Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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

22 May 2024

Contents

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 comprises:

- the decisions made by a delegate[1] of the Secretary of the Department of Health and Aged Care (the Delegate) pursuant to regulations 42CZR and 42ZCZW
- the reasons for those final decisions, and
- the date of effect of those decisions.

Defined terms

In this notice the following defined terms are used in addition to those above:

- the Therapeutic Goods Act 1989 (Cth) (the Act)
- the Scheduling Policy Framework 2018 (the SPF)
- the Scheduling handbook, Guidance for amending the Poisons Standard (the Handbook) and
- the Therapeutic Goods Administration (the TGA).

Note: additional terms are also defined for individual decisions.

[1] For the purposes of s 52D of the *Therapeutic Goods Act 1989* (Cth).

Final decisions on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #43, November 2023)

Final decision in relation to astodrimer sodium

Proposal

The applicant proposed to amend the Schedule 3 entry for astodrimer sodium to exempt the substance from scheduling when used as a barrier nasal spray. Astodrimer sodium is currently captured in the Poisons Standard under Schedule 3 with an exemption for condom lubricant preparations. Astodrimer sodium is also listed under Appendix F, clause 4 (poisons that must be labelled with warning statements and safety directions) when used for the treatment and relief of bacterial vaginosis (BV) and the prevention of recurrent BV. The substance is also captured under Appendix H, clause 1 (medicines permitted to be advertised) when used for the treatment and relief of bacterial vaginosis and for the prevention of recurrent BV. Astodrimer sodium is currently approved for use as an active ingredient in medical devices only.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to astodrimer sodium as follows:[2]

Schedule 3 - Amend Entry

ASTODRIMER SODIUM **except:**

a) when included in Schedule 2; or

b) in a condom lubricant.

Schedule 2 - New Entry

ASTODRIMER SODIUM when used in a nasal spray.

Index – New Entry

ASTODRIMER SODIUM

Schedule 3
Schedule 2
Appendix F, clause 4
Appendix H, clause 1

[2] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

Appendix F, clause 4 – Poisons that must be labelled with warning statements and safety directions.

Item	Poison	Warning statement item number	Safety direction item number
30	ASTODRIMER SODIUM – for the treatment and relief of bacterial vaginosis	63, 64, 69, 75, 109, 110	
31	ASTODRIMER SODIUM—for the prevention of recurrent bacterial vaginosis	63, 75, 109, 110	

Appendix H, clause 1 - Schedule 3 medicines permitted to be advertised.

Item	Poison
3	ASTODRIMER SODIUM—for the treatment and relief of bacterial vaginosis and for the prevention of recurrent bacterial vaginosis

Materials considered

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

- the application to amend the current Poisons Standard with respect to astodrimer sodium (the Application)
- the 167 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 43rd meeting of the Advisory Committee on Medicines Scheduling (the Committee)[3]
- the interim decision relating to astodrimer sodium and the materials considered as part of the interim decision, as published on 3 April 2024
- the 11 public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the Submissions)
- 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.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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 astodrimer sodium. 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 in the interim decision and the 11 public submissions which were received in response to the interim decision consultation. Of these submissions 10 were supportive of the interim decision and one was partially supportive.

[3] Established under sections 52B and 52C of the *Therapeutic Goods Act 1989* (Cth).

In considering the main points raised by public submissions in partial support of my interim decision, I disagree that there is negligible risk of the substance being advertised or promoted for use as a treatment for serious respiratory conditions, such as COVID-19. I am of the view that there remains potential for misleading or suggestive marketing of anti-viral products. Furthermore, as noted by the Committee, there is presently no clinical data to support the use of astodrimer sodium in the treatment of COVID-19, though clinical trials are ongoing in the UK where astodrimer sodium nasal spray is being assessed for its safety and performance in patients with COVID-19.

