Australian Government
Department of Health
Therapeutic Goods Administration

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

28 November 2019

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

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

Contents

1. Advisory Committee on Medicines Schedule (ACMS #27) – Final decisions made pursuant to regulation 42ZCZR

1.1. Final decision in relation to phenpromethamine

Final decision

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

Schedule 10 – New Entry

PHENPROMETHAMINE.

Index – New Entry

PHENPROMETHAMINE

Schedule 10

Date of effect of the decision

1 February 2020.

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

I have made a final decision to confirm my interim decision to Schedule phenpromethamine in Schedule 10 of the Poisons Standard. I note that no public submissions were received before the second closing date in response to the call for further submissions published on 12 September 2019 under regulation 42ZCZP of the Regulations.

Summary of public submissions on the interim decision

No public submissions were received in response to the interim decision.

1.2. Final decision in relation to 1,4-Dimethylpentylamine (DMPA)

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to 1,4-Dimethylpentylamine (DMPA) as follows:

Schedule 10 – New Entry

1,4-DIMETHYLPENTYLAMINE (DMPA).

Index – New Entry

1,4-DIMETHYLPENTYLAMINE (DMPA)

Schedule 10

Index – Amend Entry

ALKYLAMINES WITH STIMULANT PROPERTIES
cross reference: 1,3-dimethylbutylamine, DMBA, octodrine, 1-aminoisoheptane, DMHA, 1,5-dimethylhexylamine, 4-methylhexane-2-amine, 1,3-dimethylamylamine, DMAA, 4-amino-2-methylpentane citrate (AMP citrate), 1,4-dimethylpentylamine, DMPA.

Schedule 10

Date of effect of the decision

1 February 2020.

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

I have made a final decision to confirm my interim decision to Schedule 1,4-dimethylpentylamine in Schedule 10 of the Poisons Standard. I note that no public submissions were received before the second closing date in response to the call for further submissions published on 12 September 2019 under regulation 42ZCZP of the Regulations.

Public submissions in response to the interim decision

No public submissions were received in response to the interim decision.

1.3. Final decision in relation to sanguinarine

Final decision

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

Schedule 10 – New Entry

SANGUINARIA CANADENSIS (bloodroot) in preparations for human use **except** in preparations containing 0.01 per cent or less of SANGUINARINE.

INDEX – New Entry

SANGUINARIA CANADENSIS (bloodroot)

Schedule 10

SANGUINARINE
cross reference: **SANGUINARIA CANADENSIS (bloodroot)**

Date of effect of the decision

1 February 2020.

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

I have made a final decision to confirm my interim decision to schedule *Sanguinaria canadensis* (bloodroot) in Schedule 10 of the Poisons Standard. In making my final decision, I have taken into account the three public submissions received before the second closing date in response to the call for further submissions published on 12 September 2019 under regulation 42ZCZP of the Regulations.

I have taken into account the views expressed in the public submission regarding the cross reference to sanguinarine in the index. However, I am not persuaded that the index entry for sanguinarine impacts or restricts the extracts of other plants containing sanguinarine. Sanguinarine itself is not specifically scheduled in the Poisons Standard and therefore has no restrictions placed on it outside of the Schedule 10 entry for *Sanguinaria canadensis* (bloodroot). The inclusion of sanguinarine in the index is simply to offer clarity and direct an observer to the scheduled plant, *Sanguinaria canadensis* (bloodroot).

I have taken into consideration the views expressed in the public submission that the Schedule 10 entry for *Sanguinaria canadensis* (bloodroot) provides restriction on the use of *Sanguinaria canadensis* for research purposes. The Schedule 10 entry only restricts use of *Sanguinaria canadensis* in preparations for human use. It does not prevent the use of *Sanguinaria canadensis* in laboratory or research settings not involving humans. If it were to be demonstrated that *Sanguinaria canadensis* has the capability to provide a significant public health benefit, then re-consideration may be required and a future application for rescheduled may be submitted with the appropriate evidence. However, at present I am of the opinion that there is insufficient data to justify a lower schedule for *Sanguinaria canadensis.* On balance, I find that the current risks to public health outweigh any potential human health benefits.

I have taken into account the views expressed in the public submission over the use of the term 'human use' as opposed to 'therapeutic use' in the schedule entry for *Sanguinaria canadensis*. Given the potential for *Sanguinaria canadensis* to cause significant harm to members of the public and that there is insufficient evidence to support the therapeutic potential of *Sanguinaria canadensis*, I am of the opinion that using the term 'human use' is more appropriate in this context.

