Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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

3 April 2024

Confidentiality

All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

Notice of interim decisions made under Regulations 42ZCZN and 42ZCZV of the *Therapeutic Goods Regulations 1990*

This web publication constitutes a notice for the purposes of regulation 42ZCZP of the *Therapeutic Goods Regulations 1990* (the **Regulations**). In accordance with regulation 42ZCZP, this notice sets out:

- the interim decisions made by a delegate of the Secretary of the Department of Health and Aged Care (the **Delegate**) under regulation 42ZCZN in relation to proposed amendments to the current Poisons Standard which were referred to an expert advisory committee[1] under subdivision 3D.2 of the Regulations in November 2023.
- the interim decision made by the **Delegate** under regulation 42ZCZV in relation to proposed amendments to the current Poisons Standard which were not referred to an expert advisory committee[2] under subdivision 3D.2 of the Regulations in November 2023.
- the proposed date of effect of the proposed amendments (in circumstances where the interim decision proposes an amendment to the current Poisons Standard).

In accordance with regulation 42ZCZP, interested persons (including the applicant requesting the amendment) are invited to make submissions to the Secretary in relation to these interim decisions on or before 17 April 2024.

Submissions should be provided through our consultation hub. Submissions will be considered by the Delegate in making the final decision.

Please note that in accordance with subregulation 42ZCZQ(4) of the Regulations, the Secretary must publish all relevant submissions received, unless the Secretary considers the information to be confidential information.

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 be defined for individual decisions.

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

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

Interim 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 preparations as a condom lubricant. 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.

Interim decision

A Delegate of the Secretary[3] has made an interim decision to amend the current Poisons Standard in relation to astodrimer sodium as follows as follows:[4]

Schedule 3 - Amend Entry

ASTODRIMER SODIUM **except ~~in~~:**

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

The Delegate's interim decision differs from the applicant's proposal and the detailed reasons for the decision follow.

[3] Pursuant to regulation 42ZCZN of the Regulations.
[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.

Materials considered

In making this interim 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, with 137 including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**).
- The advice received from the 43rd meeting of the Advisory Committee on Medicines Scheduling (the **Committee**).
- Subsection 52E(1) of the Act, in particular (a) 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 that the Secretary considers necessary to protect public health.
- The SPF, and
- The Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that astodrimer sodium when used in a barrier nasal spray, be entered in Schedule 2 in the Poisons Standard in the manner set out in my interim decision.

Due to the absence of registered products that would be affected by the change in scheduling, the Committee recommended an implementation date of **1 June 2024**.

The Committee agreed on the relevant matters under subsection 52E(1) of the Act, and provided the following reasons for the advice:

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

Risks:

- Astodrimer sodium has shown limited, local and self-limiting adverse events similar to control products. The risk profile of the substance is deemed to be low risk and well tolerated.

Benefits:

- Provides a physical barrier in which to trap respiratory viruses and reduces viral load. May reduce severity of viral respiratory disease.

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

- Prevents and reduces transmission of cold and flu viruses by trapping or blocking the virus in the nasal mucosal pathway.
- Usage would be similar to other barrier nasal spray products.

c) the toxicity of a substance

- Astodrimer sodium is well established as a safe short-term treatment, with a low risk of harm from inappropriate use. It is well-tolerated, and clinical studies have shown no signs of local or systemic toxicity.

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

- The proposed product is a 1% aqueous solution of astodrimer sodium in the form of an isotonic nasal spray. It will be supplied in a 10 mL plastic bottle with a nasal pump applicator within a carton. Dosage was not provided in the application.
- There are no currently marketed astodrimer sodium nasal spray products in Australia.

e) the potential for abuse of a substance

- There is no potential for abuse given that the substance is not systemically absorbed.

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

- Safeguards may be required to address the risk as there is potential for the substance to be advertised or promoted for use as a treatment for serious respiratory conditions, such as COVID-19.
- The nasal spray may deter the public from getting vaccinated, wearing masks or taking other standard precautionary measures around prevention and transmission of viral respiratory diseases. May also delay seeking medical attention.

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

I have made the decision to amend the Poisons Standard by creating a new Schedule 2 entry for astodrimer sodium when present in nasal sprays. The application to amend the current Poisons Standard with respect to astodrimer sodium requested the entry include the term 'barrier' when describing use in a nasal spray. However, I am of the opinion that the term 'barrier' is not of primary relevance to the function of the substance. I agree with the applicant that the low toxicity of astodrimer sodium, and its claimed therapeutic benefits in preventing exposure to common cold viral particles, outweighs the potential risks of the substance when in nasal spray preparations.

I agree with the applicant that the toxicity profile of astodrimer sodium is well defined, and the substance poses a low risk of toxicity, lacking systemic absorption when used as a nasal spray. However, I am also of the opinion that astodrimer sodium poses a risk of masking or delaying seeking help for more serious health conditions. Of particular concern is the risk of delaying treatment for more serious respiratory conditions. The substance also poses risks of misuse in the treatment of serious respiratory conditions, such as COVID-19. However, in making this decision, I am of the view that the claimed therapeutic benefits of astodrimer sodium in providing broad-spectrum prevention from common cold viruses through physically trapping viral particles and reducing viral exposure outweigh these risks. In my view astodrimer sodium when used in nasal sprays aligns closely with the SPF factors of Schedule 2 of the Poisons Standard. This is in consideration of the risk profile which is well defined, and risks can be identified and managed by a consumer through appropriate packaging and labelling, including consultation with a health professional if directed by labelling.

Turning my mind to s 52E(1)(a) of the Act, I note the applicant's claim that astodrimer sodium in nasal sprays has demonstrated potent broad-spectrum efficacy against respiratory viruses through physically trapping viral particles and reducing viral load in non-clinical investigations. Further, the claim that the substance may reduce the severity of viral respiratory diseases. I also note that astodrimer sodium is commonly used internationally and is generally considered to be well tolerated with limited incidence of adverse events; the majority of which are mild and self-limiting in nature. I agree with the Committee that increased access to astodrimer sodium nasal sprays may delay people from seeking medical attention, as well as deterring vaccination, mask wearing, and other standard precautionary measures to prevent transmission of viral respiratory diseases. However, in considering SPF factors, I am satisfied that the risk of the substance masking the symptoms or

delaying diagnosis of a serious condition is unlikely, and as such aligns with the considerations for a Schedule 2 entry.

In relation to s 52E(1)(b) of the Act, the applicant claims that astodrimer sodium in nasal spray preparations could be used in the prevention of the common cold through physically trapping viral particles. The large molecular size and negative surface charge of the substance prevents systemic absorption. I note that inclusion of astodrimer sodium in nasal spray preparations in Schedule 2 would be consistent with similar nasal spray products used in treating cold-related symptoms. Astodrimer sodium is not currently registered as a medicine in Australia, though Fleurstat® vaginal flora gel containing astodrimer sodium as an active ingredient is registered as a Class IIa medical device[5] for the topical treatment and rapid relief of BV.

I agree with both the Committee and the applicant that astodrimer sodium poses a demonstratively low risk for short term treatment with the risk of harm from inappropriate use being very low. Turning my mind to s 52E(1)(c) of the Act, and the SPF factors, astodrimer sodium in nasal spray preparations aligns with Schedule 2 considerations as the medicine is substantially safe for short term treatment and the potential for harm from inappropriate use is low. I note that astodrimer sodium has limited observed adverse effects that are mild, self-limiting, and comparable to that of placebo-control treated groups in trials. I also note that the substance is readily available as a regulated low risk (Class 1) medical device in the EU, Malaysia, Vietnam, Hong Kong, and Macao, with no reportable incidents from use of astodrimer sodium outside of Australia.

Regarding s 52E(1)(d) the applicant proposes the use of astodrimer sodium in an aqueous based, isotonic nasal spray at a 1% concentration. It will be supplied in a 10 mL plastic bottle with a nasal pump applicator within a carton. I note however, that the applicant did not specify the dosage of the substance in nasal spray products.

I agree with the Committee that the risk of misuse and abuse of astodrimer sodium in nasal spray preparations is very low, particularly given the substance is not systemically absorbed. However, I agree with the Committee that there remains a risk of departure of use for more serious respiratory conditions. Turning my mind to s 52E(1)(e) of the Act, and the SPF factors, I am of the opinion that astodrimer sodium when used in nasal spray preparations aligns with Schedule 2 considerations as the substance is very unlikely to produce dependency (at either the established therapeutic dose or supratherapeutic doses) and the medicine is very unlikely to be misused, abused or illicitly used.

I have considered the 137 written public submissions received during the pre-meeting consultation period; 136 written responses received were fully supportive of the applicant's proposal, and 1 partially supportive. Interested parties were also given the choice to select from options to indicate their support or opposition to the proposed amendment without providing a written component. Of these, 30 responses in support were received. These respondents did not provide reasons for their support and as a result, the extent of my consideration is limited, noting that the submissions were generally in favour of the scheduling proposal.

After consideration of the information provided in the application, the public submissions, advice provided by the Committee and the SPF factors, I have made an interim decision to create a new Schedule 2 entry for astodrimer sodium when present in nasal spray preparations. As there are no currently approved products in Australia, except for astodrimer sodium as an active ingredient in medical devices only for the topical treatment, rapid relief and prevention of BV, I propose an implementation date of 1 June 2024.

[5] www.tga.gov.au/resources/what-classification-my-medical-device#node-554

Implementation date

1 June 2024

Interim decision in relation to bilastine

Proposal

The TGA received two proposals in relation to bilastine which were submitted by the same applicant. An '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 an 'amended application' 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 has been subjected to public consultation, but both proposals were referred to the Committee for consideration.

Interim decision

A Delegate of the Secretary[6] has made an interim decision to amend the current Poisons Standard in relation to bilastine as follows as follows:[7]

Schedule 4 – Amend Entry

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

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 older.

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

[6] Pursuant to regulation 42ZCZN of the Regulations.
[7] 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.

The Delegate's interim decision differs from the applicant's proposal and the detailed reasons for the decision follow.

Materials considered

In making this interim 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, with 5 including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**).
- The advice received from the 43rd meeting of the Advisory Committee on Medicines Scheduling (the **Committee**).
- Subsection 52E(1) of the Act, in particular (a) 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 that the Secretary considers necessary to protect public health.
- The Database of Adverse Event Notifications (DAEN) for medicines.
- The Australian Register of Therapeutic Goods (ARTG).
- The SPF, and
- The Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that the Poisons Standard be amended in relation to bilastine as set out in my interim decision.

The Committee also recommended an implementation date of **1 June 2024**, to avoid any unnecessary delay to industry.

The Committee agreed on the relevant matters under subsection 52E(1) of the Act, and provided the following reasons for the advice:

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

Risks:

- There is potential for the use of bilastine to inadvertently mask symptoms of a common cold, or more serious dermatological conditions.

Benefits:

- Bilastine is a potent non-sedating antihistamine (second generation) that is effective in the management of allergy symptoms.
- It has a strong safety profile, and its side effect profile is comparable with other agents in the class.

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

- Bilastine is used for the symptomatic relief of seasonal and perennial allergic rhinitis, rhino-conjunctivitis and urticaria.

c) the toxicity of a substance

- Bilastine has a well-defined safety and tolerability profile, with a wide therapeutic index.
- Headache, drowsiness, and lethargy are the most common adverse events reported by patients.
- Bilastine is category B3[8] in pregnancy.

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

- The proposal includes the addition of orally disintegrating tablets and oral solution formulations.
- Cautionary labelling is required in respect to indications, age (not for use in children under 6 years old), weight of patient (greater than 20 kg), and seeking advice if pregnant.

e) the potential for abuse of a substance

- There is minimal risk of abuse associated with the use of bilastine.

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

- Bilastine is available overseas in oral liquid preparations and eye drops.
- There is limited experience of the use of this medicine in Australia for children aged under 12 years.

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

I agree with the Committee's findings on the relevant provisions of section 52E of the Act.

Currently, bilastine is listed in Schedule 3 when in divided oral preparations containing 20 mg or less for adults and adolescents 12 years of age and older, and Schedule 4 for all other preparations. The applicant aims to extend the use of bilastine in a younger population and introduce more palatable bilastine preparations to the Australian market which are more suitable for these age groups.

In relation to s 52E(1)(a) and (b) of the Act, bilastine is a second-generation non-sedating antihistamine, belonging to the same class of medicines as fexofenadine, loratadine and cetirizine. It is an effective treatment for the symptomatic relief of allergies including itchy, red or watery eyes, sneezing, runny or blocked nose, itchy throat, coughing and skin rashes. Bilastine has a well-defined safety profile, and the side effects associated with its use is comparable to other non-sedating antihistamines. While I recognise the use of bilastine is associated with potential risks of masking symptoms of a common cold, or more serious dermatological conditions, I note these potential risks are also associated with the use of other antihistamines within the same class.