I agree with the public submissions that the risk of patients delaying seeking medical attention or deterring mask wearing and vaccination is relatively low. However, no new evidence was provided by public submission regarding how the proposed amendments in the Application would negate the risk of consumers delaying seeking medical advice for more serious respiratory conditions. Access to health professional advice at point of sale for a nasal spray product containing astodrimer sodium remains an important risk mitigation strategy in misdiagnosis or inappropriate use. As such the risk of delaying seeking medical attention is consistent with SPF factors of Schedule 2 and would be mitigated through pharmacy-only sale and availability of health professional intervention if required.

I remain of the opinion that inclusion of astodrimer sodium in nasal sprays in Schedule 2 of the Poisons Standard is consistent with similar nasal spray products. I agree with the public submissions that, unlike similar Schedule 2 substances, the mechanism of astodrimer sodium is non-pharmacological and the substance is not systemically absorbed. Other nasal sprays which are used to manage symptoms of colds, other than nasal saline sprays, are included in Schedule 2 of the Poisons Standard.

Implementation date

1 June 2024

Final decision in relation to bilastine

Proposal

The TGA received a proposal in relation to bilastine which was later amended by the same applicant:

The ‘original application’ to amend the Schedule 3 entry for bilastine by removing the restriction to ‘divided’ oral preparations and reducing the age restriction from 12 to 6 years of age with a recommended daily dose not exceeding 20 mg, and

The ‘amended application’ which included a proposal to create a Schedule 2 entry for bilastine for adults and children aged 12 years and older with a recommended daily dose not exceeding 20 mg.

Due to the late submission of the amended proposal, only the ‘original proposal’ was considered in the pre-meeting public consultation, but both proposals were referred to the Committee for consideration.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to bilastine as follows: [4]

Schedule 4 – Amend Entry

BILASTINE **except** when included in Schedule 2 or 3.

[4] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

Schedule 3 – Amend Entry

BILASTINE in ~~divided~~ oral preparations when labelled with a recommended daily dose not exceeding ~~containing 20~~10 mg ~~or less of~~ bilastine for the treatment of children ~~adolescents~~ 6-11~~12~~ years of age ~~and older~~ **except** when included in Schedule 2.

Schedule 2 – New Entry

BILASTINE in oral preparations when labelled with a recommended daily dose not exceeding 20 mg bilastine for the treatment of adults and children aged 12 years and over.

Index – Amend Entry

BILASTINE

Schedule 4
Schedule 3
Schedule 2
Appendix H, clause 1

Appendix H, clause 1 - Schedule 3 medicines permitted to be advertised.

Item	Poison
4	BILASTINE

Materials considered

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

- the application to amend the current Poisons Standard with respect to bilastine (the Original Application)
- the amended application to amend the current Poisons Standard with respect to bilastine (the Amended Application)
- the 25 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 43rd meeting of the Advisory Committee on Medicines Scheduling (the Committee)[5]
- the interim decision relating bilastine and the materials considered as part of the interim decision, as published on 3 April 2024
- the one public submission received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the Submission)
- 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.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

[5] Established under sections 52B and 52C of the *Therapeutic Goods Act 1989* (Cth).

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 bilastine. 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 in the interim decision and the one public submission which was received in response to the interim decision consultation, which was supportive of the interim decision.

Implementation date

1 June 2024

Final decision in relation to BPC-157

Proposal

The Delegate proposed the creation of a new Schedule 4 entry and a new Appendix D, clause 5 entry to prohibit possession without appropriate authorisation for BPC-157. The proposal was in response to 48 referrals for importation of BPC-157 received by the TGA since 1 July 2022. The proposal seeks to align the scheduling of BPC-157 with other performance- and image-enhancing substances. BPC-157 is not currently captured in the Poisons Standard.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to BPC-157 as follows: [6]

Schedule 4 – New Entry

BPC-157

Index – New Entry

BPC-157

Schedule 4
Appendix D, clause 5

Appendix D, clause 5 – New Entry – Poisons for which possession without authority is illegal.

