral preparations except herbal preparations containing 500 mg or less beta-arbutin per recommended daily dose.

Index – New/Amended Entries

ARBUTIN (ALPHA)

Cross reference: ARBUTIN (BETA); ARBUTIN (DEOXY OR OTHER DERIVATIVES)

Schedule 6

ARBUTIN (BETA)

Cross reference: ARBUTIN (ALPHA); ARBUTIN (DEOXY OR OTHER DERIVATIVES)

Schedule 6

Schedule 4

ARBUTIN (DEOXY OR OTHER DERIVATIVES)

Cross reference: ARBUTIN (ALPHA); ARBUTIN (BETA)

Schedule 6

~~ARBUTIN~~

~~cross-reference: HYDROQUINONE~~

Appendix E, Part ~~3~~ 2 – New entries

POISON	STANDARD STATEMENTS
ARBUTIN when included in Schedule 6.	A,G2,G3,E2,R2,S1
A: For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once). G2: If swallowed, give activated charcoal if instructed. (Note - the words 'at once' to be added to instruction A). G3: If swallowed, do NOT induce vomiting. E2: If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor, or for at least 15 minutes. R2: If swallowed or inhaled, remove from contaminated area. Apply artificial respiration if not breathing. Do not give direct mouth-to-mouth resuscitation. To protect rescuer, use air-viva, oxy-viva or one-way mask. Resuscitate in a well-ventilated area. S1: If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.	

Appendix F, Part 3 – New entries

POISON	WARNING STATEMENTS	SAFETY DIRECTION
ARBUTIN when included in Schedule 6.	45	1,4
1: Avoid contact with eyes 4: Avoid contact with skin 45: WARNING – If a pigmented spot or mole has recently become darker, changed colour, become enlarged or itchy, or bleeds, do not use this product, see your doctor immediately. Do not use on children. Do not use near the eyes. Mild irritation may occur; stop use if it becomes severe. If fading is not evident in three months, seek doctor's advice.		

Materials considered

In making this final decision, the Delegate considered the following material:

- The scheduling proposal to amend the current Poisons Standard with respect to arbutin;
- The five public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Meeting of the Advisory Committee on Chemicals Scheduling (ACCS#27);

- The three public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 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 (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have a made a final decision to vary my interim decision to incorporate a minor amendment to clarify the exclusion of herbal preparations containing 500 mg or less beta-arbutin from the Schedule 6 arbutin (beta) entry. I have varied the Appendix E arbutin listing to clarify its inclusion in Part 2 as it was erroneously proposed to be included in Part 3 of Appendix E in my interim decision. Notwithstanding the aforementioned minor amendments, my reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the three public submissions received before the second closing date in response to the call for further submissions published on 10 June 2020 under regulation 42ZCZP of the Regulations.

I have considered the statements made in the public submissions that oral herbal preparations containing 500 mg or less beta-arbutin should be clearly excluded from the Schedule 6 entry. I am in agreement that these preparations should be explicitly excluded from the Schedule 6 entry and I have amended my decision accordingly.

Date of effect of the decision

1 October 2020

Final decision in relation to aclonifen

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to aclonifen as follows:

Schedule 6 – New Entry

ACLONIFEN.

Index – New Entry

ACLONIFEN

Schedule 6

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to aclonifen;
- The advice received from the Meeting of the Advisory Committee on Chemicals Scheduling (ACCS#27);

- Subsection 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;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to aclonifen. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and have noted that no public submissions were received before the second closing date in response to the call for further submissions published on 10 June 2020 under regulation 42ZCZP of the Regulations.

Date of effect of the decision

1 October 2020

Final decision in relation to picramic acid (including its salts)

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to picramic acid (including its salts) as follows:

Schedule 6 – New Entry

PICRAMIC ACID including its salts (excluding other derivatives) **except** when used in hair dye products at a concentration of 0.6 per cent or less of picramic acid after mixing for use when the immediate container and primary pack are labelled with the following statements:

KEEP OUT OF REACH OF CHILDREN, and

WARNING – This product contains ingredients which may cause skin allergy to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5 mm in height.

Appendix E, Part ~~1~~ 2 – New Entry

POISON	STANDARD STATEMENTS
PICRAMIC ACID including its salts (excluding other derivatives)	A, E1
A: For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once). E1: If in eyes wash out immediately with water.	