Regarding s 52E(1)(c) of the Act, bilastine has a wide therapeutic index and is generally well tolerated. The most common side effects reported by users include headache, drowsiness and lethargy. The TGA has only received 9 reports of adverse events related to bilastine products as of

[8] www.tga.gov.au/australian-categorisation-system-prescribing-medicines-pregnancy

January 2024, and most are general in nature. However, I am also aware that there is limited data on the safety of bilastine when used during pregnancy and breastfeeding, and this substance interacts with certain medicines such as ketoconazole, erythromycin and diltiazem.

In alignment with the Committee's advice, I have decided to create a Schedule 2 entry for bilastine as proposed by the applicant. In making this decision, I note that there is sufficient local experience of bilastine use in adults and children aged 12 and above, on which to base a Schedule 2 entry. I am confident the risks identified above can be sufficiently mitigated with relevant cautionary labelling on the packaging, and that bilastine can be supplied with reasonable safety without a pharmacist input. Further, the longstanding availability of other non-sedating antihistamine products indicates that consumers can successfully identify their symptoms and manage their conditions, and a Schedule 2 classification will also ensure access to a pharmacist or trained pharmacy staff for consultation, if required. Based on this, I am satisfied that bilastine for use in adults and children aged 12 and above aligns with the factors for Schedule 2 as set out in the SPF.

With respect to the proposed amendment to the Schedule 3 entry, I have considered the data provided by the applicant in support of the safety of bilastine. I note that a 10 mg daily dose is reported as safe in children aged 6-11 with a body weight of at least 20 kg. Also, this dosage provides children aged 6-11 the equivalent systemic exposure to bilastine to a 20 mg daily dose in adults. I agree with the Committee that the amendment to the Schedule 3 entry should be consistent with this information and the maximum recommended daily dose for this age group should be 10 mg instead of 20 mg.

With regard to s 52E(1)(d) of the Act, I note that bilastine is a relatively new medicine in Australia compared to other non-sedating antihistamines. The single bilastine product listed on the Australian Register of Therapeutic Goods (ARTG), Allertine®, has only been available since 2021. There is also limited Australian experience of bilastine use in children aged under 12 since Allertine® is only approved for use in adults and children aged 12 and above. The proposed amendments may also pose risks of dosing error as it would allow the introduction of new preparations such as oral liquid to the market. Based on these matters, I am of the view that pharmacist oversight is required when supplying bilastine to children aged 6-11 to provide appropriate support to consumers and ensure the safe use of this medicine. Additionally, pharmacist interaction will facilitate monitoring and reporting of pharmacovigilance factors until more local experience is available. In line with the Committee's recommendation, I have decided to amend the Schedule 3 entry for bilastine as set out above.

In considering other matters of relevance to scheduling under s 52E(1)(f) of the Act, I note the more restrictive regulations in the United Kingdom, Ireland and Canada, where bilastine is only available as a prescription only medicine. On the other hand, in New Zealand, bilastine has been classified as a pharmacy medicine since 2018 and the restrictions on dosage form and pack sizes were removed recently. I consider the scheduling of bilastine as set out in my interim decision will broaden consumer access to bilastine while ensuring the availability of a pharmacist to support the quality use of the medicine.

I have considered the 25 public submissions received during the pre-meeting consultation period in relation to the original proposal. The 5 written responses received were fully supportive of the original proposal. Of the submissions received without a written component, 19 were supportive and 1 was partially supportive of the original proposal.

After consideration of the information provided in the application, the public submissions, advice provided by the Committee and the SPF factors, I have made an interim decision to create a new Schedule 2 entry and amend the Schedule 3 for bilastine as set out above, with an implementation date of 1 June 2024 to prevent unnecessary delay to industry.

Implementation date

1 June 2024

Interim 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.

Interim decision

A Delegate of the Secretary[9] has made an interim decision to amend the current Poisons Standard in relation to BPC-157 as follows as follows:[10]

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
4a	BPC-157

Materials considered

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

- The 22 public submissions, with 4 including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**).
- The advice received from the 43rd meeting of the Advisory Committee on Medicines Scheduling (the **Committee**).
- Subsection 52E(1) of the Act, in particular (a) 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 that the Secretary considers necessary to protect public health;
- The SPF, and

[9] Pursuant to regulation 42ZCZN of the Regulations.
[10] 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.

- The Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that BPC-157 be entered in Schedule 4 and Appendix D, clause 5 in the Poisons Standard as set out in my interim decision.

The Committee also recommended an implementation date of **1 June 2024**. As the substance is an unapproved medicine with no registered products affected by the scheduling change, the Committee saw no reason to delay the implementation of the amendment to the Poisons Standard.

The Committee agreed on the relevant matters under subsection 52E(1) of the Act, and provided the following reasons for the advice:

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

Risks:

– There is a lack of clinical data regarding the short- and long-term effects of use of the substance.

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

– The use of BPC-157 in humans has unsubstantiated claims for enhancement of healing from injuries and organ damage including stomach ulcers and healing of various tissues such as tendons, joints, nerves the intestinal tract and the skin.

c) the toxicity of a substance

– The toxicity of the substance has not been adequately characterised.

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

– BPC-157 has been identified in unapproved injectable, oral, powder, liquid and nasal spray formulations.

e) the potential for abuse of a substance

– High risk of misuse and abuse within athletes, fitness, wellness and anti-ageing consumer markets.

– There is no evidence that BPC-157 is psychoactive.

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

– Short-term and long-term safety of BPC-157 intake is unknown.

– BPC –157 is currently listed on the World Anti-Doping Authority's prohibited list (S0) and its use is at all times prohibited in competing athletes, both in and outside of competitions.

– There are concerns regarding online promotion of the substance as an alternative health supplement. Though current marketing of BPC-157 by online vendors as 'not for therapeutic use' or 'for research only' is insufficient to deter consumer misuse of the substance.

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

I have made the decision to amend the Poisons Standard by creating a Schedule 4 entry for BPC-157. I am of the opinion that there is a limited evidence basis to support the putative therapeutic benefits,

while the risk of misuse remains high, particularly among athletes, wellness consumer markets and people who are seeking medicines for the purpose of anti-ageing benefits. The need for restricting access through Schedule 4 and Appendix D, clause 5 is further justified by the current practice of online vendors in promoting BPC-157 with the disclaimer 'not for therapeutic use' or 'for research only' to circumvent existing controls on therapeutic goods.

I agree with the Committee that the putative therapeutic benefits of BPC-157 in humans are largely unsubstantiated. The substance is currently sold and marketed by online vendors with claims of enhancing healing from injuries and organ damage including stomach ulcers and regeneration of skin, tendons, joints, nerves and the intestinal tract. Presently, there is a limited evidence base to support these therapeutic claims, with only a small number of peer-reviewed studies that largely originate from a single laboratory. I am also of the opinion that the substance poses a high risk of misuse, particularly among athletic and anti-ageing consumer markets, as will be discussed below. I agree with the Committee's findings on the relevant provisions of section 52E of the Act. Chiefly, in consideration of s 52E(1)(a) and (b) of the Act, and the SPF factors, I agree that the lack of substantive therapeutic benefits, and the potential risks posed by BPC-157 usage firmly align with Schedule 4; particularly as the experience of the use of the substance under normal clinical conditions is limited.

Turning my mind to s 52E(1)(c) of the Act, I agree with the Committee that the toxicity profile of BPC-157 is largely uncharacterised and there is limited data on the safety of both short- and long-term treatment with BPC-157. There is presently a lack of clinical evidence regarding safety of BPC-157 usage, with only a single registered phase 1 clinical trial conducted in 2015. I am of the view that the lack of a clearly defined safety and toxicity profile of BPC-157 is commensurate with the SPF factors of Schedule 4. In regards to s 52E(1)(d) of the Act, BPC-157 has been identified during importation in unapproved injectable, oral, nasal spray and powder formulations.

I am of the opinion that BPC-157 poses a high risk of misuse within athletic, fitness, wellness and anti-ageing consumer markets. Misuse of BPC-157 by athletes has resulted in the World Anti-Doping Agency (WADA) listing BPC-157 under the S0 Non-Approved Substances category and prohibiting its use in sports at all times (in and out of competition) in January 2022.[11] I note that there is no evidence that BPC-157 is a psychoactive substance. I agree with the Committee that the risk of misuse will likely grow over time given the current demand for growth promoting substances, such as seen with the increase in selective androgen receptor modulator (SARM) usage. If left unscheduled, BPC-157 could fill the gaps left in the market with increased access restrictions placed on similar performance-enhancing products. In considering s 52E(1)(e) of the Act, and the SPF factors, I am of the view that BPC-157 warrants additional access restrictions via Appendix D, clause 5 as the substance has significant potential for illicit diversion and/or abuse which does not warrant inclusion in Schedule 8 but warrants particular control of possession.

Turning my mind to s 52E(1)(f), I note there is a limited evidence base regarding both the short- and long-term safety of BPC-157 usage. This aligns with the SPF factors associated with Schedule 4 as the seriousness, severity and frequency of adverse effects are such that monitoring or intervention by a medical, veterinary or dental practitioner is required to minimise the risk of using the substance. Further, I agree with the Committee that access restrictions via Schedule 4 are justified given the current practice of online vendors in marketing BPC-157 as 'not for therapeutic use' or 'for research only' are insufficient to deter or prevent misuse of the substance. Similarly, the potential for abuse of

[11] www.sportintegrity.gov.au/news/integrity-blog/2021-10/2022-prohibited-list-released

BPC-157 by athletic and fitness consumer circles is evidenced by the WADA's decision to include BPC-157 on the prohibited list (S0) at all times, both during and outside of competition settings.

I have considered the 4 written public submissions received during the pre-meeting consultation period. Of these 4 written responses received, all were in full support of the delegate's proposal. Interested parties were also given the choice to select from options to indicate their support or opposition to the proposed amendment without providing a written component. Of these 18 responses were received, with 17 supportive and 1 partially supportive. These respondents did not provide reasons for their support and as a result, the extent of my consideration is limited to noting that the submissions were generally in favour of the scheduling proposal. I have proposed an implementation date of 1 June 2024 as there are no currently approved products containing BPC-157 in Australia.

Implementation date

1 June 2024

Interim decision in relation to glycopyrronium

Proposal

The applicant proposed to create an Appendix H entry for glycopyrronium to allow advertising of Schedule 3 glycopyrronium preparations. Glycopyrronium is currently listed in Schedule 4 of the Poisons Standard when in preparations for injections, and Schedule 3 for all other preparations. The proposal aims to allow advertising of a topical glycopyrronium preparation which would be classified as a Schedule 3 medicine under the current scheduling.

Interim decision

A Delegate of the Secretary[12] has made an interim decision to amend the current Poisons Standard in relation to glycopyrronium as follows as follows:[13]

Schedule 4 – Amend Entry

GLYCOPYRRONIUM ~~in preparations for injection~~.

Schedule 3 – Delete Entry

~~GLYCOPYRRONIUM except when included in Schedule 4.~~

Index – Amend Entry

GLYCOPYRRONIUM

Schedule 4
~~Schedule 3~~

The Delegate's interim decision differs from the applicant's proposal and the detailed reasons for the decision follow.

[12] Pursuant to regulation 42ZCZN of the Regulations.
[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 interim decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to glycopyrronium (the **Application**).
- The 28 public submissions, with 6 including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**).
- The advice received from the 43rd meeting of the Advisory Committee on Medicines Scheduling (the **Committee**).
- Subsection 52E(1) of the Act, in particular (a) 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 that the Secretary considers necessary to protect public health.
- The Therapeutic Guidelines.
- Guidelines for advertisements for medicines containing Schedule 3 medicines.
- The Australian Register of Therapeutic Goods (ARTG).
- The SPF, and
- The Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that the Poisons Standard be amended in relation to glycopyrronium as set out in my interim decision.

The Committee also recommended an implementation date of **1 June 2024**. As there are no registered products affected by the scheduling change, the Committee saw no reason to delay the implementation of the amendment to the Poisons Standard.

The Committee agreed on the relevant matters under subsection 52E(1) of the Act, and provided the following reasons for the advice:

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

Risks:

- Risk of systemic anti-cholinergic effects and misdiagnosis of endocrine diseases if not adequately assessed.
- Risk of hyperthermia (overheating) from inappropriate use or without medical guidance.

Benefits:

- A topical product of glycopyrronium provides less interventional treatment than oral or injectable dosage forms.
- Treatment for hyperhidrosis would increase quality of life for patients.

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

- Glycopyrronium is indicated for the treatment of primary axillary hyperhidrosis.

c) *the toxicity of a substance*

- Glycopyrronium is well tolerated topically. Oral absorption is variable and toxicity at doses available in topical forms would be low.
- Anticholinergic side effects can be experienced. Adverse effects can include affected eyesight and altered muscle movement which increases risk of accidents and/or misadventure.
- Gastric slowing associated with use of the substance increases the risk of bowel obstruction.
- The use of glycopyrronium in high temperature environments to counter excessive sweating can result in overheating or heat stroke.