Item	Poison
5	BPC-157

Materials considered

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

- the application to amend the current Poisons Standard with respect to BPC-157 (the Application)
- the 22 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 43rd meeting of the Advisory Committee on Medicines Scheduling (the Committee)[7]

[6] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

[7] Established under sections 52B and 52C of the *Therapeutic Goods Act 1989* (Cth).

- the interim decision relating BPC-157 and the materials considered as part of the interim decision, as published on 3 April 2024
- the one public submission received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the Submission)
- 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.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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 BPC-157. 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 in the interim decision and the one public submission which was received in response to the interim decision consultation, which was supportive of the interim decision.

Implementation date

1 June 2024

Final decision in relation to methenamine

Proposal

The applicant proposed the creation of a new Schedule 2 entry for methenamine and its derivatives, in preparations for oral therapeutic use. Methenamine is approved for the suppression or elimination of bacteriuria associated with chronic or recurrent urinary tract infections (UTIs) and is currently available for general sale.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to methenamine as follows:[8]

Schedule 3 – New Entry

METHENAMINE in preparations for therapeutic use.

Schedule 5

METHENAMINE in cosmetic preparations, **except** in preparations containing 0.15% or less of methenamine.

Index – Amend Entry

METHENAMINE
cross reference: 1,3,5,7-TETRAAZATRICYCLO[3.3.1.13,7] DECANE, HEXAMINE, HEXAMETHYLENETETRAMINE

[8] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

Schedule 5
Schedule 3
Appendix H, clause 1

Appendix H, clause 1 – New Entry - Schedule 3 medicines permitted to be advertised.

Item	Poison
29	METHENAMINE

Materials considered

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

- the application to amend the current Poisons Standard with respect to methenamine (the Application)
- the 25 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 43rd meeting of the Advisory Committee on Medicines Scheduling (the Committee)[9]
- the interim decision relating methenamine and the materials considered as part of the interim decision, as published on 3 April 2024
- the 4 public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the Submissions)
- 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.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and the Handbook.

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 methenamine. 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 in the interim decision and the 4 public submissions which were received in response to the interim decision consultation. Out of the submissions, 1 was supportive, 2 were partially supportive and 1 opposed to the interim decision.

I note 2 submissions were supportive of the creation of the Schedule 3 (pharmacist only) entry and Appendix H entry (to permit advertising) as outlined in my interim decision. I also note two submissions which suggested that a Schedule 2 (pharmacy only) classification is more appropriate for the therapeutic use of methenamine.

In considering the submissions, I agree with the Committee's advice that methenamine for therapeutic use is consistent with the SPF factors for Schedule 3, in particular the requirement for pharmacist intervention to ensure the safe and appropriate use of this medicine. Further, I retain concerns that the use of methenamine may potentially mask the symptoms, or delay the diagnosis of, a serious medical condition. I acknowledge that consumers with a recurrent UTI who have been medically diagnosed and recommended to take methenamine by a medical practitioner are unlikely to inappropriately self-medicate. However, the availability of methenamine as a pharmacy only (Schedule 2) medicine presents risks of inappropriate use by consumers who have not been medically assessed and are in

[9] Established under sections 52B and 52C of the *Therapeutic Goods Act 1989* (Cth).

need of medical intervention. Therefore, I remain of the opinion that Schedule 3 is the most appropriate classification for methenamine in preparations for therapeutic use.

I have also considered the request for a delay to the implementation date for this decision. I acknowledge the implementation date of 1 October 2024 may cause disruption to the supply of methenamine products due to the implementation of packaging changes in response to the decision. As such, I have made a final decision to extend the implementation date to 1 October 2025.