Appendix F, Part ~~2~~ 3– New Entries

POISON	WARNING STATEMENTS	SAFETY DIRECTION
PICRAMIC ACID including its salts (excluding other derivatives)	28	5
Warning Statements 28: Repeated exposure may cause sensitisation. Safety Directions – General: 5: Wear protective gloves when mixing or using.		

Index – New Entry

PICRAMIC ACID (including its salts)

CROSS-REFERENCE: 2-amino 4 6 dinitrophenol

Schedule 6

Appendix E, Part 1

Appendix F, Part 2

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to picramic acid;
- The two public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Meeting of the Advisory Committee on Chemicals Scheduling (ACCS#27);
- The one public submission received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 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;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to vary my interim decision to incorporate a minor amendment to clarify the inclusion of the Appendix E picramic acid listing in Part 2 as it was erroneously proposed to be included in Part 1 of Appendix E in my interim decision. I have also varied the Appendix F picramic acid listing to clarify its inclusion in Part 3 of Appendix F as it was erroneously proposed to be included in Part 2 of Appendix F in my interim decision.

Notwithstanding the aforementioned editorial changes, my reasons for making the final decision are those set out in the interim decision.

In making my final decision, I have taken into account the material detailed in the interim decision and the one public submission received before the second closing date in response to the call for further submissions published on 10 June 2020 under regulation 42ZCZP of the Regulations.

I have considered the one public submission, which requests a change to the implementation date from 1 June 2021 to 1 October 2021. I am of the view that since no immediate health signals have been identified, a change in the implementation date to 1 October 2021 is appropriate. This new implementation date will allow industry approximately 13 months for compliance with any labelling and/or reformulation changes.

Date of effect of the decision

1 October 2021.

3.3 Final decisions on proposed amendments referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #24, March 2020)

Final decision in relation to marker dyes and pigments

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to marker dyes and pigments as follows:

Part 1 of the Poisons Standard, Interpretation – New Entry

"Marker dyes or pigments" means any product that is added to a liquid used in agricultural or veterinary chemicals to identify or distinguish treated from untreated objects, land or organisms by temporarily imparting colour on the relevant object, land or organism through, for example, spot – or boom-spraying.

Materials considered

In making this final decision, the Delegate considered the following material:

- The scheduling proposal to amend the current Poisons Standard with respect to marker dyes and pigments;
- The three public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Joint meeting of the Advisory Committees on Medicines and Chemicals Scheduling (Joint ACMS-ACCS#24); and
- The one public submission received in response to the interim decision consultation under regulation 42ZCZP of the Regulations.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision to amend the current Poisons Standard to include an explicit definition of 'marker dyes and pigments' in Part 1, Interpretation. My reasons for making the final decision are those set out in the interim decision. In making my

final decision. I have taken into account the material detailed in the interim decision and the one public submission received before the second closing date in response to the call for further submissions published on 10 June 2020 under regulation 42ZCZP of the Regulations. I note the public submission was in support of my interim decision.

Date of effect of the decision

1 October 2020

Final decision in relation to nicotine (heated tobacco products)

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision, which is not to amend the current scheduling of nicotine in the Poisons Standard, specifically, not exempt from Schedule 7 nicotine when in tobacco when prepared and packed for heating.

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to nicotine (heated tobacco products);
- The 36 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Joint meeting of the Advisory Committees on Medicines and Chemicals Scheduling (Joint ACMS-ACCS#24);
- The 85 public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 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; (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018);
- The Scheduling handbook: Guidance for amending the Poisons Standard;
- World Health Organisation Heated tobacco products (HTPs) market monitoring information sheet;
- PMI's own *in vivo* clinical data on biomarkers of potential harm in Americans an analysis of Phillip Morris International data which shows their tobacco heating system is not detectably different from conventional cigarettes;
- US Food & Drug Administration (FDA) News Release dated 30 April 2019: FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway;
- The Analysis of FDA's IQOS marketing authorisation and its policy impacts which found that the evidence PMPSA submitted did not demonstrate reduction in long-term disease risks and that IQOS aerosol emits toxins with carcinogenic and genotoxic potential. This research also outlined further risks to users, including hepatotoxic, cardiovascular and pulmonary risks.

- FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information from 7 July notes that authorisation for HTP now includes requirements for the company to conduct post market surveillance, including monitoring its increased use amongst youth.
- PMI's heated tobacco products marketing claims of reduced risk and reduced exposure may entice youth to try and continue using these products from the British Medical Journal, assessed the potential misunderstanding of reduced risk claims of HTP and thereby increasing the risk of tobacco initiation.
- WHO statement on heated tobacco products and the US FDA decision regarding IQOS
- The WHO, 2020, Heated tobacco products: A brief which recommends the preventing the introduction of HTPs.
- Heated tobacco products: information sheet – 2nd edition from the World Health Organisation (WHO) 10 July 2020 which states there is no evidence to demonstrate that HTPs are less harmful than conventional tobacco products. This information sheet also states that all forms of tobacco are harmful, inherently toxic and contains carcinogens, even in its natural form.
- The Australian Institute of Health and Welfare National Drug Strategy Household Survey 2019 report which shows a decrease in smoking rates in Australia.
- The Centers for Disease Control and Prevention webpage on Heated Tobacco Products from 17 July 2020 which advises that the use of any tobacco product - including heated tobacco products - is harmful.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision, which is not to amend the current scheduling of nicotine in the Poisons Standard, specifically, not exempt from Schedule 7 nicotine when in tobacco when prepared and packed for heating. In making my final decision, and further to the reasons set out in my interim decision, I have taken into consideration the 85 public submissions received before the second closing date in response to the call for further submissions published on 10 June 2020 under regulation 42ZCZQ of the Regulations.

I note the submissions from the Lung Foundation, Cancer Council Australia, Australian Council on Health and Smoking and National Heart Foundation supported the interim decision, reiterating their strong concerns about the public health risks of exempting heated tobacco products from scheduling. There was one submission from a consumer who was concerned about the use of nicotine products amongst youths.

I have considered the 82 submissions that opposed my interim decision, including 77 submissions from individuals who, in general, had family members who were trying to quit smoking or were smokers themselves, and were advocating for access to heated tobacco products (HTPs) or e-cigarettes as an alternative to smoking. I note the five submissions from peak bodies and researchers opposing the interim decision, which outlined similar arguments as made in previous opposing submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations.

I have considered the applicant's submission in response to my interim decision, which, in my assessment, does not present compelling evidence to establish a public health benefit from greater access to nicotine in HTPs. There are a number of assertions made by the applicant, which I will specifically comment on:

- The statement by the applicant that smoking rates in Australia have stagnated over recent years is not supported by recent data from the Australian Institute of Health and Welfare

(AIHW)[1]. The AIHW data shows a decrease in smoking rates from 12.2 % in 2016 to 11 % in 2019, which demonstrates that smoking rates in Australia continue to decline. I note this is a 9.8% decrease since the 2016 survey.

- The applicant contends that their product contains less nicotine than conventional cigarettes, making it safer in the case of accidental paediatric exposure. As scheduling affects substances rather than an individual product, I have taken into account that the concentration of nicotine in HTP products, more broadly, is variable and potentially higher than in cigarettes. I remain concerned that HTPs may increase the risk of exposure to greater quantities of nicotine in accidental paediatric exposures.

I have further considered the regulatory status of HTPs internationally and the guidance from the CDC[2] and WHO[3]. I note the recent US FDA authorisation of the marketing[4] of the IQOS tobacco heating system with 'reduced exposure' information. The FDA states: "**these products are not safe, so people, especially young people, who do not currently use tobacco products should not start using them or any other tobacco product.**" I note that the FDA will closely monitor these products post-market, including the potential for use among youth. I also note that the FDA did not issue a risk modification order. As such, the exposure modification orders do not permit the company to make any other modified risk claims or any express or implied statements that could mislead consumers into believing that the products are endorsed or approved by the FDA, or that the FDA deems the products to be safe for use by consumers. I note the WHO statement regarding heated tobacco products and the US FDA decision on IQOS, reiterates that reducing exposure to harmful chemicals in HTPs does not render them harmless, nor does it translate to reduced risk to human health.

Having considered the Applicant's proposal, including the data provided with the application and their submission on the interim decision, I reiterate my finding that there are significant safety concerns with HTPs, notably as identified by the Committee, the various risks of use of nicotine when in tobacco when prepared and packed for heating, its toxicity and the potential for abuse with no demonstrated benefit of its use. In this regard, I consider that the Applicant's focus on using tobacco cigarettes as a relevant comparator is too narrow and does not fully reflect the matters I am required to take into account, under subsection 52E(1), when making a decision to amend the Poisons Standard.