Summary of public submissions on the interim decision

Three (3) public submissions were received in response to the call for further submissions published on 12 September 2019 under regulation 42ZCZP of the Regulations. One (1) submission

was in support of the interim decision with amendments, one (1) submission was in opposition of the interim decision and one (1) suggested a less restrictive schedule to the one proposed in the interim decision.

The main points in support with amendments of the proposed amendment were:

- The scheduling entry will address the concerns raised by the Applicant and will not inadvertently impact the existing complementary medicines containing *C. majus*.
- The broadening of the entry to capture "human use" as opposed to the "therapeutic use" consulted on, raises concerns as to the process given that the application, the submissions, the background information, the ACMS recommendation and the interim decision itself only considered the narrower field of "therapeutic use".

The main points in opposition of the proposed amendment were:

- The public submission does not fully support the Delegate's interim decision regarding sanguinarine, most especially the inclusion of sanguinarine in the index, with a cross reference to *Sanguinaria canadensis*.
- The proposed cross reference of sanguinarine in the index could impact the extracts of other plants and place needless restrictions on other herbal medicines.
- The public submission supports the ACMS recommendation, but not the Delegate's interim decision.

Main points of a suggested less restrictive schedule to the one proposed in the interim decision:

- The interim decision to replace scheduling of sanguinarine with that of *S. canadensis* (unless less than 0.01% sanguinarine) is an appropriate measure to prevent unintended consequences on other commonly available preparations.
- The proposed removal of community access to *S. canadensis* is consistent with the literature recommendations on safety and identified risk with community use.
- The scheduling entry could be reviewed for an alternative entry that provides a similarly strict restriction of public access but one that also permits further approved research under State and Territory permit (something that appears generally unavailable for Schedule 10). Further areas of research include anti-inflammatory, antimicrobial, antimycobacterial and anticancer capabilities of *S. canadensis*.

1.4. Final decision in relation to finasteride

Final decision

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

Date of effect of the decision

28 November 2019.

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

I have made a final decision to confirm my interim decision to retain the Schedule 4 entry for finasteride in the current Poisons Standard. I note that no public submissions were received before the second closing date in response to the call for further submissions published on 12 September 2019 under regulation 42ZCZP of the Regulations.

Public submissions in response to the interim decision

No public submissions were received in response to the interim decision.

2. Joint meeting of the Advisory Committee on Chemicals and Medicines Scheduling (ACCS-ACMS #22) – Final decision made pursuant to regulation 42ZCZR

2.1. Final decision in relation to arbutin

In considering the public submissions received on the interim decision in relation to arbutin, the Delegate of the Secretary, under regulation 42ZCZQ of the Regulations, has decided to seek additional advice on the scheduling of arbutin before coming to a final decision. A summary of the public submissions received in response to the interim decision can be found below.

Seven (7) public submissions were received before the second closing date in response to the call for further submissions published on 12 September 2019 under regulation 42ZCZP of the Regulations. Six (6) submissions were in support and one (1) submission was in opposition of the proposed amendments.

The main points in support of the proposed amendment were:

- The public submission expressed support for the delegate's interim decision to permit 500 mg or less of arbutin in oral herbal preparations to be available for access and the removal of the cross reference of arbutin to hydroquinone.
- The public submission noted that they would also like to see restrictions lifted for registered Chinese Medicine Practitioners for herbs like prepared Fu Zi (Radix aconiti lateralis preparata), and Ma Huang (Herba Ephedrae). These herbs have no danger when prepared correctly and combined with other herbs in a prepared Chinese Herbal Medicine Formula and prescribed by a registered practitioner.

The main points in opposition of the proposed amendment were:

- It is frustrating that the cosmetic use of arbutin is captured within the hydroquinone schedule entry as a 'derivative', but it is not being considered now when the substance is being carved out of the hydroquinone schedule entry.
- The risks and benefits of the use of arbutin in cosmetic and topical dermal therapeutic products have not been considered by the regulatory system, despite the restrictions being in place.
- Noted the European Commission's Scientific Committee on Consumer Safety (SCCS) conclusion on α-arbutin and β-arbutin cut-offs.
- The discussion section of the SCCS opinion for α-arbutin notes that the total internal value of hydroquinone (released from α-arbutin) used for safety assessment related to ochronosis and other end points is 42 times lower than the internal exposure resulting from the use of a product containing 1% hydroquinone, a concentration at which ochronosis may occur. For β-arbutin it is 174 times lower.