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

- The application proposes a cream containing glycopyrronium for topical application.
- All currently listed products on the ARTG, including preparations for injection and inhalation, are packaged as Schedule 4 prescription-only medicine.

e) *the potential for abuse of a substance*

- The substance is not psychoactive and does not have an identified abuse potential.

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

- Topical glycopyrronium is a prescription only medicine in several international jurisdictions, with no comparable Schedule 3 listing in any other country.
- There is some risk of inappropriate use in high-risk environments, for cosmetic reasons.
- Diagnosis is required by a medical practitioner, to rule out secondary causes of hyperhidrosis.
- The non-prescription availability and advertising of glycopyrronium may increase the risks associated with use of the substance.

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

I have made an interim decision to delete the Schedule 3 entry and amend the Schedule 4 entry for glycopyrronium such that all glycopyrronium preparations are captured in Schedule 4. The detailed reasons for my decision follow.

I agree with the Committee's findings on the relevant provisions of section 52E of the Act.

In relation to s 52E(1)(a) and (b) of the Act, glycopyrronium is an anti-muscarinic medicine approved for use for various conditions, including the management of chronic obstructive pulmonary disease (COPD), perioperative bradycardia, reduction of secretions, prevention of muscarinic adverse effects of neostigmine, and severe drooling in children with neurological conditions. I recognise the diagnosis and management of these conditions all require medical intervention. In addition, I note the topical preparation of glycopyrronium, as outlined in the Application, is intended for the management of primary axillary hyperhidrosis. Both the Application and the Therapeutic Guidelines indicate that the diagnosis of primary axillary hyperhidrosis should be confirmed by a medical practitioner, as hyperhidrosis can be secondary to many causes, such as medications or an underlying condition like endocrine or neurological conditions.

With regards to s 52E(1)(c) of the Act, the use of glycopyrronium is associated with anticholinergic side effects, such as dry mouth, constipation, urinary retention, bowel obstruction, blurred vision, increased heart rate, and decreased sweating. These effects could be exacerbated when glycopyrronium is used in high temperature environments, which may also result in overheating or heat stroke. Further, concurrent use with other medicines with anticholinergic effects, such as sedating antihistamines, antipsychotics, and antidepressants may also increase the risks of these side effects.

I have considered the 6 written public submissions received during the pre-meeting consultation period, 4 were fully supportive, 1 was partially supportive, and 1 was opposed to the Proposal. In particular, I note the Pharmacy Guild and the Pharmaceutical Society of Australia both suggested that the proposed Appendix H entry be limited to 'topical preparation' to prevent the advertising of other preparations of glycopyrronium, such as inhalers, which may not be suitable for advertising. I also acknowledge the concerns expressed in the submission and by the Committee, noting that serious adverse events associated with the use of topical glycopyrronium preparations at therapeutic doses were reported.

I acknowledge that non-prescription availability and advertising of Schedule 3 preparations of glycopyrronium may increase consumer awareness of available treatment options and encourage them to seek medical advice. However, as pointed out by the Committee, such availability may promote self-diagnosis and inappropriate use of glycopyrronium, which may mask symptoms, delay the diagnosis and treatment of underlying conditions, and lead to serious health outcomes. Having considered the matters set out in the Guidelines for advertisements for medicines containing Schedule 3 medicines, I am of the view that there is potential for inappropriate use that may be exacerbated by advertising, and there are potential interactions with other medicines that require increased patient education to ensure safe use of this substance. Aligned with the Committee's advice, I am of the opinion that glycopyrronium is not suitable for advertising, and this substance should not be included in Appendix H, clause 1.

I have also considered the current scheduling of glycopyrronium in the Poisons Standard and whether it remains appropriate. I note that, under s 52E(1)(d) and (f) of the Act, at present all glycopyrronium-containing medicines on the Australian Register of Therapeutic Goods (ARTG) are classified as Schedule 4 (Prescription Only) medicines. Of note, Seebri Breezehaler®, a glycopyrronium inhaler used for the management of COPD, is registered as a Schedule 4 medicine despite its use aligning with many of the Schedule 3 factors, highlighting the need for medical oversight associated with the use of this substance and the ongoing management of such conditions. I also recognise that a topical preparation of glycopyrronium has not been evaluated by the TGA and such a preparation has never been available in Australia. I find that there is insufficient data and local experience at present to support the suitability and safety for this preparation to be used without medical oversight.

In addition, the Schedule 3 entry for glycopyrronium was made as part of the Trans-Tasman Harmonisation of Scheduling of Drug and Poisons in 1999, and it does not appear that significant assessment in terms of safety was undertaken at the time. New Zealand's regulation over glycopyrronium was tightened in July 2013, which is now only available with a prescription. Other international jurisdictions such as the United Kingdom, United States, Ireland, Austria, and Finland also classify glycopyrronium, including topical preparations, as prescription only medicines.

Taking these matters into consideration, in particular, that all uses of glycopyrronium require medical intervention, and at present there is insufficient data and experience to support the safe use of topical glycopyrronium preparations without medical oversight, I am not satisfied that glycopyrronium meets the factors for Schedule 3 as set out in the SPF. I am of the view that

Schedule 4 is the most appropriate Schedule for this substance as it aligns with the factors for prescription medicines (Schedule 4, factor 1, 2 and 4). In agreement with the Committee's advice, I have decided to remove the Schedule 3 entry for glycopyrronium such that all glycopyrronium preparations are captured in Schedule 4 of the Poisons Standard.

I have decided on an implementation date of 1 June 2024. As there are no Schedule 3 glycopyrronium products currently marketed in Australia, no products would be affected by the changes to the scheduling of glycopyrronium and this decision will not impact consumers in accessing existing glycopyrronium medicines.

Implementation date

1 June 2024

Interim decision in relation to methenamine

Proposal

The applicant proposed to create a 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.

Interim decision

A Delegate of the Secretary[14] has made an interim decision to amend the current Poisons Standard in relation to methenamine as follows as follows:[15]

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

Schedule 5
Schedule 3
Appendix H, clause 1

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

Item	Poison
27a	METHENAMINE

[14] Pursuant to regulation 42ZCZN of the Regulations.
[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.

The Delegate's interim decision differs from the applicant's proposal and the detailed reasons for the decision follow.

Materials considered

In making this interim 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, with 5 including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**).
- The advice received from the 43rd meeting of the Advisory Committee on Medicines Scheduling (the **Committee**).
- Subsection 52E(1) of the Act, in particular (a) 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 that the Secretary considers necessary to protect public health.
- Guidelines for advertisements for medicines containing Schedule 3 substances.
- The Therapeutic Guidelines.
- The SPF, and
- The Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that the Poisons Standard be amended in relation to methenamine as set out in my interim decision.

The Committee recommended an implementation date of **1 October 2024** to give industry adequate time to make necessary changes to product labelling and supply chains.

The Committee agreed on the relevant matters under subsection 52E(1) of the Act, and provided the following reasons for the advice:

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

Risks:

- Long term use of methenamine may be associated with long-term formaldehyde exposure, the risks of which are unquantified (localised bladder risk).
- Gastrointestinal and skin irritation have been identified as rare adverse effects of methenamine intake.

Benefits:

- Methenamine is a low-risk treatment to suppress urinary tract bacteria. There is low-quality evidence suggesting that methenamine may also prevent recurrent urinary tract infections (UTIs).
- Methenamine provides an alternative to antibiotics for the suppression and elimination of urinary tract bacteria (reduction of reliance on antibiotics).

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

- Methenamine is currently an unscheduled medicine available from pharmacies for the prevention and suppression of UTIs.

c) the toxicity of a substance

- There is low risk of toxicity associated with methenamine intake.

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

- Currently unscheduled for therapeutic use and available in tablets of varying pack size.

e) the potential for abuse of a substance

- Low risk of misuse.

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

- New Zealand Medsafe's made a recent decision to reclassify methenamine as a 'restricted medicine' as of December 2023, which is equivalent to a Schedule 3 pharmacist-only classification in Australia.
- The condition being treated requires medical diagnosis and treatment recommendations, and there is a risk of masking underlying conditions. Discussion with a pharmacist is considered necessary before ongoing therapy can be safely supplied without a prescription.
- There is a significant risk of consumers purchasing for inappropriate indications if the substance remains unscheduled and health professional advice is not readily available at the point of sale.
- Methenamine has been widely available in pharmacies, for many years. There have been recent attempts to sell in non-pharmacy environments.
- No reason was identified to exclude from Appendix H entry (product has been advertised for many years).

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

I have made an interim decision to create a new Schedule 3 entry for methenamine for therapeutic use, and include methenamine in Appendix H, clause 1 to permit advertising of this substance.

I agree with the Committee's findings on the relevant provisions of section 52E of the Act.

Methenamine for therapeutic use is currently unscheduled and such methenamine products have been commercially available for 50 years in Australia. In relation to s 52E(1)(a) and (b) of the Act, methenamine is a medicine used for the prevention of recurrent urinary tract infections (UTIs), which the diagnosis requires medical intervention to identify any possible underlying conditions. I note that methenamine is a low-risk alternative to antibiotics for the suppression and elimination of urinary tract bacteria, which reduces the community's reliance on antibiotics and the risk of organisms developing resistance to antibiotics.

With respect to s 52(E)(1)(c) of the Act, while I recognise methenamine has a well-established safety profile, methenamine is not suitable for use for every patient, such as those affected by gout, liver diseases or kidney diseases. Therefore, patients should be assessed by a medical practitioner to determine whether this medicine is suitable for them before use. I note that following an initial medical diagnosis and recommendation from a medical practitioner, methenamine can be used by

patients without close medical management and side effects are generally limited to gastrointestinal side effects such as nausea and upset stomach, as well as skin irritation such as rash.

Despite methenamine's longstanding unscheduled classification, methenamine was only available for sale in pharmacies, and majority of the purchases were results of recommendation from a healthcare professional. However, recent evidence indicates that access to methenamine products has been extended, and these products can now be purchased outside pharmacies. I acknowledge the applicant's concerns regarding the lack of access to healthcare professional for consultation in these settings. There are potential risks of consumers mistaking methenamine for the treatment of active UTIs or other inappropriate indications. Further, methenamine also interacts with certain medicines, notably urinary alkalinisers used for the symptomatic relief of UTIs, which can also be purchased in grocery stores and supermarkets.

Based on these concerns, I agree with the Committee that the availability of methenamine outside of pharmacy settings poses a public health risk. The current unrestricted access is associated with risks of inappropriate use of methenamine, as well as risks of self-diagnosis, which may result in the masking of symptoms or causing a delay in the diagnosis and treatment of a potentially more serious condition. As such, I am of the view that access to a pharmacist at the point of sale is required to better assist consumers in selecting the most appropriate medicines and support the safe use of medicines.

I have considered the SPF criteria for Schedule 2 and Schedule 3 as set out in the SPF to determine the most relevant schedule for methenamine. Based on the matters set out above, I am of the opinion that methenamine best fits the scheduling factors for Schedule 3 and does not meet the SPF criteria for Schedule 2 (factor 1, 2, and 5).

I have considered the 25 public submissions received during the pre-meeting consultation period. The 5 written responses received were fully supportive of the Proposal. Of the submissions received without a written component, 19 were supportive and 1 was partially supportive of the Proposal. In further support of my decision, I note the submission that states data regarding calls received in relation to methenamine therapeutic error. I am of the view that an interaction with a pharmacist at the point of sale may help reduce therapeutic errors and mitigate these risks.

In considering s 52E(1)(d) and (f) of the Act, I note this decision will cause minimal inconvenience to consumers who are using methenamine for ongoing treatment. There are currently two methenamine products, Hiprex® and Uramet®, where the larger pack size (100 tablet bottle) are subsidised by the Pharmaceutical Benefits Scheme (PBS), and consumers who are using methenamine for ongoing treatment typically access this medicine via prescription with PBS subsidisation. Therefore, the access to methenamine for these consumers will remain unchanged, and a Schedule 3 classification will allow them to continue to access methenamine if they were unable to obtain a prescription in a timely manner.

With regards to international regulation of methenamine, I note the United Kingdom and the United States classify methenamine as a prescription only medicine, and New Zealand has made a recent decision to reclassify methenamine as a 'restricted medicine', which is equivalent to Schedule 3 (Pharmacist only) in Australia. As such, this decision to classify methenamine as a Schedule 3 medicine will bring Australia's regulation on methenamine more in line with these international jurisdictions.

I have also considered whether methenamine is suitable for advertising, noting that methenamine products have been advertised for many years. Having considered the matters set out in the Guidelines for advertisements for medicines containing Schedule 3 substances and reviewing the relevant websites, I find that there is low potential of inappropriate use of this substance that may be

exacerbated by advertising. Considering that methenamine has a long history of safe use in Australia, I am of the view that the potential impact of the advertising of methenamine on public health is low. I agree with the Committee that methenamine should be included in Appendix H, clause 1 to permit advertising of this substance.