Implementation date

1 October 2025

Final decision in relation to naratriptan

Proposal

The applicant proposed the creation of a new Schedule 3 entry for certain preparations of naratriptan for the acute relief of migraine in patients who have a stable, well-established pattern of symptoms. The proposal includes listing naratriptan in Appendix H to permit advertising for Schedule 3 preparations of naratriptan. The proposal would align the scheduling of naratriptan with other substances in the triptan class, including sumatriptan, zolmitriptan, eletriptan and rizatriptan.

Final decision

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

Schedule 4 – Amend Entry

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

Schedule 3 – New Entry

NARATRIPTAN when in divided oral preparations containing 2.5 mg or less of naratriptan 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 symptoms.

Index – Amend Entry

NARATRIPTAN

Schedule 4
Schedule 3
Appendix H, clause 1

Appendix H – New Entry - Schedule 3 medicines permitted to be advertised.

Item	Poison
32	NARATRIPTAN

Materials considered

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

- the application to amend the current Poisons Standard with respect to naratriptan (the Application)
- the 26 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations

- the advice received from the 43rd meeting of the Advisory Committee on Medicines Scheduling (the Committee)[10]
- the interim decision relating naratriptan and the materials considered as part of the interim decision, as published on 3 April 2024
- the one public submission received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the Submission)
- 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.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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 naratriptan. 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 in the interim decision and the one public submission which was received in response to the interim decision consultation, which was supportive of the interim decision.

Implementation date

1 June 2024

Final decision in relation to paracetamol

CONTENT WARNING

The information below contains details of self-poisonings some people may find distressing. The Department of Health and Aged Care acknowledges the devastating effects associated with acts of self-harm on individuals, their families, friends and communities. If you or someone you know needs additional support, please contact any of the below crisis support helplines:

Support services and information sources

Adult

Lifeline: 13 11 14

Suicide Call Back Service: 1300 659 467

Beyond Blue: 1800 512 348

MensLine Australia: 1300 789 978

Youth

Kids Helpline (5-25 years): 1800 551 800

Headspace: 1800 650 890

[10] Established under sections 52B and 52C of the *Therapeutic Goods Act 1989* (Cth).

ReachOut

Proposal

A final decision to amend the Poisons Standard was published in May 2023 (the 2023 Decision) relevantly amending the scheduling of paracetamol to require tablets and capsules for both general and Pharmacy Only sale to be in blister or strip packaging from 1 February 2025.

An application was received in July 2023 to amend the entry under Schedule 2 to create an exception for effervescent paracetamol preparations of 16 tablets or less packed in a container with a child-resistant closure (instead of blister or strip packaging) and made available for general sale.

Final decision

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

Materials considered

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

- the application to amend the current Poisons Standard with respect to paracetamol (the Application)
- the 45 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 43rd meeting of the Advisory Committee on Medicines Scheduling (the Committee)[11]
- the interim decision relating paracetamol and the materials considered as part of the interim decision, as published on 3 April 2024
- the 6 public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the Submissions)
- 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.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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

I have made a final decision to confirm my interim decision to not amend the current Poisons Standard with respect to paracetamol. 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 in the interim decision and the 6 public submissions which were received in response to the interim decision consultation.

I acknowledge the 2 written public submissions that did not support the interim decision. I recognise there are several aspects of paracetamol formulations that may reduce the extent of intentional self-poisoning, such as effervescent tablets being typically larger in size and its reaction with liquid. However, as per the reasons set out in my interim decision, I am not persuaded the benefits of making effervescent paracetamol in a child resistant closure available on general sale outweigh the potential risks in the absence of further evidence.

[11] Established under sections 52B and 52C of the *Therapeutic Goods Act 1989* (Cth).

Note, the changes to the paracetamol entries from the 2023 Decision are still set to be in force on 1 February 2025.