None of the submissions provided have changed my assessment that nicotine presents a severe hazard from repeated use leading to potential addiction and a significant risk of producing irreversible toxicity, which may involve serious, acute or chronic health risks or death. I am not persuaded that HTPs would not attract 'never smokers' including youth. In this regard, I note that the application, if agreed, would exempt nicotine when in tobacco when prepared and packed for heating from all regulation as a poison, which would allow anyone, including previous or non-smokers, to access these products and potentially expose a new cohort to the health risks arising from the use of tobacco If exempted from scheduling, there would be no ability to restrict the supply of HTPs to smokers seeking to quit.

Further, I am satisfied that HTPs can expose users long term to a range of known and unknown toxicants. I am not satisfied that the dosage, formulation, packaging and presentation of nicotine in HTPs mitigates the risk profile of nicotine such as to warrant a less restrictive scheduling classification than is currently in place.

I reiterate my finding from the interim decision that I am not satisfied that there is a net public health benefit from wider availability of nicotine in the form of HTPs. I do not consider that HTPs

[1] Australian Institute of Health and Welfare (AIHW): National Drug Strategy Household Survey 2019.
[2] The Centers for Disease Control and Prevention webpage on Heated Tobacco Products from 17 July 2020
[3] The WHO, Heated tobacco products: A brief, 2020
[4] FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information from 7 July

would make a significant contribution to population harm reduction if I agreed to amend the Poisons Standard as proposed in the application. I consider that maintaining the current scheduling for HTPs is necessary to protect public health from the risks associated with introducing a new nicotine product for non-therapeutic use. I note that the current pathway to supply Schedule 4 nicotine products for smoking cessation is available for HTPs. An application for registration on the ARTG could be made, which would involve assessment of the safety, efficacy and quality by the TGA, consistent with the requirements for existing nicotine replacement products. Should current smokers wish use HTPs as a method to quit smoking, unregistered HTPs are accessible with a prescription under Schedule 4, consistent with the scheduling of e-cigarettes containing nicotine.

Date of effect of the decision

24 August 2020

Final decision in relation to pentobarbital

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to pentobarbital as follows:

Appendix D, Item 9 – New entry

9.	**Poisons which must be stored in a locked container to prevent unauthorised access**
	PENTOBARBITAL in injectable preparations.

Materials considered

In making this final decision, the Delegate considered the following material:

- The scheduling proposal to amend the current Poisons Standard with respect to pentobarbital;
- The 11 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Joint meeting of the Advisory Committees on Medicines and Chemicals Scheduling (Joint ACMS-ACCS#24);
- Subsection 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; (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018);
- The Scheduling handbook: Guidance for amending the Poisons Standard;
- The National Coronial Information System (NCIS) report on pentobarbital-related deaths in Australia 2000 – 2017; and
- Specialist advice on veterinary medicine from two veterinary surgeons.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision to amend the current Poisons Standard to clarify the storage requirements for Schedule 4 injectable pentobarbital through the provision of a new Appendix D listing. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and I have noted that no public submissions were received before the second closing date in response to the call for further submissions published on 10 June 2020 under regulation 42ZCZP of the Regulations.

Date of effect of the decision

1 October 2020

4 Final decisions on proposed amendments to the current Poisons Standard under regulation 42ZCZU

In my capacity as a delegate of the Secretary for the purpose of regulation 42ZCZU of the *Therapeutic Goods Regulations 1990* (**Regulations**), I have made final decisions to amend the current Poisons Standard in the manner set out in the application under regulation 42ZCZU with respect to the following substances:

- Sodium bromide;
- Polyoxin D zinc salt;
- Tigilanol tiglate;
- Selenium; and
- Fomesafen sodium.

4.1 Final decision in relation to sodium bromide

Final decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to sodium bromide as follows:

Schedule 5 – New Entry

SODIUM BROMIDE **except** when included in Schedule 4.

Schedule 4

SODIUM BROMIDE for therapeutic use.