After consideration of the information provided in the application, the public submissions, advice provided by the Committee and the SPF factors, I have made an interim decision to create a new Schedule 3 entry for methenamine, and the inclusion of methenamine in Appendix H, clause 1, with an implementation date of 1 October 2024 to allow industry sufficient time to implement packaging changes in response to the decision.

Implementation date

1 October 2024

Interim decision in relation to naratriptan

Proposal

The applicant has proposed to create 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.

Interim decision

A Delegate of the Secretary[16] has made an interim decision to amend the current Poisons Standard in relation to naratriptan as follows as follows:[17]

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 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

[16] Pursuant to regulation 42ZCZN of the Regulations.

[17] 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 H – New Entry - Schedule 3 medicines permitted to be advertised.

Item	Poison
30a	NARATRIPTAN

Materials considered

In making this interim 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, with 4 including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**).
- The advice received from the 43rd meeting of the Advisory Committee on Medicines Scheduling (the **Committee**).
- Subsection 52E(1) of the Act, in particular (a) 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 that the Secretary considers necessary to protect public health.
- The Therapeutic Guidelines.
- The Migraine in Australia Whitepaper, Deloitte Access Economics Report, 2018.
- The Database of Adverse Event Notifications (DAEN) for medicines.
- Guidelines for advertisements for medicines containing Schedule 3 substances.
- The SPF, and
- The Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that the Poisons Standard be amended in relation to naratriptan as set out in my interim decision.

The Committee also recommended an implementation date of **1 June 2024**. Due to the absence of registered products that would be affected by the scheduling change, the Committee saw no reason to delay the implementation of the amendment.

The Committee agreed on the relevant matters under subsection 52E(1) of the Act, and provided the following reasons for the advice:

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

Risks:

- The potential for interaction potential for interaction with selective serotonin reuptake inhibitors (SSRIs) may lead to serotonin toxicity.
- The risk of medication overuse headache (MOH) with excessive use, which can require complex treatment.

Benefits:

- Naratriptan is effective for providing migraine relief at 2 and 4 hours and sustained relief over 24 hours.
- Migraine is considered debilitating and the use of triptans could reduce workforce losses and reduced productivity.
- The use of triptans to treat migraine may reduce use and misuse of other simple analgesics. Facilitating access may also lead to a reduction in costs and burden of medical appointments for patients.
- Naratriptan provides an alternative OTC option for relief from migraines.

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

- For the acute relief of migraine in patients who have a stable, well-established pattern of symptoms.
- Migraine affects approximately 12-20% of women and 6% of men.

c) the toxicity of a substance

- Naratriptan is well-tolerated, with few reports of adverse events where naratriptan was an involved substance.
- Between July 2013 and July 2023, there were 4 reports of adverse events where naratriptan was an involved substance, and no reports where naratriptan was the sole suspected medicine.
- The safety profile is well-established and consistent with post-marketing experience. Compared to placebo, 2.5 mg naratriptan demonstrates no increased risk of causing nausea, vomiting, dizziness, malaise, chest pain or tightness.

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

- The application involves packs of 2 oral tablets to be available over the counter. Schedule 4 packs are also available in packs of 2, 4 and 6 tablets.

e) the potential for abuse of a substance

- The overall risk of abuse for all triptans is low. There is minimal risk of a major adverse effect or death following intentional self-ingestion of a triptan.

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

- The proposal aims to align a Schedule 3 entry for naratriptan with other substances in the class, including eletriptan, sumatriptan, rizatriptan and zolmitriptan.
- Headaches are a common symptom of many medical conditions and there is a risk of misdiagnosis associated with the over-the-counter availability of triptans.

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

I have made an interim decision to amend the current Poisons Standard in relation to naratriptan to create a new Schedule 3 entry 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. This would align the scheduling of naratriptan with other substances in the triptan class, including sumatriptan, zolmitriptan, eletriptan and rizatriptan.

I agree with the Committee's findings on the relevant provisions of section 52E of the Act. I have considered the 26 public submissions received with 24 in support and 2 in partial support. The written submissions in support of the down scheduling of naratriptan, highlighted its tolerability, comparable effectiveness to sumatriptan, and pharmacists able to ensure the appropriate use of the medicine. The concerns raised in the submissions, included access to naratriptan without a formal diagnosis of migraine, and the potential for risks associated with drug interactions.

In relation to s 52E(a) of the Act, I find naratriptan to be an effective and well-tolerated medication for acute migraine relief, comparable to other triptans in Schedule 3. Migraines are a debilitating condition and cause significant socioeconomic burden, including significant wellbeing costs on sufferers.[18] Prompt treatment of migraine with naratriptan can reduce the risk of worsening and prolonged symptoms. Having naratriptan available over-the-counter (OTC) in Schedule 3 (Pharmacist Only Medicine) would offer an alternative option that may be better tolerated than other triptans for some individuals and can help reduce the inappropriate use of simple analgesics.[19] I note there have only been 4 case reports involving naratriptan in the last 10 years on the Database of Adverse Event Notifications (DAEN) for medicines.

However, I recognise there are several risks associated with the use of naratriptan. Consistent with scheduling factor 1 for Schedule 3 in the SPF, naratriptan may mask symptoms, or delay diagnosis, of a more serious condition. In addition, excessive use of naratriptan has the potential to cause medication overuse headaches (MOH).

In turning my mind to the remaining scheduling factors for Schedule 3 in the SPF, I consider the adverse effects, interactions, and contraindications to be known, identifiable and manageable by a pharmacist. By narrowing the indication to the acute relief of migraine in patients who have a stable, well-established pattern of symptoms in the new Schedule 3 (Pharmacist Only Medicine) entry, along with the limit on pack size, I am satisfied down scheduling naratriptan will provide outweighing benefit with minimal risk of misuse.

Having considered the existing availability of other triptans in Schedule 3 (Pharmacist Only Medicine) that are able to be advertised, I am of the view it is also appropriate to include naratriptan in Appendix H. This would provide greater opportunity for those prescribed naratriptan to be made aware of it being newly accessible as a Schedule 3 (Pharmacist Only Medicine).

Implementation date

1 June 2024

[18] headacheaustralia.org.au/what-is-headache/prevalence-and-cost-of-headache/#:~:text=4.9%20million%20people%20in%20Australia,86%25%20are%20of%20working%20age.
[19] www.tg.org.au/

Interim 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
- 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.

Interim decision

A Delegate of the Secretary[20] has made an interim decision to not make any amendments to the Poisons Standard in relation to paracetamol (including the version that is set to be in force on 1 February 2025).

The Delegate's interim decision differs from the applicant's proposal and the detailed reasons for the decision follow.

Materials considered

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

- The application to amend the current Poisons Standard with respect to paracetamol (the **Application**).

[20] Pursuant to regulation 42ZCZN of the Regulations.

- The 45 public submissions, with 16 including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**).
- The advice received from the 43rd meeting of the Advisory Committee on Medicines Scheduling (the **Committee**).
- Subsection 52E(1) of the Act, in particular (a) 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 that the Secretary considers necessary to protect public health.
- A journal article on paracetamol overdose as cited in the reasons below.
- The final decision to amend the Poisons Standard in relation to paracetamol published in May 2023 (the 2023 Decision).
- The SPF, and
- The Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that no change be made to the current Poisons Standard or anticipated scheduling changes for PARACETAMOL, due to come into effect in February 2025, as those changes remain appropriate.

The Committee agreed on the relevant matters under subsection 52E(1) of the Act, and provided the following reasons for the advice:

a) *the risks and benefits of the use of a substance*
   - The risks and benefits of the use of paracetamol in humans are well established.

b) the purposes for which a substance is to be used and the extent of use of a substance
   - Paracetamol is widely used as a simple analgesic.
   - Effervescent paracetamol products in blister packaging are already available.

c) the toxicity of a substance
   - Paracetamol can cause severe liver toxicity in adults in excess doses and has been fatal in children and adolescents.

d) the dosage, formulation, labelling, packaging and presentation of a substance
   - The absence of blister or strip packaging increases the risk of larger doses being taken in deliberate self-harm by adults and adolescents, and inadvertent poisoning in children.
   - Under the proposal, effervescent tablets would not have individual wrapping; instead, the packaging will be tablets enclosed in a tube with a child-resistant closure.
   - There is no established evidence that a child-resistant closure would prevent or reduce the incidence of associated self-harm.
   - The deterrent against self-harm of individual packaging is not present with a child-resistant closure as it is for blister strip packaging.

e) the potential for abuse of a substance

- Paracetamol has low potential for abuse with regards to psychoactive effects. However, there is considerable evidence of non-medical use in the context of intentional self-poisoning.

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

- The proposed benefit of the new packaging requirements to be introduced for paracetamol in 2025 is to reduce ingestion of paracetamol in an impulsive overdose.
- Effervescent paracetamol products that are compliant with the February 2025 scheduling changes are already available.

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

I agree with the Committee's findings on the relevant provision of section 52E of the Act.

I have considered the 45 public submissions received during the pre-meeting consultation period. Of the 16 written public submissions, half supported the proposal, and the other half did not support the proposal. Organisations that provided a written response were not in support of the proposal, citing evidence that blister or strip packaging reduces the amount of paracetamol taken in cases of intentional overdose. Responses received in support of the proposal were brief responses highlighting paracetamol to be safe and effective. They also noted effervescent paracetamol tablets offer an alternative for individuals who cannot take tablets or capsules.

In making my decision, I have weighed the benefits of effervescent paracetamol use against its toxicity and risks from abuse, in accordance with paragraphs 52E(1)(a), (c) and (d) of the Act. The key factor in my decision is balancing the need to provide access to paracetamol, acknowledging its benefits as a widely used and effective analgesic and antipyretic, with the need to address the risks of harm and death from its use in intentional overdose.

I recognise the concerns raised in the submissions, and by the applicant, in relation to the unique benefits of effervescent paracetamol preparations for those that have difficulty with, or cannot take, tablets or capsules. However, in considering the written submissions, I can clarify that the version of the Poisons Standard that is set to come into effect 1 February 2025 would still permit effervescent paracetamol to be available on self-selection sale and as Schedule 2 (Pharmacy Only Medicine), provided it is supplied in blister or strip packaging. Therefore, individuals seeking the unique advantages of effervescent tablets can still obtain them as a Pharmacy Only Medicine (Schedule 2).

In turning my mind to 52E(a) and (d) of the Act, I have assessed the risks associated with effervescent tablets in a child resistant closure compared to blister or strip packaging in relation to intentional paracetamol overdose. I give significant weight to the implementation of paracetamol blister packs in the United Kingdom (UK), following which there was a 21% reduction in all paracetamol overdoses and a 64% reduction in severe overdoses.[21] The applicant did not provide evidence to support child-resistant closures as a means of harm minimisation for adolescents and adults that impulsively, and intentionally, overdose on paracetamol. I note Consumer Healthcare Products (CHP) Australia and the Pharmacy Guild of Australia (PGA) did not support a child-resistant-closure as an adequate mechanism against intentional paracetamol overdose. In the absence of compelling evidence demonstrating that child-resistant closures are as effective as blister or strip packaging in reducing overdose sizes among adolescents and adults, I am of the view there are higher risks associated with paracetamol in child-resistant closures that should be subject to tighter access controls.

[21] www.sciencedirect.com/science/article/pii/S0140673600023552

The applicant compared effervescent paracetamol tablets to powders and sachets of granules. However, it is an ongoing requirement for powders or sachets of granules that are made available on General Sale to be individually wrapped, a time consuming form of packaging when used in intentional overdose that is comparable to blister or strip packaging. This is distinct from a child resistant closure where, once the cap is removed, contents can be removed rapidly. I am therefore satisfied that the 2023 decision remains appropriate.

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

Interim 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.

Interim decision

A Delegate of the Secretary[22] has made an interim decision to amend the current Poisons Standard in relation to animal blood products as follows as follows:[23]

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.

[22] Pursuant to regulation 42ZCZN of the Regulations.

[23] 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

The Delegate's interim decision varies from the applicant's proposal and the detailed reasons for the decision follow.

Materials considered

In making this interim 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, with 6 including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**);
- The advice received from the 37th meeting of the Advisory Committee on Chemicals Scheduling (the **Committee**);
- Subsection 52E(1) of the Act, in particular (a) 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; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health.
- The SPF, and
- The Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that animal blood products be entered in Schedule 4 in the Poisons Standard as set out in my interim decision.

The Committee also recommended an implementation date of **1 October 2024**, to allow industry sufficient time to implement the required changes in response to the decision.

The Committee agreed on the relevant matters under subsection 52E(1) of the Act, and provided the following reasons for the advice:

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

Risks:

– Individual blood products may present risk to human health if misused but the risk of infectious disease can be made safe in manufacture.

Benefits:

– Blood products increasingly support the treatment of surgical procedures, ailments and injuries in non-human animals.