Final decisions on proposed amendments referred to the Advisory Committee on Chemicals Scheduling (ACCS #37, November 2023)

Final decision in relation to animal blood products

Proposal

The applicant proposed the creation of a new Schedule 4 entry for animal blood products for veterinary use. The proposal intends to control the access of animal blood products for veterinary use under the Poisons Standard. Animal blood products are not currently captured in the Poisons Standard and have not previously been considered for scheduling.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to animal blood products as follows: [12]

Schedule 4 – New Entry

ANIMAL BLOOD PRODUCTS for veterinary use 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);

(viii) thrombin;

(ix) haemoglobin.

[12] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

Index – New Entry

ANIMAL BLOOD PRODUCTS

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 animal blood products (the Application)
- the 20 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 37th meeting of the Advisory Committee on Chemicals Scheduling (the Committee)
- the interim decision relating to animal blood products and the materials considered as part of the interim decision, as published on 3 April 2024
- the one public submission received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the Submission)
- 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; (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.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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 animal blood products. 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 in the interim decision and the one public submission which was received in response to the interim decision consultation, which was supportive of the interim decision.

Implementation date

1 October 2024

Final decision in relation to bile acids

Proposal

The applicant proposed an exemption to the Schedule 4 entries for chenodeoxycholic acid, cholic acid, and deoxycholic acid, herein referred to as bile acids, when used as an animal feed additive or in feed pre-mixes. Chenodeoxycholic acid was first included in Schedule 4 in March 1980, while cholic acid and deoxycholic acid were included under Schedule 4 in March 2015 and March 2016, respectively. None of these substances have been considered for re-scheduling since their respective initial scheduling in the Poisons Standard.

Final decision

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

Materials considered

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

- the application to amend the current Poisons Standard with respect to bile acids (the Application)
- the 17 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 37th meeting of the Advisory Committee on Chemicals Scheduling (the Committee)
- the interim decision relating to bile acids and the materials considered as part of the interim decision, as published on 3 April 2024
- the one public submission received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the Submission)
- 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.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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

I have made a final decision to confirm my interim decision to not amend the current Poisons Standard with respect to bile acids. 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 in the interim decision and the one public submission which was received in response to the interim decision consultation, which was opposed to the interim decision.

In considering the public submissions, I am of the view that no new evidence has been provided that supports that the benefits of bile acid use outweigh the risks (such as enterohepatic accumulation of bile acids) or that any other new information contradicts alignment of this substance to the Schedule 4 factors in the SPF. The main risks posed by bile acid use in feed additives are (i) the potential to result in human toxicity during consumption of animal livers; and (ii) the interaction of exogenous bile acids with other drugs, chemicals and foods outweighs the benefits in pig, poultry and aquaculture applications.

I do not agree with the public submissions that state there is sufficiently low risk of toxicity in humans to justify a scheduling exemption. I remain of the view that limited toxicity data was provided by the applicant for each of the proposed bile acids. Furthermore, acute oral toxicity of bile acids may be higher in animals that are undergoing concurrent drug treatment while being fed bile acid enriched feedstocks. No new evidence was provided that contradicts the risk of these bile acids causing skin and respiratory irritation and causing serious eye irritation in cases of human exposure. Additionally, beyond assuring that regulatory compliance standards for feed additives would be met, no new information was provided that the risk of inappropriate use in companion animals or use in ruminant feeds are incongruent with Schedule 4 SPF factors. In considering the SPF factors, I therefore remain of the opinion that Schedule 4 is appropriate for bile acids when used as animal feed additives.

Final decisions on proposed amendments referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #35, November 2023)

Final decision in relation to adrenaline

Proposal

The applicant proposed the inclusion of topical preparations containing 0.1% or more of adrenaline in the existing Schedule 4 entry for adrenaline. Adrenaline is typically included in gels and lotions with local anaesthetic substances for the treatment of wounds. An independent evaluation of the risks associated with the use of adrenaline on wounds recommended that relevant products should be available by prescription only (Schedule 4). The proposal also sought to clarify the existing entries for adrenaline with regards to injectable preparations.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to adrenaline as follows:[13]

Schedule 4 – Amend Entry

ADRENALINE in ~~**except**~~:

(a) ~~when included in Schedule 3~~ topical preparations for the treatment of wounds in humans; or

(b) ~~in~~ all other preparations containing ~~0.02% or less of~~ adrenaline ~~unless packed and labelled for injection~~ **except** when included in or expressly excluded from Schedule 3.