Index – Amend Entry

SODIUM BROMIDE

Schedule 5

Schedule 4

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to sodium bromide;
- Subsection 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; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

In determining, that this matter will be a delegate-only decision I have taken into account the information provided in the application from the Applicant (APVMA), and the matters outlined under Section 52E of *the Therapeutic Goods Act 1989* and the Scheduling Policy Framework (2018). In particular, I note that:

- The proposed change to the Poisons Standard to include a new entry for sodium bromide in Schedule 5 indicates that there are benefits to public health and safety from its use as an important agent in the control of water-borne pathogens in swimming pools and spas. Sodium bromide is currently listed in Schedule 4 for therapeutic uses. However, sodium bromide is also used in Australia as a sanitiser in swimming pools and spas in combination with other Scheduled chemicals, e.g. sodium dichloroisocyanurate. The proposed change to the Poisons Standard would account for the use of sodium bromide alone as a sanitiser in swimming pools and spas. The risks associated with human exposure to the substance have been adequately addressed by the regulator of pool and spa chemicals (APVMA) (52E(1)(a)).
- The purpose and extent for which the substance is to be used has been adequately outlined by the applicant. The substance is currently used as a sanitiser (*ca* 150 g/kg) in swimming pools and spas in combination with other chemicals. It is currently available for use alone (>98%) in various OECD countries, including Canada and the USA, as a sanitiser in swimming pools and spas (52E(1)(b)).
- Bromine is a naturally occurring element, found in seawater and volcanic rock. It is present as bromide ions in living organisms and in the environment. On addition of an activator e.g. chlorine, sodium bromide will hydrolyse in water to form hypobromous acid, which is the active disinfectant. Swimming pool bromination is currently endorsed in all Australian jurisdictions as a standard method for residual sanitation (52E(1)(b)).
- Sodium bromide has low acute toxicity by oral, dermal and inhalational routes and is a very slight skin and slight eye irritant but not a skin sensitiser (in the GPMT). Repeat dose toxicity effects on the central nervous system (CNS) and endocrine system have been seen in human studies with sodium bromide, but these effects occurred at high doses compared to normal use and were reversible on cessation of exposure. Evidence indicates that bromide salts are neither genotoxic nor carcinogenic. Utilising an internationally established Health Based Guidance Value from the FAO/WHO Joint Meeting on Pesticide Residues (JMPR), i.e. an Acceptable Daily Intake (ADI) for bromide, the Applicant has determined that the risk of adverse human health effects from exposure to sodium bromide in spa or swimming pool water would be negligible. Furthermore, risks associated with the use of products containing sodium bromide during sanitising procedures, can be adequately managed through warning statements, safety directions and first aid instructions on APVMA approved product labels (52E(1)(c)).
- It is considered that the toxicity profile of sodium bromide is consistent with a Schedule 5 classification (52E(1)(c)).
- The applicant has demonstrated that appropriate risk mitigation measures will be put in place for the proposed product containing the substance that may be registered for use in Australia, and that account for the dosage (application rate), formulation, labelling, packaging and presentation of sodium bromide. As a result, no additional measures are required in the Poisons Standard (53E(1)(d)).
- There is no information to indicate that the substance could pose a risk to humans from abuse of the substance (52(E)(1)(e)).
- Disinfection by-products (DBPs) are formed when sanitisers/disinfectants react with each other and with organic and inorganic matter in swimming pools and spas. Bathers and/or swimmers may be exposed to sodium bromide dissociation products as well as the activator chemical and disinfection by-products (DBPs) e.g. sodium bromate. The occurrence and type

of DBPs depends on a number variables, including the type of pool, type of disinfectants used, disinfectant dosages, bather loads, temperature and pH of the pool/spa water. The applicant noted that the risks from exposure to DBP and other substances were considered to be beyond the scope of the current application, as levels in swimming pool water are a function of the quality of the water and methods of disinfection, as opposed to the substance *per se*. The potential risks associated with exposure to DBPs including bromate and aquatic pathogens, can be mitigated by adherence to State and Territory guidelines/standards on the use of sodium bromide in swimming pools and spas (52(E)(1)(f)).

- An Acceptable Daily Intake (ADI) value of 1 mg/kg bw/day was established by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) (1998) for bromide (Br^-). This was based on a 12-week oral human study using sodium bromide where no neurophysiological or endocrinological effects were observed at the highest tested dose of 9 mg Br^-/kg bw/day (equivalent to 11.6 mg/kg bw/day sodium bromide), using a 10 fold safety factor (52(E)(1)(f)).
- Therefore, based on the information provided in the application, I have decided to amend the current Poisons Standard in the manner set out in the application. The proposed amendment was not referred to an expert advisory committee.

Date of effect of the decision

1 October 2020

4.2 Final decision in relation to polyoxin D zinc salt

Final decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to polyoxin D zinc salt as follows:

Schedule 5 – New entry

POLYOXIN D ZINC SALT.