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

– Veterinary use in transfusions in other non-human animals to support the treatment of surgical procedures following various ailments and injuries such as snake bites,

anaemia, cancers, bleeding disorders, after a traumatic accident, and other medical conditions or diseases.

- These products are currently extracted in private veterinary practices and used in-house for other animals.
- There are a small number of unscheduled commercial products registered with APVMA and available for purchase.
- Indications for use of animal blood products require veterinary oversight.

c) the toxicity of a substance

- Not relevant.

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

- These facets can vary significantly; the products are currently extracted in private veterinary practices and used in-house for other animals.
- Commercial products registered with APVMA include canine erythrocytes (>350 mL bag), canine plasma (100 mL or 200 mL bag) and equine gamma globulins (1,000 mL bag).
- Internationally, animal blood products include: Oxyglobin (bovine haemoglobin glutamer-200) and Oxapex (bovine haemoglobin betafumaril), both of which are commercially available in Europe.

e) the potential for abuse of a substance

- The potential abuse would be very limited with veterinary use.
- There may be some risk of misuse in animal racing industries. However, these would likely be more attributable to breaches of professional practice standards rather than scheduling.

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

- There are at least 7 products currently registered with the APVMA and listed on PubCRIS as unscheduled products, including canine plasma and erythrocytes and equine gamma globulins.
- Inclusion of haemoglobin as an amendment to the APVMA submission is to be considered, for example, "... (b) Blood components including red cells, white cells, platelets, plasma (including cryoprecipitate) and haemoglobin (including its derivatives); and...", and to include 'blood-derived therapeutic proteins' instead of just 'plasma–derived therapeutic proteins'.
- Human blood products are included in Appendix A solely due to the controls implemented by the National Blood Authority. While the quality of animal blood products is regulated by the APVMA, there are presently no controls on access to these products.
- Consideration should be given to how any new scheduling entries for animal blood products may interact or overlap with existing entries, e.g., immunoglobulins.

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

I have made the decision to amend the Poisons Standard by creating a Schedule 4 entry for animal blood products for veterinary use. I agree with the Committee's findings on the relevant provisions of section 52E of the Act. I am of the opinion that the need for veterinary oversight to reduce risks to users and animal welfare, in particular the risks of product contamination and transmission of zoonotic diseases to humans, justifies implementing Schedule 4 access restrictions.

In consideration of s 52E(1)(a) of the Act, I am of the opinion that the risk of zoonotic disease transmission to humans by animal blood products and the potential for contamination supports the need for access restrictions consistent with Schedule 4. I agree with the Committee that the creation of a Schedule 4 entry for animal blood products would allow for controls over the supply, manufacture and usage of the products. In turn this would reduce the risks to animal welfare and improper handling when used outside of veterinary practices. I similarly agree with the Committee that animal blood products are increasingly being used in the treatment of ailments and injuries in animals, and to support surgical procedures. However, I am also of the opinion that the risk of disease transmission is largely posed by whole blood products, and this risk is often mitigated during product manufacturing and by regular screening of the donor animal prior to donation. Further, I note that these procedures are not easily performed without adequate training, and indications requiring treatment with animal blood products would require veterinary diagnosis. With respect to the SPF factors, it is my view that animal blood products strongly align with the considerations of Schedule 4 as the diagnosis, management or monitoring of the medical conditions are such that it requires veterinary intervention before the substance is used.

In considering s 52E(1)(b) of the Act, animal blood products are used in veterinary transfusions in non-human animals to support the treatment of surgical procedures. The current indications for use of animal blood products requires veterinary oversight, and blood products are often extracted from animal donors in-house. Manufacturing of these products is largely focused on plasma elements of animal blood products which are unlikely to pose a risk of disease transmission to humans. I note there are a small number of unscheduled commercial products registered with the APVMA that are available for purchase. I agree with the Committee that due to the increase in importance of companion animals to the public, there is likely a growing demand for animal blood products required in life-saving procedures.

The Committee noted, with respect to s 52E(1)(d) that the packaging, labelling and the presentation of animal blood products are likely to vary significantly given these products are largely extracted in private veterinary practices and used in-house. Further, commercially available products that are registered with the APVMA include canine erythrocytes (>350 mL bag), canine plasma (100 mL or 200 mL bag) and equine gamma globulins (1,000 mL bag). I note that several animal blood products are available internationally, including for example Oxyglobin (bovine haemoglobin glutamer-200) and Oxapex (bovine haemoglobin betafumaril).

I note that Committee raised concerns regarding reports of overseas veterinarians using human blood protein products in animal patients due to not having access to alternative veterinary products. I agree with the Committee, that while there is no evidence of this occurring within Australia, increased access restrictions would mitigate this risk. I note that while the Committee raised concerns regarding the risk of misuse of animal blood products within animal racing industries, I disagree that scheduling is the most appropriate mechanism to address this. I am of the view that such misuse would be more attributable to breaches of professional practice standards rather than scheduling. In consideration of s 52E(1)(e) of the Act, I am of the opinion that animal blood products have a moderate propensity for misuse, abuse or illicit use and that control of access to the therapy veterinary practitioner is required to minimise this risk.

With respect to s 52E(1)(f) of the Act, I note that in Australia there are currently 7 products registered with the veterinary medicines regulator (APVMA) and the number of registered products is expected to increase, with the prevalence of veterinary transfusion medicine steadily following that of human transfusion medicine. While not specified by the applicant, I agree with a written submission received during public consultation, and the Committee, that haemoglobin (including its derivatives) be included as part of the proposed scheduling given animal haemoglobin products are currently available internationally. I also agree with the Committee that while the quality of animal blood products is regulated by the APVMA, there are presently no controls on access to these products. In considering the SPF factors, I am of the opinion that without access controls for use of animal blood products the risk of zoonotic disease transmissions to humans or contamination is such that animal blood products requires specialised handling for administration.

I would emphasise that the proposed scheduling change will not affect the ability of veterinarians to access and prepare their own animal whole blood and blood products for in-house emergency use. For these provisions, the Australian Veterinary Association (AVA) provides veterinarians guidance[24] regarding in-house use of companion animal blood products.

I have considered the 6 written public submissions received during the pre-meeting consultation period; 5 written responses received were fully supportive of the applicant's proposal and 1 partially supportive. Interested parties were also given the choice to select from options to indicate their support or opposition to the proposed amendment without providing a written component. A total of 14 responses were received, with 13 supportive and 1 opposed. These respondents did not provide reasons for their support or opposition and as a result, the extent of my consideration is limited to noting that the submissions were generally in favour of the scheduling proposal. In consideration of the commercial products currently available in Australia, I propose an implementation date of 1 October 2024 to allow industry time to implement the required changes.

Implementation date

1 October 2024

Interim 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.

Interim decision

A Delegate of the Secretary[25] has in relation to the proposed amendment, made an interim decision to not amend the current Poisons Standard in relation to bile acids.

[24] www.ava.com.au/policy-advocacy/policies/companion-animals-health/provision-of-blood-supplies-for-use-in-dogs-and-cats/

[25] Pursuant to regulation 42ZCZN of the Regulations.

Materials considered

In making this interim 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, with 2 including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**).
- The advice received from the 37th meeting of the Advisory Committee on Chemicals Scheduling (the **Committee**).
- Subsection 52E(1) of the Act, in particular (a) 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 that the Secretary considers necessary to protect public health.
- The SPF, and
- The Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that the current Poisons Standard entry for bile acids remains appropriate.

The Committee agreed on the relevant matters under subsection 52E(1) of the Act, and provided the following reasons for the advice:

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

Risks:

- The potential for the interaction of exogenous bile acids administered in feed with other medications. This applies particularly to antibiotics administered to pigs, poultry and aquaculture species, and coccidiostats and ionophores administered to poultry and pigs.
- Inadvertent human exposure to exogenous bile acids during consumption of animal liver products may occur. However, consumer exposure should be negligible as they will be only available as a component of animal food.
- Work Health and Safety considerations for farmers and others involved with preparing and distributing the feed additives. Concentrated bile acids pose the risk of causing human eye and respiratory irritation.
- Risk of inappropriate use in companion animals.

Benefits:

- Bile acids increase the efficiency of production in pigs, poultry and aquaculture (for example, faster growth and antibacterial properties). They also improve heat tolerance, with improved growth rates and reduced morbidity in poultry.

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

- The proposed amendment to the Poisons Standard would enable use of bile acids, from any source, as a feed additive or premix to be fed to any animal species.

c) the toxicity of a substance

- Toxicity data provided by the applicant was limited in scope and not specific to each bile acid.
- Acute oral toxicity may be higher in animals undergoing concurrent drug treatment and feeding with bile acid fortified feedstocks.
- Bile acids can be harmful if swallowed, cause serious eye irritation, cause skin irritation and may cause respiratory irritation in cases of human exposure.

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

- Feed concentration of bile acids varies between animal species (for example, 200 mg/kg for poultry and 350 mg/kg for pigs).
- Dosage in feedstocks varies with rate of feeding and composition of bile acids in the feed.
- Bile acid feed additives are available in 20 kg bags and are presented in the form of solid pellets for mixing with animal feed.

e) the potential for abuse of a substance

- Potential for feeding to ruminants, or ruminants accessing bile acid amended feed, deliberately or accidentally, is high, particularly where pigs and poultry are produced on the same property.
- Manufacturers may incorporate bile acids from mammal sources, particularly if supply of avian sourced material is limited, resulting in breaches of Australian swill feeding legislation and a potentially significant biosecurity risk.
- Risk of diversion into the human food chain through consumption of livestock liver products.

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

- Exempting bile acids for use in animal feeds relies on APVMA regulation, which requires registration. However, APVMA may not be required to register these substances.
- Bile acids are currently sourced from the gallbladder of chickens, but could be sourced from ruminants, and potentially fed to ruminants which could be a risk for prion disease. Alternative sourcing of bile acids could also promote bear bile farming.
- The permit to import, issued by the Australian DAFF applies a condition that all packaging must be clearly labelled as "This product contains restricted animal material. DO NOT FEED TO CATTLE, SHEEP, GOATS, DEER OR OTHER RUMINANTS."
- If exempt from scheduling in the Poison Standard, and APVMA considers it meets END [excluded nutritional or digestive] product requirements, it will not require label statements regarding appropriate use, PPE requirements to reduce risk of exposure, and warning against pregnant women handling of the product.
- The proposed wording of the amendment would allow feeding of bile acids in feeds to all animals. Feeding to ruminants would breach the National Ruminant Feed ban, creating a significant biosecurity/disease risk.
- A safe exemptible cut-off cannot be determined based on the information available.

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

I have made the decision to not amend the Poisons Standard in relation to the current Schedule 4 entries for bile acids when used as an animal feed additive and in feed pre-mixes. I am of the opinion that the risk of enterohepatic accumulation of bile acids with: (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 agree with the Committee and the applicant that the benefits of exogenous bile acids in poultry, pig and aquaculture industries are well established. I note that bile acids have been shown to increase growth rates and boost antibacterial properties in these animals, as well as improving heat tolerance and reducing morbidity in poultry. However, I am of the opinion that the risks posed by bile acids in animal feeds outweigh these benefits. In consideration of s 52E(1)(a) of the Act, I agree with the Committee that the main risks posed by exogenous bile acids is two-fold. Firstly, the use of bile acids in animal feeds poses a risk of potential drug-drug and drug-food interactions; particularly with respect to antibiotics administered to pigs, poultry and aquaculture, and coccidiostats and ionophores administered in pigs and poultry. Some of these products, such as ionophores, have narrow margins of safety and the applicant did not provide sufficient evidence that the risk of bile acids interacting with other drugs was mitigated. Further, I note that exogenous bile acids could significantly affect the absorption and metabolism of many chemical substances, including natural products and xenobiotics in animals.

Secondly, I agree with the Committee that while human exposure to these bile acids is minimal, as they are a component of animal feed, there remains a risk of human exposure to exogenous bile acids during consumption of animal liver products. I am of the opinion that that the applicant did not provide sufficient evidence that the risk of potential hepatic accumulation of exogenous bile acids in animals would not, in turn, pose an indirect risk to humans during consumption of liver products. I am also of the opinion that the applicant did not provide sufficient evidence that there is negligible risk of occupational exposure to bile acids concentrates prior to mixing in the animal feed. I note that the work health and safety considerations would include farmers and others involved with preparing and distributing the feed additives. Bile acid feed additive products would be available as concentrates that require mixing and distributing with animal feeds. Further, insufficient evidence has been provided that the risk of human exposure, with the potential to result in eye and respiratory irritation, is sufficiently low to justify exempting these substances from scheduling. In considering s 52E(1)(a) of the Act, I also note that exempting bile acids when used in animal feeds from scheduling would increase the risk of use in companion animal foods.