Schedule 3 – Amend Entry

ADRENALINE in preparations containing 1% or less of adrenaline **except** in preparations that are not for injection containing 0.02% or less of adrenaline ~~unless packed and labelled for injection~~.

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ADRENALINE

Schedule 4
Schedule 3
Appendix H, clause 1

Appendix H, clause 1 – Schedule 3 medicines permitted to be advertised.

Item	Poison
2	ADRENALINE

[13] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

Materials considered

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

- the application to amend the current Poisons Standard with respect to adrenaline (the Application)
- the 23 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 35th meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the Committee)
- the interim decision relating to adrenaline and the materials considered as part of the interim decision, as published on 3 April 2024
- the 2 public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the Submissions)
- 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.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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 adrenaline. 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 in the interim decision and the 2 public submissions which were received in response to the interim decisions, both of which were supportive of the interim decision.

Implementation date

1 June 2024

Final decision in relation to benzoic acid

Proposal

The applicant proposed new entries in Schedules 5, 6 and 7 for benzoic acid, which is presently unscheduled. The new entries in Schedules 5 and 6 would place labelling requirements on the use of benzoic acid in agricultural and veterinary products, while the Schedule 7 entry would impose controls on access to preparations containing more than 10% benzoic acid.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to benzoic acid as follows:[14]

Schedule 5 – New entry

BENZOIC ACID (excluding its salts and derivatives) in preparations for agricultural use **except** those containing 1% or less of benzoic acid.

[14] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

Index – New entry

BENZOIC ACID

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 benzoic acid (the Application)
- the 21 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 35th meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the Committee)
- the interim decision relating to benzoic acid and the materials considered as part of the interim decision, as published on 3 April 2024
- the 2 public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the Submissions)
- 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.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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 benzoic acid. 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 in the interim decision and the 2 public submissions which were received in response to the interim decision, both of which were supportive of the interim decision.

Implementation date

1 June 2024

Final decision in relation to meloxicam

Proposal

The applicant proposed an amendment to the Schedule 6 entry for meloxicam to include certain injectable veterinary vaccines containing less than 1% of meloxicam for single use in lambs undergoing routine animal husbandry procedures. Meloxicam is an anti-inflammatory medicine that can be used for pain relief. The amendment would enable farmers to access the medicine in a coformulation with certain vaccines, without the requirement for a prescription.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to meloxicam as follows: [15]

Schedule 6 – Amend entry

MELOXICAM in:

(a) oral transmucosal preparations containing 1% or less meloxicam for pre-surgical treatment and pain management in livestock during routine husbandry procedures; or

(b) injectable vaccines containing bacterial antigens and 1% or less of meloxicam for single use in lambs undergoing husbandry procedures at marking.

Schedule 4

MELOXICAM **except** when included in Schedule 6.

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MELOXICAM

Schedule 6
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 meloxicam (the Application)
- the 83 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 35th meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the Committee)
- the interim decision relating to meloxicam and the materials considered as part of the interim decision, as published on 3 April 2024
- the 11 public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the Submissions)
- 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.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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 meloxicam. 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 in the interim decision and the 11 public submissions which were received in response to the interim decision, all of which were supportive of the interim decision.

Implementation date

[15] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

1 June 2024

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

In my capacity as a delegate of the Secretary for the purpose of regulation 42ZCZW of the Regulations, I have made final decisions under regulation 42ZCZW with respect to the following substances:

capromorelin

prasterone

Final decision in relation to capromorelin

Final Decision

Pursuant to regulation 42ZCZW of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to capromorelin as follows: [16]

Schedule 4 – New Entry

CAPROMORELIN

Index – New Entry

CAPROMORELIN

Schedule 4
Appendix D, clause 5

Appendix D, clause 5 – New Entry - Poisons for which possession without authority is illegal.