Index – New entry

POLYOXIN D ZINC SALT

Schedule 5

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to polyoxin D zinc salt;
- Subsection 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; (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

In determining that this matter will be a delegate-only decision I have taken into account the information provided in the application from the Applicant (APVMA), and the matters outlined under Section 52E of the *Therapeutic Goods* Act *1989* and the Scheduling Policy Framework (SPF, 2018). In particular, I note that:

- The proposed change to the Poisons Standard to include a new entry for Polyoxin D zinc salt, indicates that there are benefits to the agricultural industry from the introduction of this fungicidal active constituent. Polyoxin D is a naturally occurring compound, with fungicidal activity, produced by *Streptomyces cacaoi* var. *asoensis*. The target enzyme is fungal chitin synthetase. Polyoxin D is very water soluble so it is formulated as the zinc salt to give longer residence time on plant surfaces. It is proposed for the control of certain fungal diseases in various food crops, however no products containing polyoxin D zinc salt has been proposed for registration at this time. The risks to human health and safety from the active constituent *per se* have been addressed by the pesticide regulator (APVMA) in it application (52E(1)(a)).
- The purpose and extent for which the substance is to be used has been adequately outlined by Applicant. Products containing polyoxin D zinc salt have been approved for use in Japan (>40 years), other countries in Asia, USA (since 1997), Canada (2017) and New Zealand (2016). These products are registered for use in a range of fruit and vegetable crops, as well as turf and ornamentals (52E(1)(b)).
- Polyoxin D zinc salt preparations have low acute oral, dermal and inhalational toxicity. It is a slight-moderate eye irritant, not a skin irritant but is a weak skin sensitiser in guinea pigs. Mild to no treatment-related effects were observed in the short- and long-term repeat dose toxicity studies with polyoxin D zinc salt preparations in mice, rats, rabbits and dogs at the highest doses tested. Polyoxin D zinc salt preparations did not demonstrate any carcinogenic, developmental or reproductive toxicity, immunotoxicity or neurotoxicity potential. The weight of evidence indicates that polyoxin D zinc salt preparations do not have genotoxic potential (52(E)(1)(c)).
- The toxicity profile of polyoxin D zinc salt is such that it meets the factors for inclusion in Schedule 5 of the Poisons Standard (52(E)(1)(c)).
- At this time, no products have been proposed for registration in Australia. Any future products seeking registration in Australia must first seek authorisation from the APVMA, and will be labelled with an APVMA approved label. This will set out the directions for use and the required label statements, including: first aid instructions; safety directions; precaution/restraint statements; and re-entry or re-handling statements, as well as instructions for safe storage (52(E)(1)(d)).
- There is no information to indicate that the substance could pose a risk to humans from abuse of the substance (52(E)(1)(e)).

Therefore, based on the information provided in the application, I have decided to amend the current Poisons Standard in the manner set out in the application. The proposed amendment was not referred to an expert advisory committee.

Date of effect of the decision

1 October 2020.

4.3 Final decision in relation to tigilanol tiglate

Final decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to tigilanol tiglate as follows:

Schedule 4 – New Entry

TIGILANOL TIGLATE.

Index – New Entry

TIGILANOL TIGLATE

Schedule 4

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to tigilanol tiglate;
- Subsection 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; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

In determining, that this matter will be a delegate-only decision I have taken into account the information provided in the application from the Applicant (APVMA), and the matters outlined under Section 52E of the *Therapeutic Goods Act 1989* and the Scheduling Policy Framework (2018). In particular, I note that:

- The proposed change to the Poisons Standard to include a new entry for tigilanol tiglate indicates that there are benefits to the veterinary medicine industry from the introduction of this new therapeutic agent for the treatment of mast cell tumours in dogs. The proposed product contains 1 mg/mL of tigilanol tiglate. The product is intended to be administered by veterinarians by intra-tumoral injection. The most likely human exposure to the substance, may be the result of accidental needle stick injury, but adverse effects are considered limited to local inflammatory reactions at the site of self-injection. Accidental eye exposure has been reported that resulted in transient eye irritation. The applicant has recommended appropriate label statements to mitigate these risks. Moreover, exposure to the substance to pet owners or the general public following treatment, is anticipated to be very limited given that the administration is via intra-tumoral injection and very limited residual substance is expected to remain on the treated animal's skin (52E(1)(a)).
- The purposes and extent for which the substance is to be used has been adequately outlined by applicant, i.e. for the treatment of cutaneous and subcutaneous mast cell tumours in dogs. The product containing tigilanol tiglate will only be made available for use by registered

veterinarians based on the requirement for the diagnosis and management of the condition by suitably trained individuals (veterinarians), and the high level of expertise required for the administration of the product by a controlled injection method (52E(1)(b)).