With respect to s 52E(1)(b) of the Act, the applicant has proposed usage of exogenous bile acids as animal feed additives or in feed premixes. I note the applicant's proposed scheduling did not specify that this would be restricted to pig, poultry and aquaculture feeds. As such, I am of the opinion that adopting the applicant's proposed scheduling would increase the risk of use of bile acids in the feedstocks for cattle, sheep, goats and other ruminants. Feeding of bile acids to ruminants would breach the National Ruminant Feed ban and create a significant biosecurity and animal disease risk.

I agree with the Committee that the toxicity data provided by the applicant was of limited scope and was not specific to each of the proposed bile acids. In considering s 52E(1)(c) of the Act, I note that these bile acids can cause skin and respiratory irritation and can cause serious eye irritation in cases of human exposure. While I do not consider the event of human consumption of bile acids to be likely, these substances have been shown to be harmful if swallowed. I also agree with the Committee that the acute oral toxicity of bile acids may be higher in animals that are undergoing concurrent drug treatment while being fed bile acid enriched feedstocks. As previously discussed, exogenous bile acids could significantly affect the absorption and metabolism of many substances

and have the potential to interact with other xenobiotics such as coccidiostats and ionophores administered in pigs and poultry. In considering the SPF factors, I am of the opinion that the bile acids in animal feed additives align closely with Schedule 4 as the seriousness or severity and frequency of the interactions of bile acids (medicine-medicine or medicine-food) are such that monitoring or intervention is required by a veterinary practitioner.

In considering s 52E(1)(d) of the Act, the applicant has specified that the feed concentration of bile acids varies between animal species, with the example of 200 mg/kg usage for poultry and 350 mg/kg for pigs. Similarly, the dosage of bile acids in feedstocks would vary by the rate of feeding and the composition of bile acids in the animal feeds. I note that bile acid feed additives are available as concentrates in 20 kg bags and are presented in the form of solid pellets for mixing with the animal feed.

In considering s 52E(1)(e) of the Act, I agree with the Committee that the risk of ruminants deliberately or accidentally feeding on bile acid enriched feedstocks is high, particularly in environments where ruminants and pigs, or poultry, are produced on the same property. As previously noted, this would breach the National Ruminant Feed ban and could also create a significant biosecurity and animal disease risk. Further, I agree with the Committee that retaining the Schedule 4 entries for bile acids is necessary to maintain product standards. I note that exempting bile acid usage in animal feeds has the potential to increase the risk of manufacturers incorporating bile acids from other mammalian sources, particularly if avian source material is limited. The use of alternative animal sources of bile acids, such as from mammals, would breach Australian swill feeding legislation and pose a potential biosecurity risk. I am also of the opinion that exempting bile acids in feed additives would increase the risk of diversion of exogenous bile acids into the human food chain through the consumption of livestock liver products.

I agree with the Committee that exempting bile acids for use in animal feeds would not impact APVMA regulations, including registration of these products. However, in considering s52E(1)(f) of the Act, I note that APVMA registration of products may not be necessary if such products met the requirements of an excluded nutritional or digestive (END) product. In this case labelling statements regarding use of Personal Protection Equipment (PPE), best practice to reduce risk of exposure, and warnings against handling by pregnant women would not be required. I also note that applicant's proposed scheduling would increase the availability of exogenous bile acids, and in turn may promote the unregulated alternative sourcing from unscrupulous practices such as bear bile farming.

I agree with the applicant and the Committee, that despite international usage of bile acids in animal feeds there are no current reports of adverse events or abuse of these products. However, as previously discussed, the proposed wording of the amendment would also allow use of bile acids in feeds for all animals, including ruminants, in breach National Ruminant Feed ban. I also note, in response to this concern, that the permit to import issued by the Australian DAFF applies a condition that all packaging must be clearly labelled as 'This product contains restricted animal material. DO NOT FEED TO CATTLE, SHEEP, GOATS, DEER OR OTHER RUMINANTS'. However, I am strongly of the opinion that scheduling remains a necessary mechanism in preventing misuse of these products. I note the Committee considered the potential merits in establishing an exemptible cut-off for bile acid feed additive products, but that there was insufficient evidence currently available to reasonably establish a safe cut-off.

I have considered the 2 written public submissions received during the pre-meeting consultation period; 2 written responses received were fully supportive of the applicant's proposal. Interested parties were also given the choice to select from options to indicate their support or opposition to the proposed amendment without providing a written component. A total of 15

non- written responses were received, with 14 supportive and 1 opposed. These respondents did not provide reasons for their support or opposition and as a result, the extent of my consideration is limited to noting that the submissions were generally in favour of the scheduling proposal. As my decision is to not amend the Schedule 4 entries for bile acids, an implementation date is not relevant for this decision.

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

Interim 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.

Interim decision

A Delegate of the Secretary[26] has made an interim decision to amend the current Poisons Standard in relation to adrenaline as follows:[27]

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

[26] Pursuant to regulation 42ZCZN of the Regulations.

[27] 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 interim 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, with 5 including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**).
- The advice received from the 35th meeting of the Advisory Committee on Medicines and Chemicals Scheduling in joint session (the **Committee**).
- Subsection 52E(1) of the Act, in particular (a) 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 that the Secretary considers necessary to protect public health.
- The SPF, and
- The Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that the Poisons Standard be amended in relation to adrenaline as outlined in the proposal.

The Committee also recommended an implementation date of **1 June 2024**.

The Committee agreed on the relevant matters under subsection 52E(1) of the Act, and provided the following reasons for the advice :

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

Risks:

- Risks of topical adrenaline as a substance are low. In combination with local anaesthetics for wound management, the risks may increase due to the nature of the condition being treated and the presence of local anaesthetic.
- The relevant clinical studies reported infrequent/no reported adverse events, with most being complications of the wound repair rather than true adverse events related to topical application of the substances.
- There are potential (theoretical) risks of inappropriate use in cosmetic procedures and for burns, abrasions, leg ulcers, dog bites, deep wounds and wounds where vasoconstriction might result in ischemia and, in extreme cases, skin necrosis.

Benefits:

- There is good historical evidence of efficacy. This product was developed at the request of clinicians.
- Adrenaline is a vasoconstrictor and reduces bleeding wound suturing/repair.

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

- Adrenaline, in combination with lidocaine, may be used to reduce bleeding and provide topical anaesthetic relief for cleaning, irrigation and debridement of painful minor wounds.
- In Australia, the sponsor has manufactured and supplied a topical local anaesthetic solution containing adrenaline since 2003 as an exempt therapeutic good. This product has been refined over the years and reformulated as a viscous application in 2020 which has been trialled at several hospitals.
- The product that is the subject of the application is to be used by medical and nursing staff in medical facilities.

c) the toxicity of a substance

- The use of adrenaline is contraindicated for wounds with end arteriolar supply due to vasoconstriction and the risk of ischemia, including ear pinnae, tip of the nose and penis.
- Adrenaline has low toxicity and is rated Category A in pregnancy.

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

- The product is a gel for topical application. It is presented as 4 mL of gel in a 7 mL single-use amber glass sealed vial with a flip off cap, ring pull metallic collar and siliconised rubber stopper, in a pack of 5 vials.
- The dosage for children is dependent on age and bodyweight, with children 1–3 years Maximum Recommended Dose (MRD) of 2 mL and children over 3 years MRD of 3 mL. In adults and adolescents, the recommended dosage is 0.5 mL/cm laceration to a maximum of 3 mL.
- The gel is for external use only, not for oral use.

e) the potential for abuse of a substance

- The potential for abuse is low, however, there are potential risks with inappropriate use and misuse with Schedule 3 availability.

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

- The product that is the subject of the application is for use in wound treatment. However, consideration should be given as to whether all topical preparations are to be included in the entry.

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

I agree with the Committee's findings on the relevant provisions of section 52E of the Act.

Adrenaline is a hormone that is used medicinally (under the synonym epinephrine) for the treatment of various conditions, including allergic anaphylaxis and cardiac arrest. This application to amend the Poisons Standard is associated with the use of adrenaline, in the form of a topical gel, for the treatment of wounds in humans. The substance's vasoconstrictive properties aid in the reduction of bleeding and facilitate healing.

The application to amend the Poisons Standard with regards to adrenaline included an external evaluation, commissioned by the TGA, of a new fixed-dose combination (FDC) product containing adrenaline co-formulated with topical anaesthetics. Such a product would be classified as a

Schedule 3 medicine under the current scheduling and be available without a prescription after consultation with a pharmacist. The evaluation cited concerns regarding the possible side-effects of the indiscriminate use of adrenaline for the treatment of wounds, suggesting that the use of the substance for this indication was instead more consistent with a Schedule 4 (prescription-only) classification.

In considering s 52E(1)(a) and (b) of the Act, I note that the prospective product containing adrenaline for topical use is intended to be used in medical facilities, indicating that the sponsor's assessment of proper use of the product includes a requirement for medical oversight. In addition, I am of the view that any wounds that are serious enough in nature to require the application of topical adrenaline should be treated with medical personnel in attendance. These considerations are consistent with the scheduling factors in the SPF for a Schedule 4 classification and are the primary drivers for my decision to amend the Poisons Standard with regards to adrenaline.

I note that adrenaline has a long history of safe and efficacious use in a medical setting and is regarded as being low in toxicity by all routes of administration. However, with regards to s 52E(1)(c) of the Act, the primary concern regarding the adverse effects of topical adrenaline is the contraindication for use on wounds with end arteriolar supply, such as the anatomical extremities. Use of topical adrenaline on these areas comes with a significant risk of ischemia and, in severe cases, necrosis, which is not compatible with the use of such a product by the consumer when not in the presence of a medical professional.

With regards to s 52E(1)(e) of the Act, and while acknowledging that there is very low potential for abuse of such products, I agree with the Committee's advice regarding the potential for misuse of topical preparations of adrenaline on wounds. Topical anaesthetics may have some benefits in the treatment of burns, ulcers, or in cosmetic procedures such as tattooing; however, the use of FDC preparations in such cases may lead to undesirable complications due to the presence of adrenaline. I am of the view that monitoring by a medical practitioner is appropriate to minimise the risks of these potentially serious adverse effects.

I have considered, under s 52E(1)(f), whether all topical preparations of adrenaline might be suitable for a Schedule 4 entry. I can see no evidence that would justify classifying all topical preparations of adrenaline, such as those intended for use on intact skin or the surfaces of other tissues, as prescription-only medicines. Further, I note that there are currently no topical preparations containing adrenaline on the Australian Register of Therapeutic Goods. Therefore, I have decided to limit the amendment to the Poisons Standard only to preparations for the treatment of wounds. Any topical preparations containing less than 1% of adrenaline that are not indicated for the treatment of wounds, such as those that may be prepared by compounding pharmacists, will remain in Schedule 3.

Based on the Committee's advice, I have considered the revisions to the wording of the scheduling entries in the proposal, which were intended to clarify the scheduling of injectable preparations of adrenaline. I am of the view that the revised wording more clearly represents the intent of scheduling of injectable preparations of adrenaline, while also accurately reflecting the changes regarding topical use for the treatment of wounds in humans.

I have considered the 5 written public submissions received during the pre-meeting consultation period, all of which were fully supportive of the applicant's proposal. In particular, I have noted that the Pharmacy Guild and the Pharmaceutical Society were both supportive of the proposal to classify topical adrenaline for wound management as a Schedule 4 medicine, each citing agreement with the concerns raised in the external evaluation of the new product.

As there are no currently marketed products that would be affected by the changes to the scheduling of adrenaline, I see no reason to delay the implementation of the amendment.

Implementation date

1 June 2024

Interim 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.

Interim decision

A Delegate of the Secretary[28] has made an interim decision to amend the current Poisons Standard in relation to benzoic acid as follows:[29]

Schedule 5 – New entry

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

Index – New entry

BENZOIC ACID

Schedule 5

The Delegate's interim decision varies from the applicant's proposal and the detailed reasons for the decision follow.

Materials considered

In making this interim 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, with 5 including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**).
- The advice received from the 35th meeting of Advisory Committee on Medicines and Chemicals Scheduling in joint session (the **Committee**).
- Subsection 52E(1) of the Act, in particular (a) 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

[28] Pursuant to regulation 42ZCZN of the Regulations.

[29] 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.

substance; and (f) any other matters that the Secretary considers necessary to protect public health.

- The SPF, and
- The Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that the Poisons Standard be amended in relation to benzoic acid as follows:

Schedule 5 – New entry

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

Index – New entry

BENZOIC ACID

Schedule 5

The Committee did not provide an explicit recommendation for an implementation date of the amended scheduling. Instead, it was suggested that the Delegate investigate the scope of the advised scheduling change to marketed products before deciding when the amendment should come into effect.

The Committee agreed on the relevant matters under subsection 52E(1) of the Act, and provided the following reasons for the advice:

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

Risks:

– The application is for a new use of benzoic acid in a sterilising spray and the main risk factor is toxicity to the eye.

Benefits:

– Benzoic acid has a wide range of effective uses in food, cosmetics, medicines and agricultural products.