Item	Poison
6	CAPROMORELIN

Materials considered

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

- The application to amend the current Poisons Standard with respect to capromorelin (the Application)
- the interim decision relating to capromorelin and the materials considered as part of the interim decision, as published on 3 April 2024
- 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.

[16] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

- Pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- The Handbook.

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 capromorelin. 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. I have noted that there were no public submissions received before the second closing date in response to the call for further submissions published on 3 April 2024 under regulation 42ZCZP of the Regulations.

Implementation date

1 June 2024

Final decision in relation to prasterone

Background

Prasterone, also known as dehydroepiandrosterone (DHEA), is an androgenic hormone therapy used in the treatment of vulvar and vaginal atrophy in postmenopausal women. Recent studies have shown that prasterone supplementation may improve assisted reproductive outcomes in women with poor ovarian response or diminished reserves.

The proposed use of prasterone is as an oral capsule administered over a short to medium term prior to egg freezing procedures in women with low ovarian reserves. Prasterone is already administered as a pessary in the treatment of vulvar and vaginal atrophy. DHEA is naturally produced within the adrenal glands and can be converted to both estrogenic and androgenic hormones within the body.

Current Scheduling

Schedule 4

PRASTERONE (dehydroepiandrosterone, dehydroisoandrosterone).

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PRASTERONE
cross reference: DEHYDROEPIANDROSTERONE, DEHYDROISOANDROSTERONE
Schedule 4
Appendix D, clause 5 (Anabolic and/or androgenic steroidal agents)

Appendix D, clause 5 - Poisons for which possession without authority is illegal.

Item	Poison
1	ANABOLIC STEROIDAL AGENTS, including those separately specified in Schedule 4
2	ANDROGENIC STEROIDAL AGENTS, including those separately specified in Schedule 4

Alternative names

dehydroepiandrosterone, dehydroisoandrosterone, DHEA

Proposal

The applicant proposed an exemption to the Schedule 4 entry for prasterone when in oral capsule preparations for short-term use in women during egg-freezing. The new entry would allow packs of 25 mg DHEA oral capsules to be exempt from scheduling for use in women two months prior to undergoing egg freezing and fertility preservation.

Final Decision

Pursuant to regulation 42ZCZW of the Regulations, a Delegate of the Secretary has made a final decision to not amend the current Poisons Standard in relation to prasterone. The detailed reasons for the decision are provided within.

Materials considered

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

- The application to amend the current Poisons Standard with respect to prasterone (the Application)
- 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; (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health.
- Pursuant to paragraph 52E(2)(a) of the Act,
- the SPF, and
- The Handbook.

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

I have made an interim decision to not amend the current Poisons Standard in relation to prasterone. The detailed reasons for my decision are as follows.

The basis of my decision is that the substance meets the scheduling factors for inclusion in Schedule 4, as outlined in the SPF, and that additional controls on possession and supply through Appendix D are required for use, including those specified in the Application.

The Application proposes that oral preparations of prasterone administered to support women's fertility prior to egg-freezing and fertility preservation be exempt from scheduling. I note that whilst the application refers to dehydroepiandrosterone (DHEA) throughout, I will discuss my reasoning for the decision with respect to prasterone, for consistency with IUPAC naming conventions and the current schedule entry for DHEA in the Poisons Standard.

I consider the risks of misuse and the need for medical supervision during treatment with prasterone, an anabolic and androgenic agent, are not sufficiently addressed in the proposed use. I am of the view that the scheduling factors associated with Schedule 4 and Appendix D, clause 5 access restrictions remain appropriate for prasterone in these applications.