- Single and repeat dose toxicity studies were conducted with tigilanol tiglate, along with target animal safety studies. The main findings were injection site inflammation after subcutaneous injection and hypotension following intravenous dosing. Tigilanol tiglate was not genotoxic in a battery of *in vivo* and *in vitro* tests. Carcinogenicity and multigenerational reproductive toxicity studies were not conducted; but these were not considered necessary by the regulator based on the proposed use pattern, in particular as the product is not intended for use in food producing species (52E(1)(c)).
- Studies with the proposed product, included an acute dermal toxicity in nude mice (which revealed low acute dermal toxicity), an *in vitro* skin irritation study (the product was classified as a skin irritant) and an *in vitro* ocular irritation study (the product was not classified as an ocular irritant). No sensitisation studies were conducted (52E(1)(c)).
- The toxicity profile and use pattern of tigilanol tiglate is such that it meets the factors for inclusion in Schedule 4 of the SUSMP (52E(1)(c)).
- The applicant has demonstrated that appropriate risk mitigation measures will be put in place for the proposed product containing tigilanol tiglate that may be registered for use in Australia, and that account for the dosage (application rate), formulation, labelling, packaging and presentation of tigilanol tiglate. As a result, no additional measures are required in the Poisons Standard. Further use of tigilanol tiglate in other products will be addressed by the veterinary chemicals regulator (APVMA) in any future applications to the regulator (53E(1)(d)).
- There is no information to indicate that the substance could pose a risk to humans from abuse of the substance (52(E)(1)(e)).

Therefore, based on the information provided in the application, I have decided to amend the current Poisons Standard in the manner set out in the application. The proposed amendment was not referred to an expert advisory committee.

Date of effect of the decision

1 October 2020

4.4 Final decision in relation to selenium

Final decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to selenium as follows:

Schedule 4 – Amend Entry

SELENIUM:

a) for human oral use with a recommended daily dose of more than 300 micrograms; or

b) for the treatment of animals **except**:

i) when included in Schedule 6 or 7;

ii) in solid, slow release bolus preparations ~~each weighing 100 g or more and~~ containing 300 mg or less of selenium per dosage unit;

iii) in other divided preparations containing 30 micrograms or less of selenium per dosage unit;

iv) as elemental selenium, in pellets containing 100 g/kg or less of selenium; or

v) in feeds containing 1 g/tonne or less of selenium.

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to selenium;
- Subsection 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; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

In determining, that this matter will be a delegate-only decision I have taken into account the information provided in the application from the Applicant (APVMA), and the matters outlined under Section 52E of the *Therapeutic Goods Act 1989* and the Scheduling Policy Framework (2018). In particular, I note that:

- The proposed amendment to the Poisons Standard entry is to exempt from scheduling selenium products used for the treatment of animals that are solid, slow release bolus preparations for ruminants containing 300 mg or less of selenium per dosage unit based on its human health risk. The applicant, APVMA indicated the boluses for sheep are of a smaller size and shape, which reduces the likelihood of regurgitation, and requires administration using a bolus applicator. It would not be physically possible to administer 100 g boluses (required for Schedule 4 exemption) to sheep so the cut-off limit in the SUSMP cannot accommodate for a sheep bolus product. No exposure to public is anticipated following use and the risk is no greater than that of the current approved use as a dietary supplement, for the treatment of animals. The risks have been adequately addressed by the pesticide regulator (APVMA) in its application (52E(1)(a)).
- The purposes and extent for which the substance is to be used has been adequately outlined by Applicant (52E(1)(b)).
- There has been no substantive change in the information available regarding the toxicity of the substance since it was last considered for Scheduling, that would warrant a change to its Scheduling Classification in the Poisons Standard based on the criteria set out in SPF (2018) (52E(1)(c)).The dosage, formulation, labelling, packaging and presentation of the substance from its currently approved uses in animal dietary supplement will change as a result of its proposed use as a dietary supplement, for sheep. The applicant is responsible for ensuring appropriate labelling. The pattern of potential professional exposure is expected to be of short-term duration, with negligible public exposure. As a result, no additional measures are required in the Poisons Standard. Further use of the substance in other veterinary products will be addressed by the pesticide regulator (APVMA) in any future applications to the

regulator. The proposed amended entry for the substance in the Poisons Standard will not affect selenium-containing ingredients listed under the ARTG (52E(1)(d)).