– The potential benefits of the commercial product containing 9% benzoic acid outweigh the risks when the product is handled by trained personnel in industrial situations.

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

– Benzoic acid is mainly used to as antimicrobial in therapeutic preparations and as a preservative.

– The commercial product containing benzoic acid will be used to sterilise and disinfect hard surfaces in agricultural and food production and storage. It will also be used to sterilise tools used during cultivation, pruning and harvesting.

c) the toxicity of a substance

– Benzoic acid is not systemically toxic in adults, with some evidence of systemic toxicity in young children.

- Regarding localised toxicity however, it is a known skin irritant and can cause irreversible damage to the eye.

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

- Appropriate labelling must be used for the concentrate emphasising precautions associated with a Schedule 7 substance, including outlining necessary PPE. These requirements would be the responsibility of the product regulator, in addition to any requirements stemming from scheduling.

e) the potential for abuse of a substance

- Not relevant.

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

- Concerns regarding current general public access of benzoic acid.
- The application describes a new purpose of use as an anti-microbial foam for the agricultural and fresh food sector at 9% concentration, in a range of container sizes for the concentrate ranging from 1 L to 220 L. There are concerns regarding general public access to this product.
- Derivatives of benzoic acid should not be captured by any new scheduling entries – there is a vast array of these due to the simple chemical structure of the substance.

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

I agree with the Committee's findings on the relevant provisions of section 52E of the Act.

Benzoic acid is a commonly utilised substance in a range of products and industries, with a considerable history of use in relatively low concentrations for its antimicrobial properties and low systemic toxicity and is currently an unscheduled substance (s 52E(1)(a)). However, the application for consideration of the scheduling of benzoic acid refers to a new presentation of the substance for agricultural use (s 52E(1)(b)).

I have considered the proposal to create new entries in Schedules 5, 6 and 7 of the Poisons Standard for benzoic acid. The new entries would apply to agricultural and veterinary preparations containing less than 1% of benzoic acid; agricultural and veterinary products containing 1-10% of benzoic acid; and all preparations containing greater than 10% of benzoic acid, respectively.

In reference to s 52E(1)(c), the main concern regarding the toxicity of the substance is its potential for causing serious damage to the eye, with comparatively low toxicity from oral and dermal exposure (although the substance is a potential skin irritant). Typical use of the substance to this point, at relatively low concentrations, has not provided any reason to place controls on use of the substance through scheduling. However, I am of the view that the new presentation of benzoic acid outlined in the application carries additional risks.

I note that the assessment of the hazards presented to the eye, as presented in the application, are based on the finished product (sanitising spray) rather than the active ingredient itself. I further note that, apart from the potential for eye toxicity, all other acute toxicity data for benzoic acid is consistent with the scheduling factors for Schedule 5.

Based on this, I am unconvinced that the data provided in the application justifies the proposal for 3 separate cut-off-levels and scheduling entries. On a balanced consideration of all the available information, benzoic acid does not meet the SPF's scheduling factors for Schedule 7. I am of the view that there is an unacceptable risk of unintended consequences associated with use of the substance

in industry were such an entry adopted, for example, some state regulations prohibit the transport of food or pharmaceuticals when stored with a Schedule 7 poison.

In addition, the prominent use of benzoic acid as a starting material in industrial synthesis, including in the manufacture of pharmaceuticals, plastics and plasticisers, would require licensing under a Schedule 7 entry. I do not consider that there is sufficient evidence of adverse effects to human health to justify such a change in scheduling.

I agree with the Committee that there is a lack of relevant available data to support the proposed cut-off concentrations in each entry in the application (s 52E(1)(f)). I observe that under the proposed scheduling, the controls on benzoic acid under the Poisons Standard would be comparable with the scheduling of inorganic acids such as hydrochloric acid. This substance is included in Schedules 5 and 6 and is generally regarded as significantly more hazardous than benzoic acid, with a far more limited range of use.

To this end, I have considered whether benzoic acid requires scheduling at all, given its long history of exemption from the Poisons Standard and its wide and varied use. However, in considering s 52E(1)(d) of the Act, I note that inclusion in a schedule not only mandates the signal header for this new presentation of the substance, but also triggers the regulator's requirements for labelling of first aid instructions. Therefore, scheduling of the substance for agricultural use will assist in mitigating the identified risks associated with use of the product that is the subject of the application, as well as any similar products in future which may present similar risks to human health.

I have considered the 5 written public submissions received during the pre-meeting consultation period. Two written responses received were fully supportive of the applicant's proposal, and 3 were opposed. I have noted the general opposition to the proposed Schedule 7 entry, with respondents citing existing mitigation of risks associated with concentrated solutions of benzoic acid through work health and safety laws, which render the licensing requirements associated with a Schedule 7 unnecessary.

After considering this information, I have decided to create a new Schedule 5 entry for benzoic acid for agricultural use, with an exemption for preparations containing 1% or less of benzoic acid. This cut-off is based on the toxicity data and the body of evidence produced by previous use of this substance, which indicates that preparations of less than 1% benzoic acid do not meet the scheduling factors for any schedule. All other uses of the substance remain unscheduled at all concentrations, as I am of the view that the hazards associated with other uses do not present a sufficient risk to justify scheduling at this time. The new Schedule 5 entry ensures that products containing benzoic acid for agricultural use display appropriate warning labels and instructions for use that reflect the associated hazards, while not unduly inhibiting access to a substance that presents risks of adverse effects on human health that are consistent with the factors for a Schedule 5 substance.

I agree with the Committee's advice that the simple chemical structure of benzoic acid necessitates exclusion of derivatives and salts of the substance from the new scheduling entry. This exclusion prevents the inadvertent scheduling of a myriad of substances that are chemically related to benzoic acid. Similarly, salts of benzoic acid do not present the same hazards as benzoic acid itself and have also been excluded from scheduling on these grounds (s 52E(1)(f)).

As there are no currently marketed products that will be affected by the amended scheduling, there is no reason to delay the implementation of the change to the scheduling of benzoic acid.

Implementation date

1 June 2024

Interim 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.

Interim decision

A Delegate of the Secretary[30] has made an interim decision to amend the current Poisons Standard in relation to meloxicam as follows:[31]

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.

Index

MELOXICAM

Schedule 6
Schedule 4

Materials considered

In making this interim 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, with 60 including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**).
- The advice received from the 35th meeting of the Advisory Committee on Medicines and Chemicals Scheduling in joint session (the **Committee**).
- Subsection 52E(1) of the Act, in particular (a) 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 that the Secretary considers necessary to protect public health.

[30] Pursuant to regulation 42ZCZN of the Regulations.

[31] 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.

- The application received in November 2021 to reschedule injectable preparations of meloxicam for veterinary use.
- The SPF, and
- The Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that the Poisons Standard be amended in relation to meloxicam as outlined in the proposal.

The Committee also recommended an implementation date of **1 June 2024**.

The Committee agreed on the relevant matters under subsection 52E(1) of the Act, and provided the following reasons for the advice:

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

Risks:

- The potential for accidental self-injection or needle stick injury. Injecting a solution containing both meloxicam and a bacterial antigen could cause local and systemic adverse effects.
- Topical occupational exposure including hypersensitivity that may arise due to exposure upon administration.
- Vaccines are usually given as a set dose, but meloxicam is dosed based on weight. For large lambs this might mean that they are given a large dose of the vaccine which has a higher chance of adverse reactions.

Benefits:

- The proposed scheduling change has potential to improve animal welfare by enhancing access to meloxicam for pain management when performing routine animal husbandry procedures on lambs.
- Multiple injectable meloxicam products for sheep are already marketed in Australia as prescription animal remedies.

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

- Meloxicam in combination with routine bacterial antigen vaccine will be used in routine husbandry procedures, given as a single subcutaneous injection to lambs at marking.
- Due to meloxicam's combination with a bacterial antigen vaccine such as clostridial vaccine, the extent of use should be limited to a single dose in lambs at marking only.
- Both constituents of the preparation are already individually approved to treat lambs.

c) the toxicity of a substance

- Meloxicam has a moderate toxicity based on acute oral, intravenous and intraperitoneal studies. Topical use of meloxicam in humans can be associated with dermal effects such as irritation, erythema, itching and rash.

- The acute toxicity profile of meloxicam was determined as consistent with the Scheduling Policy Framework scheduling factors for Schedule 6 at a concentration of 1% meloxicam or less.

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

- The vaccine contains existing registered bacterial antigens with 1% or less of meloxicam in a sterile, ready-to-use suspension.
- The packaging will be similar to that commonly used for multi-dose livestock injectable products such as vaccines and mineral supplements (multidose pillow packs).

e) the potential for abuse of a substance

- Use of the product to treat species other than sheep without veterinary oversight is possible, but unlikely due to the combination of meloxicam (1%) with a vaccine that is intended specifically for sheep.

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

- Concerns regarding possible attempts to apply the new entry to human vaccines should be avoided by specifying animal husbandry procedures.
- Given that a product has not been formulated yet, concerns regarding dosing were outside the scope of scheduling considerations and would be addressed by the relevant regulator (APVMA) during the product registration process.

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

I agree with the Committee's findings on the relevant provisions of section 52E of the Act.

I have considered the proposal to amend the Schedule 6 entry for meloxicam to include preparations of 1% or less when combined with a veterinary vaccine containing bacterial antigens for lambs undergoing husbandry procedures. These preparations would currently be scheduled as Schedule 4 prescription-only medicines and require the involvement of a veterinarian or other medical professional for access.

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) that is used for pain relief in routine husbandry procedures such as tail docking, castration and mulesing. Oral transmucosal preparations of 1% meloxicam for a similar purpose were previously down-scheduled to Schedule 6 on 1 February 2023. I note that vaccines for veterinary use that contain bacterial antigens, such as clostridial vaccines that are likely to be used in a product related to this proposal, are not scheduled. Therefore, access to the co-formulated product mentioned in the application is contingent on the scheduling of meloxicam (s 52E(1)(b)).

In consideration of s 52E(1)(a) of the Act, I note the painful nature of the procedures outlined in the application, and the mandate for the use of pain relief measures for affected animals before, during, and after such procedures. The vaccination of lambs at marking is a common practice and there would be benefits in providing a combination product that includes both a pain relief agent and a vaccine, as such a product will encourage the uptake of pain relief measures and reduce the number of injections required (s 52E(1)(d)).

I have considered the previous application to reschedule injectable preparations of meloxicam for veterinary use, which was received in November 2021. That application included a proposal to include 2% injectable meloxicam in Schedule 6 for animal husbandry procedures but did not progress due to concerns regarding the risks associated with administration and the associated need for veterinary oversight to mitigate the potential for diversion and misuse.

While acknowledging the safety issues previously identified with the use of injectable meloxicam, I recognise the different circumstances in this application. Most notably, the lower concentration of meloxicam and the co-formulation with a veterinary vaccine are important factors to be considered when assessing this current proposal. In particular, I observe that the concentration of 1% meloxicam specified in the proposed amendment aligns with the existing permissible concentration for oral transmucosal preparations of meloxicam in Schedule 6. Importantly, with reference to s 52E(1)(c) of the Act, the acute toxicity endpoints for meloxicam align with the scheduling policy framework factors for a Schedule 6 classification.

In considering s 52E(1)(e), I recognise that some of the risks identified with potential misuse in discussions of previous scheduling applications for meloxicam are counteracted in this proposal by the co-formulation with a vaccine. I agree with the Committee's advice that the presence of the vaccine provides a sufficient deterrent to misuse, while the presence of meloxicam encourages the uptake of pain relief measures by farmers when performing husbandry procedures at marking. In addition, misuse of the product for pain relief in humans is unlikely due to the low concentration of meloxicam and potential adverse effects that may be experienced in reaction to the vaccine component.

In considering other matters of relevance to scheduling under s 52E(1)(f) of the Act, I acknowledge that this proposal relates to the use of meloxicam during a routine procedure, with no formal diagnosis required. Therefore, I am of the view that veterinary oversight is not essential in these circumstances. The weight-dependent nature of meloxicam dosage in a veterinary setting may be relevant to considerations of this application, as the weight of lambs at marking can vary significantly. However, I agree with the Committee that concerns regarding dosing are outside the scope of scheduling considerations. As there are currently no applicable marketed products that will be affected by this decision, such concerns will be addressed by the Australian Pesticides and Veterinary Medicines Authority (APVMA) during the product registration process if that occurs.

I have considered the 60 written public submissions received during the pre-meeting consultation period; 54 of which were fully supportive of the applicant's proposal. Of particular interest was the submission from the Australian Veterinary Association, which did not oppose the proposed amendment, citing the reduced risk associated with the co-formulated product compared to a stand-alone preparation of injectable meloxicam. I acknowledge comments included in the submissions that veterinary professionals should ideally be involved in the administration of pain relief to animals as they are best placed to identify contraindications and respond to adverse events. However, I deem the risks associated with these factors to be sufficiently mitigated by the stipulations in this proposal.