3. Advisory Committee on Chemicals Scheduling (ACCS #25) – Final decisions made pursuant to regulation 42ZCZR

3.1. Final decision in relation to lambda-cyhalothrin

Final decision

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

Date of effect of the decision

28 November 2019.

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

I have decided to confirm the interim decision to not amend the current Poisons Standard in relation to lambda-cyhalothrin. I note that no public submissions were received before the second closing date in response to the call for further submissions published on 12 September 2019 under regulation 42ZCZP of the Regulations.

Public submissions in response to the interim decision

No public submissions were received in response to the interim decision.

3.2. Final decision in relation to sarolaner

Final decision

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

Schedule 6

SAROLANER **except** when included in Schedule 5.

Schedule 5 – Amend Entry

SAROLANER for veterinary use in divided preparations each ~~the treatment, prevention and control of fleas and ticks in dogs in oral divided preparations each~~ containing 120 mg or less of sarolaner per dosage unit.

Index

SAROLANER

Schedule 6
Schedule 5

Public submissions in response to the interim decision

No public submissions were received in response to the interim decision.

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

I have made a final decision to confirm my interim decision to amend the Schedule 5 entry for sarolaner to include veterinary use. I note that no public submissions were received before the second closing date in response to the call for further submissions published on 12 September 2019 under regulation 42ZCZP of the Regulations.

Date of effect of the decision

1 February 2020.

3.3. Final decision in relation to broflanilide

Final decision

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

Schedule 6 – New Entry

BROFLANILIDE **except** when included in Schedule 5.

Schedule 5 – New Entry

BROFLANILIDE in preparations containing 0.3 per cent or less of broflanilide.

INDEX – New Entry

BROFLANILIDE

Schedule 6
Schedule 5

Date of effect of the decision

1 February 2020.

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

I have made a final decision to confirm my interim decision to include broflanilide in Schedules 5 and 6 of the Poisons Standard. I note that no public submissions were received before the second closing date in response to the call for further submissions published on 12 September 2019 under regulation 42ZCZP of the Regulations.

Public submissions in response to the interim decision

No public submissions were received in response to the interim decision.

3.4. Final decision in relation to trifludimoxazin

Final decision

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

Schedule 5 – New Entry

TRIFLUDIMOXAZIN **except** in preparations containing 12.5 per cent or less.

INDEX – New Entry

TRIFLUDIMOXAZIN

Schedule 5

Date of effect of the decision

1 February 2020.

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

I have made a final decision to confirm my interim decision to include trifludimoxazin in Schedule 5 of the Poisons Standard. I note that no public submissions were received before the second closing date in response to the call for further submissions published on 12 September 2019 under regulation 42ZCZP of the Regulations.

Public submissions in response to the interim decision

No public submissions were received in response to the interim decision.

3.5. Final decision in relation to saflufenacil

Final decision

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

Schedule 7

SAFLUFENACIL **except** when included in Schedule 5.

Schedule 5 – Amend Entry

SAFLUFENACIL in water dispersible granules ~~preparations~~ or a water-based suspension concentrate.

Index

SAFLUFENACIL

Schedule 7
Schedule 5

Date of effect of the decision

1 February 2020.

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

I have made a final decision to confirm my interim decision to amend the Schedule 5 entry for saflufenacil to include use in water-based suspension concentrate. I note that no public submissions were received before the second closing date in response to the call for further submissions published on 12 September 2019 under regulation 42ZCZP of the Regulations.

Public submissions in response to the interim decision

No public submissions were received in response to the interim decision.

4. Final decisions (without interim decision) made pursuant to regulation 42ZCZU

4.1. Final decision in relation to bixlozone

Final decision

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

Appendix B, Part 3 – New Entry

Substance	Date of entry	Reasons for listing	A
BIXLOZONE	1 February 2020	a	1.1

Index – New Entry

BIXLOZONE

Appendix B, Part 3

Date of effect of the decision

1 February 2020.

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

The proposed amendment was not referred to an expert advisory committee. In not referring this matter to either the ACCS or the Joint ACCS-ACMS, I am satisfied that sufficient information has been provided by the Applicant for me to exercise my delegation.