- There is no information to indicate that the substance could pose a risk to humans from abuse of the substance (52(E)(1)(e)).
- Selenium has been extensively considered by the National Drugs and Poisons Schedule Committee (NDPSC), the Advisory Committee on Medicines Scheduling (ACMS), the Advisory Committee on Chemical's Scheduling (ACCS), and the Delegate. Treatment of animals in solid, slow release bolus preparations each weighing 100 g or more and containing 300 mg or less of selenium per dosage unit have been exempted from scheduling. Amending this to treatment of animals in solid, slow release bolus preparations containing 300 mg or less of selenium per dosage unit has been adequately justified by the applicant (52(E)(1)(f)).

Therefore, I have decided to amend the current Poisons Standard in the manner set out in the application. The proposed amendment was not referred to an expert advisory committee.

Date of effect of the decision

1 October 2020

4.5 Final decision in relation to fomesafen sodium

Final decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to fomesafen sodium as follows:

Schedule 6 – New Entry

FOMESAFEN SODIUM.

Index – New Entry

FOMESAFEN SODIUM

Schedule 6

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to fomesafen sodium;
- Subsection 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; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

In determining, that this matter will be a delegate-only decision I have taken into account the information provided in the application from the Applicant (APVMA), and the matters outlined under Section 52E of the *Therapeutic Goods Act 1989* and the Scheduling Policy Framework (2018). In particular, I note that:

- The proposed change to the Poisons Standard to include a new entry for fomesafen sodium indicates that there are benefits to the agricultural industry from the introduction of this new herbicide for the control of broad leaf weeds in various food crops. The risks associated with human exposure to the substance have been adequately addressed by the pesticide regulator (APVMA) (52E(1)(a)).
- The purposes and extent for which the substance is to be used has been adequately outlined by the applicant (52E(1)(b)).
- Fomesafen sodium is a new substance (active constituent) which is not currently scheduled in the SUSMP. Fomesafen sodium has low acute toxicity by oral, dermal and inhalational routes, is not a skin sensitiser but is a slight to moderate skin irritant and a severe eye irritant. The substance is not a developmental or reproductive toxin, is not genotoxic in a battery of *in vivo* and *in vitro* assays and did not produce carcinogenic effects of human relevance in life-time studies in mice and rats (52E(1)(c)).
- The proposed product containing 240 g/L of fomesafen sodium, has low acute toxicity by the oral, dermal and inhalational routes, is a slight skin and severe eye irritant but is not a skin sensitiser (52E(1)(c)).
- The toxicity profile of fomesafen sodium is such that it meets the factors for inclusion in Schedule 6 of the SUSMP. The toxicity profile of the proposed product is also consistent with a Schedule 6 signal heading and consequently no cut off to Schedule 5 or exemption is supported on the basis of the currently available data (52E(1)(c)).
- The parent substance, fomesafen acid, is less of an irritant than the sodium salt (at most a slight skin irritant and slight eye irritant) and has similarly low acute oral, dermal and inhalational toxicity based on the data provided in the application. Although the fomesafen acid may be consistent with a Schedule 5 entry there is no application for use in an agricultural product of the acid as such (52E(1)(c)).
- The applicant has demonstrated that appropriate risk mitigation measures will be put in place for the proposed product containing the substance that may be registered for use in Australia, and that account for the dosage (application rate), formulation, labelling, packaging and presentation of fomesafen sodium. As a result, no additional measures are required in the Poisons Standard. Further use of fomesafen sodium in other pesticide products will be addressed by the pesticide regulator (APVMA) in any future applications to the regulator (53E(1)(d)).
- There is no information to indicate that the substance could pose a risk to humans from abuse of the substance (52(E)(1)(e)).
- National Health Based Guidance Values will be established for the substance that will protect consumers from residues of the substances in food (52(E)(1)(f)).

Therefore, based on the information provided in the application, I have decided to amend the current Poisons Standard in the manner set out in the application. The proposed amendment was not referred to an expert advisory committee.

Date of effect of the decision

1 October 2020