The proposed changes to the scheduling of meloxicam benefit health outcomes by encouraging uptake of pain relief in routine animal husbandry procedures and reducing the number of injections required during such procedures by combining the NSAID with a vaccine. Given the reduced risk of diversion or misuse of the meloxicam due to the co-formulation with a veterinary vaccine, I have decided to amend the Poisons Standard as proposed in the application. As there are currently no relevant marketed products, I have decided there are no grounds to delay the implementation of this decision.

Implementation date

1 June 2024

Interim decision in relation to palmitoylethanolamide (PEA)

Proposal

The applicant has proposed a new Schedule 6 entry for palmitoylethanolamide (PEA) with an exemption for use in listed human medicines. The proposal would require products containing PEA that are not listed as human medicines, such as veterinary products, to have distinctive packaging with strong warnings and safety directions on the label.

Interim decision

A Delegate of the Secretary[32] has made an interim decision to amend the current Poisons Standard in relation to palmitoylethanolamide (PEA) as follows:[33]

Schedule 6 – New entry

PALMITOYLETHANOLAMIDE (excluding derivatives) **except** in preparations for therapeutic use.

Index – New entry

PALMITOYLETHANOLAMIDE
cross reference: PALMIDROL

Schedule 6

The Delegate's interim decision varies from the applicant's proposal and the detailed reasons for the decision follow.

Materials considered

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

- The application to amend the current Poisons Standard with respect to PEA (the **Application**).
- The 19 public submissions, with 3 including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**).
- The advice received from the 35th meeting of the Advisory Committee on Medicines and Chemicals Scheduling in joint session (the **Committee**).
- Subsection 52E(1) of the Act, in particular (a) 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 that the Secretary considers necessary to protect public health.
- The Australian Register of Therapeutic Goods (ARTG).
- The SPF, and
- The Handbook.

[32] Pursuant to regulation 42ZCZN of the Regulations.

[33] 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.

Summary of Committee advice to the Delegate

The Committee recommended that the Poisons Standard be amended in relation to PEA as set out in my interim decision.

The Committee also recommended an implementation date of **1 June 2024**, as there are no known registered products would be impacted by this decision.

The Committee agreed on the relevant matters under subsection 52E(1) of the Act, and provided the following reasons for the advice:

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

Risks:

- Risks arise from human exposure of the 'raw' chemical. Corrosivity and irritant as powdered manufacturing concentrated products.

Benefits:

- PEA is used in human and animal therapeutic products and is used as an active ingredient in export only and listed medicines.

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

- The substance is to be used in manufacturing concentrate and raw material for a new veterinary product.

c) the toxicity of a substance

- PEA produces low oral and dermal acute toxicity. However, it can cause severe and irreversible corrosive effects on the eye and severe irritant effects on the skin.

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

- The use of PPE where the product is in powder form would aid risk mitigation, as would safety labels.

e) the potential for abuse of a substance

- Not relevant.

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

- Derivatives of PEA should be excluded from scheduling (for example, palmitic acid which is in Appendix B).
- CAS number and IUPAC nomenclature should be considered in the entry to aid readers in identification.

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

I have made an interim decision to amend the current Poisons Standard in relation to palmitoylethanolamide (PEA) to create a new Schedule 6 entry that excludes derivatives and preparations for therapeutic use. The detailed reasons for my decision follow.

I agree with the Committee's findings on the relevant provisions of section 52E of the Act. I have considered the 19 public submissions received during the pre-meeting consultation period with 17 supportive, 1 partially supportive, and 1 opposing the proposal. The 2 written submissions recommended the proposed entry be broadened from listed medicines to include all therapeutic preparations.

PEA is a natural fatty acid amide component of certain foods and endogenously synthesised in animals and humans. I note PEA is an active ingredient[34] in TGA listed medicines with several permitted indications, such as an anti-inflammatory, analgesic, and to maintain and support general health and wellbeing. It is also anticipated that PEA will be used more widely as a manufacturing concentrate for use in veterinary products, which triggered the scheduling proposal.

I note that the oral consumption of PEA has low acute toxicity. However, in considering the SPF, PEA has the potential to cause severe but reversable effects on the skin, consistent with scheduling factor 1 for Schedule 6, and severe and irreversible effects on the cornea, consistent with factor 1 for Schedule 7 (s 52E(1)(b)).

In relation to s 52E(1)(a) and (d) of the Act, there is a considerable risk of PEA aerosolisation when large, concentrated quantities are handled, but I have formed the view that this risk can be managed in a manufacturing environment. While the handling of large packaging, such as those that are slit open or poured, increase the risk of eye injury and skin irritation, relevant Work Health and Safety (WHS) requirements would apply. The outcome of an Australian Pesticides and Veterinary Medicines Authority (APVMA) WHS assessment demonstrated safe use of PEA when using the recommended label safety directions, warnings, appropriate personal protective equipment, and observation of good manufacturing practices. This outcome aligns PEA with factors 3 and 4 for Schedule 6 in the SPF. Since the risks of skin and eye injury of PEA can be managed in a manufacturing environment, and with insufficient data to set any cut-offs, I am satisfied it is most appropriate to create a new Schedule 6 entry.

I recognise that the risks associated with the use of a PEA manufacturing concentrate differ considerably to the use of PEA in therapeutic preparations, particularly for human use (s 52E(1)(b)). I have reviewed the Australian Register of Therapeutic Goods (ARTG) and of the 26 products listed, 24 were in tablet or capsule formulations and 2 products were in powder formulations. I am of the view that these products (tablets or capsules) hold a very low aerolisation risk. The two products otherwise made available in powders are in much lower quantities (≤ 100 grams) and concentrations (5.9% and 15%), and are different in the way they are handled, compared to the use of PEA for manufacturing purposes. I also acknowledge the concerns raised by Consumer health Products (CHP) Australia and Complementary Medicines Australia (CMA) that propose all products for human therapeutic use should be excluded. I am of the view my reasons would be relevant to human therapeutic preparations more broadly, and as I have not found data to suggest the risks would differ for human therapeutic use than for veterinary use, I am assured it is currently warranted to exclude all therapeutic preparations.

I agree with the Committee's advice that the exclusion of derivatives would prevent perverse outcomes by not scheduling substances that are chemically similar to PEA (s 52E(1)(f)). I am not aware of any major signals that calls for a need to include the scheduling of PEA derivatives at this time.

I have decided to include palmidrol, the Australian Approved Name (AAN), in the index for additional clarity. Other names for PEA are available on the TGA website, including the IUPAC name.

I see no reason to delay implementation as the products currently in the market are those excluded from the new Schedule 6 entry and will be unaffected by the new scheduling of PEA.

Implementation date

1 June 2024

[34] www.tga.gov.au/resources/resource/compositional-guidelines/palmidrol

Interim decision on a proposed amendment not referred to an expert advisory committee

In my capacity as a delegate of the Secretary for the purpose of regulation 42ZCZV of the Regulations, I have made interim decisions with respect to capromorelin.

Interim decision in relation to capromorelin

Proposal

The applicant proposed to create a new Schedule 4 entry for capromorelin in preparations for veterinary use. Capromorelin is a growth hormone releasing peptide-mimetic that is typically used for body weight gain in cats experiencing poor appetite or unintended weight loss resulting from chronic medical conditions including kidney disease. Capromorelin may currently be classified as a Schedule 4 medicine under the group entry for growth hormone secretagogues (GHSs). The proposal seeks to clarify the scheduling of the substance by introducing a specific entry into Schedule 4.

Schedule 4 – Proposed New Entry

CAPROMORELIN in preparations for veterinary use.

Index – Proposed New Entry

CAPROMORELIN

Schedule 4

Interim decision

A Delegate of the Secretary[35] has made an interim decision to amend the current Poisons Standard in relation to Capromorelin as follows as follows:[36]

Schedule 4 – New Entry

CAPROMORELIN.

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

Item	Poison
4a	CAPROMORELIN

Index – New Entry

CAPROMORELIN

Schedule 4
Appendix D, clause 5

[35] Pursuant to regulation 42ZCZV of the Regulations (delegate only decision)

[36] 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.

The Delegate's interim decision differs from the applicant's proposal and the detailed reasons for the decision follow.

Materials considered

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

- The application to amend the current Poisons Standard with respect to capromorelin (the **Application**).
- Subsection 52E(1) of the Act, in particular (a) 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 that the Secretary considers necessary to protect public health.
- The SPF, and
- The Handbook.

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

I have made the decision to amend the Poisons Standard by creating a Schedule 4 entry for Capromorelin. The need for restricting access through Schedule 4 and Appendix D, clause 5 is justified by the human risks of the substance that led to its inclusion in the World Anti-Doping Agency (WADA) Prohibited List 2024[37] and is also in alignment with the scheduling of other growth hormone secretagogues in the Poisons Standard.

I have considered[38] the information provided in the Application, by the Australian Pesticides and Veterinary Medicines Authority (APVMA), and the matters specified under s 52E of the Act and the SPF.

Regarding s 52E(1)(a) of the Act, relating to the benefits and risks of the use of a substance, the proposed amendment is to include a new entry for capromorelin in preparations for veterinary use in Schedule 4. The proposal specifies veterinary use and is based on the benefits of the therapeutic use of capromorelin to aid food intake in cats experiencing poor appetite or unintended weight loss resulting from chronic weight gain in cats. Capromorelin belongs to the growth hormone (GH)-releasing peptide class of GH-releasing agents and acts as a selective ghrelin receptor agonist. It has a well-established record of efficacy in treating weight loss as an appetite stimulant in cats and dogs in various international jurisdictions. However, I note that clinical trials involving capromorelin for the treatment of similar conditions in humans have been discontinued prior to completion.[39] Capromorelin remains an unapproved medicine for human use.

In relation to s 52E(1)(b) of the Act and the purposes and extent of use of the substance, I have noted that the Application refers only to veterinary use of the substance (active constituent), although there are no currently registered products on the APVMA's PubCRIS[40] database that contain capromorelin. This Application relates to an application to the APVMA that is under consideration for a new product containing capromorelin, an oral solution for use in cats.

I have noted that, as outlined in s 52E(1)(c) of the Act, the effects of capromorelin on mice, rats, rabbits, and dogs in repeat dose toxicity tests were primarily related to the known pharmacological

[37] www.wada-ama.org/sites/default/files/2023-09/2024list_en_final_22_september_2023.pdf
[38] Pursuant to paragraph 52D(2)(a) of the Act
[39] www.ncbi.nlm.nih.gov/pmc/articles/PMC5813110/
[40] portal.apvma.gov.au/pubcris

effects of the substance, that is, weight gain and increased appetite. Reported adverse toxic effects were minimal with minor topical reactions being noted, which are unlikely to present an issue in the oral dosage forms that capromorelin is typically presented in. There was no evidence of capromorelin-induced maternotoxicity or developmental toxicity in rats or rabbits. In an adequate battery of in vitro and in vivo studies, capromorelin was not shown to be a likely genotoxin. No acceptable daily intake (ADI) or acute reference dose (ARfD) is required for the substance as it is not proposed for use in food-producing animals or crops.

I am satisfied that, for the purposes of paragraph 52E(1)(d) of the Act, the regulator (APVMA) will consider the dosage (application rate), formulation, labelling, packaging, and presentation of any commercial products during the product registration process.

In considering paragraph 52E(1)(e) of the Act, while the new product that this scheduling application relates to does not in itself present significant potential for diversion or abuse, I have identified such potential for the active ingredient, capromorelin. The Schedule 4 entry as originally proposed specifies veterinary use, which would effectively make capromorelin for human use unscheduled. I consider that this is an undesirable outcome as capromorelin is a growth hormone secretagogue and therefore presents with potential for misuse, in athletes.

Risk of misuse of capromorelin by athletes has resulted in the World Anti-Doping Agency (WADA) listing capromorelin under the S2.2. Peptide Hormones and their Releasing Factors category[41] and prohibiting its use in sports at all times (in and out of competition), as of January 2024. It is primarily for this reason that I have chosen to amend the Poisons Standard in a different manner to that proposed by the applicant, and to include capromorelin in Schedule 4 without any specifications on how the substance is used, thereby addressing all uses.

In addition to the Schedule 4 entry, I have decided to include capromorelin in clause 5 of Appendix D of the Poisons Standard, which prohibits possession of the substance without authority. This is consistent with other growth hormone secretagogues that are already included in the Poisons Standard and is further recognition of the potential for diversion and misuse of this substance.

On the basis of the above considerations and the information provided in the application, I have decided to amend the current Poisons Standard in the manner set out above. The proposed amendment was not referred to an expert advisory committee. As the amendment differs from that proposed in the application, this is an interim decision under r 42ZCZV of the Regulations and will be subject to the legislated consultation period.

Implementation date

1 June 2024

[41] www.wada-ama.org/sites/default/files/2023-09/2024list_en_final_22_september_2023.pdf

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