In determining that this matter will be a delegate-only decision, I note that:

- Bixlozone has a very low toxicity profile and the weight of evidence from the toxicological database indicates that it does not appear to present any substantial toxicological hazard for acute, short term or long term exposures. Bixlozone has very low dermal absorption and normal use patterns are unlikely to lead to toxicologically significant systemic exposures. The data indicates that bixlozone has very low toxicity by oral and dermal routes. It is not a skin or eye irritant in rabbits or a skin sensitiser in the local lymph node assay (LLNA) test in mice. Although the inhalational LC_{50} for bixlozone was >2110 mg/m^3, this was the highest technically achievable and there were no deaths or clinical signs of systemic toxicity. Therefore, the inhalational toxicity of bixlozone is considered low to negligible. There is no evidence of neurotoxicity, immunotoxicity, endocrine disruption, genotoxicity, carcinogenicity, effects on reproduction or teratogenicity (52E(1)(a)(c)(f)).
- Bixlozone is intended for the control of certain grasses and broad leaf weeds as an 'incorporated by sowing' (IBS) pre-emergent herbicide for grain crops including barley, canola and wheat. It will be used once per crop, and, even for contract workers, exposure is likely to limited to only a few weeks. The product is intended only for professional use and will not be available to the general public (52E(1)(b)).
- The Applicant has demonstrated that appropriate risk mitigation measures will be put in place for the proposed product containing the substance that may be registered for use in Australia, and that account for the dosage (application rate), formulation, labelling, packaging and presentation of bixlozone. As a result, no additional measures are required in the Poisons Standard. Further use of bixlozone in other pesticide products will be addressed by the pesticide regulator (APVMA) in any future applications to the regulator (52E(1)(d)).

- There is no information to indicate that the substance could pose a risk to humans from abuse of the substance (52E(1)(e)).

Therefore, based on the information provided in the application, it is considered that bixlozone does not meet the factors for inclusion in the Schedules of the Poisons Standard. Bixlozone should be listed in Appendix B due to low toxicity (Part 1, a; Part 2, 1.1).

4.2. Final decision in relation to thymol

Final decision

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

Schedule 6 – Amend Entry

THYMOL when packed and labelled for ~~the control of Varroa mites in bee hives~~ use as a pesticide.

Index

THYMOL

Schedule 6

Date of effect of the decision

1 February 2020.

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

The proposed amendment was not referred to an expert advisory committee. In not referring this matter to either the ACCS or the Joint ACCS-ACMS, I am satisfied that sufficient information has been provided by the Applicant for me to exercise my delegation and that I have taken into consideration the matters outlined under 52E of the *Therapeutic Goods Act 1989* and the Scheduling Policy Framework (SPF, 2018).

I have decided to amend the current Poisons Standard in the manner set out in the application.

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

- The proposed change to the Poisons Standard entry for thymol, from its limited indication for the '*control of Varroa mites in bee hives*' to the more expansive indication for the '*use as a pesticide*', indicates potential benefits to the agricultural industry from the broader use of the substance as a pesticide while also noting that there may be risks from the increase in exposure to humans using or coming into contact with this substance. These risks have been adequately addressed by the pesticide regulator (APVMA) in its application (52E(1)(a)). The product is intended for professional use only and is not intended for application to areas accessible to the general public. Bystander risk is possible due to spray drift. I note that adherence to good agricultural practice will minimise potential risks.
- The purposes and extent for which the substance is to be used has been adequately outlined by the Applicant (52E(1)(b)). I have taken into account the broader uses of thymol other than in connection with Varroa mites in bee hives, of particular note, that it is currently used for therapeutic uses in humans. I find that my decision would not affect such use in humans because the wording the applicant has proposed and that I have agreed to is limited to use in pesticides.
- There has been no substantive change in the information available regarding the toxicity of the substance since it was last considered for Scheduling that would warrant a change to its Scheduling Classification in Schedule 6 in the Poisons Standard based on the criteria set out in the SPF (2018) under the scheduling factors for Schedule 6 substances (52E(1)(c)).
- The dosage (application use), formulation, labelling, packaging and presentation of the substance will change as a result of its broader use in pesticide products containing this substance. However, the Applicant has demonstrated that appropriate risk mitigation measures will be put in place should the proposed product containing the substance be registered for use in Australia. As a result, no additional measures are required in the Poisons Standard. Further

use of the substance in other pesticide products will be addressed by the pesticide regulator (APVMA) in any future applications to the regulator. The proposed amended entry for the substance in the Poisons Standard will not affect thymol-containing ingredients listed under the ARTG (52E(1)(d)).