With respect to paragraphs 52E(1)(a) and (b) of the Act, I note that the application proposes short-term use (not exceeding two months) of prasterone prior to egg freezing procedures. However, the application does not provide substantive evidence that the seriousness, severity, and frequency of adverse effects are reduced in this modality such that it would no longer require medical monitoring or intervention. For this reason, Schedule 4 remains appropriate for prasterone in the short-term treatment of women prior to egg freezing and fertility preservation.

Turning my mind to paragraph 52E(1)(c) of the Act, I note that prasterone is a naturally occurring hormone produced within the adrenal gland. Side effects and drug interactions, such as hormonal therapies, corticosteroids, and anticoagulants, are consistent with other androgenic and anabolic steroids included under Appendix D, clause 5. Short-term usage within an appropriate dosage range is well tolerated with no significant adverse effects. I note that steroidal prasterone may increase the risk of hormone-sensitive cancers such as breast and ovarian cancer in patients.

With regard to paragraph 52E(1)(e) of the Act, I am of the opinion that the potential risk of diversion, misuse or abuse of prasterone as an androgenic/anabolic steroid is commensurate with the SPF factors of Schedule 4, part 3. Chiefly, as an androgenic substance and precursor steroid that can be converted to estrogen and testosterone, there is a risk of abuse as a performance and image enhancing drug.

I note under paragraph 52E(1)(f) of the Act, that the consultation period prior to undergoing egg-freezing and fertility preservation is performed under medical supervision. I have considered that the proposal to increase access to prasterone through down-scheduling would provide minimal benefit given the presence of medical supervision through-out the pre-operative period.

I acknowledge that the Applicant seeks to align scheduling of prasterone in the treatment of women's fertility prior to egg freezing with international regulations, namely, the US and UK where prasterone is available as an over-the-counter dietary supplement. However, turning my mind to the SPF factors, I am of the opinion that Schedule 4 remains appropriate given the potential for misuse, abuse and diversion of the substance, as well as the need for medical oversight during periods leading up to, and during, egg-freezing procedures.

I consider the SPF factors for an Appendix D provision to be applicable to prasterone in the application of treatment in women undergoing egg freezing. The SPF factors for Appendix D are relevant for any human or veterinary medicine, where:

- a specific health risk that may be mitigated by restricting availability through specialist medical practitioners, or
- significant potential for illicit diversion and/or abuse which does not warrant inclusion in Schedule 8 but warrants particular control of possession, or
- a specific high potential for abuse, particular international treaty on restrictions on availability or other matters of national public health policy which when weighed against the need for access to the substance, warrants, in addition to inclusion of the substance in Schedule 4 or 8, further restrictions on access, such as authorisation by the Secretary of the Department of Health or some other appropriate State/Territory or Commonwealth authority.

Based on the above reasons, it is my view that the existing scheduling entry for prasterone is appropriate and aligns with the relevant factors listed in the SPF. I am also of the opinion that the application did not provide evidence that the risk of this substance, when used to support women's fertility prior to egg-freezing and fertility preservation or otherwise, has changed since the substance was last considered for scheduling.

I have made a final decision to not amend the current Poisons Standard in relation to prasterone. The detailed reasons for my decision are as outlined in the interim decision. I note that a response to the interim decision was sought from the applicant, though a response was not received.

Amendments to the Poison Standard in relation to New Chemical Entities (NCEs)

The NCEs listed below will be included in the new Poisons Standard that will come into effect on 1 June 2024.

Abrocitinib

Schedule 4 – New Entry

ABROCITINIB.

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ABROCITINIB

Schedule 4

Bulevirtide

Schedule 4 – New Entry

BULEVIRTUDE.

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BULEVIRTUDE

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Clascoterone

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Elranatamab

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ELRANATAMAB

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Etranacogene dezaparvovec

Schedule 4 – New Entry

ETRANACOGENE DEZAPARVOVEC.

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ETRANACOGENE DEZAPARVOVEC

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ETRASIMOD

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Schedule 4 – New Entry

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Schedule 4

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