- There is no information to indicate that the substance could pose a risk to humans from abuse of the substance (52E(1)(e)).
- National and International Health Based Guidance Values have been or will be established for the substance that will protect consumers from residues of the substances in food (52E(1)(f)). I have considered that the public may also be exposed in the diet from ingestion of product residues, however, I note that maximum residue limits (MRLs) are set by the applicant to protect consumers from exposure to residue levels above the Acceptable Daily Intakes (ADI). The applicant has determined that human health risk posed by the products is acceptable according to the criteria stipulated in Section 5A of the *Agricultural and Veterinary Chemicals Code Ac*t (1994) and made recommendations for personal protective equipment. I find these matters relevant in the interest of protecting public health.

4.3. Final decision in relation to metcamifen

Final decision

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

Appendix B, Part 3 – New Entry

Substance	Date of entry	Reason for listing	Area of use
METCAMIFEN	1 February 2020	a	1.1

Index – New Entry

METCAMIFEN

Appendix B, Part 3

Date of effect of the decision

1 February 2020.

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

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

- The proposed change to the Poisons Standard to include a new entry for metcamifen, indicates there are benefits to the agricultural industry from the introduction of this new seed safener, to protect grain and other seeds from the phytotoxic effects of *S*-metalochlor herbicides. Risks associated with human exposure to the substance have been adequately addressed by the pesticide regulator (APVMA) in its application (52E(1)(a)).
- The purpose and extent for which the substance is to be used has been adequately outlined by the Applicant (52E(1)(b)). This includes the intention of metcamifen to protect grain or forage sorghum seed from the phytotoxic effects of S-metalochlor herbicides. Metcamifen will be applied once to seed, either prior to storage and sale, or on-farm prior to sowing. The product is intended only for professional use, and will not be available to the general public. The proposed use is related only to broad acre farming.
- The data indicates that metcamifen has very low toxicity across the toxicological database and does not appear to present any substantial toxicological hazard. Metcamifen has very low acute toxicity by oral, dermal and inhalational routes. It is not a skin irritant or sensitiser but causes a slight eye irritation in rabbits. Metcamifen was not genotoxic in a battery of *in vivo* and *in vitro* assays and was not considered carcinogenic in lifetime studies in mice and rats. Metcamifen was not a reproductive or developmental toxicant in rats but caused an increased incidence of skeletal and cartilage variations in rabbits that was slightly outside the historical control range for these variations. Metcamifen was considered to pose a negligible risk of developmental toxicity in humans. The potential for skin irritation due to metcamifen can be managed with appropriate safety directions on the label of the proposed product (52E(1)(c)).
- The Applicant has demonstrated that appropriate risk mitigation measures will be put in place for the proposed product containing the substance that may be registered for use in Australia, and that account for the dosage (application rate), formulation, labelling, packaging and presentation of the substance. As a result, no additional measures are required in the Poisons

Standard. Further use of the substance in other pesticide products will be addressed by the pesticide regulator (APVMA) in any future applications to the regulator (52E(1)(d)).

- There is no information to indicate that the substance could pose a risk to humans from abuse of the substance (52E(1)(e)).

- National Health Based Guidance Values will be established for the substance that will protect consumers from residues of the substances in food (52E(1)(f)).

Therefore, based on the information provided in the application, I have considered that metcamifen does not meet the factors for inclusion in the Schedules of the Poisons Standard. Metcamifen should be listed in Appendix B due to low toxicity (Part 1a; Part 2, 1). The proposed amendment was not referred to an expert advisory committee.

4.4. Final decision in relation to polyacrylamide

Final decision

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

Schedule 4 – Amend Entry

POLYACRYLAMIDE in preparations for injection or implantation:

a) for tissue augmentation; or

b) for cosmetic use; or

c) for veterinary use.

Index

POLYACRYLAMIDE.

Schedule 4

Date of effect of the decision

1 February 2020.

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

The proposed amendment was not referred to an expert advisory committee.

I have decided to amend the current Poisons Standard in the manner set out in the application.

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

- The proposed change to the Poisons Standard entry for polyacrylamide is limited to the current entry under Schedule 4. The proposed change is at the request of the veterinary medicines regulator (APVMA) for a registration application currently under its consideration, for a product designed for the intra-articular administration to horses for the treatment of non-infectious inflammation of joints. The Applicant (APVMA) has indicated that the use of the substance may be beneficial in the treatment of lameness in horses and is anticipated to improve the welfare of treated animals. The increased use of polyacrylamide in the community does pose an increased risk of exposure to the substance, but this is limited to accidental self-injection by veterinarians in the course of treating animals with product(s) containing the substance. I am satisfied that the risks from accidental self-injection/needle stick injury are relatively low on the basis that the maximum volume that could be self-injected would be expected to be the maximum volume of the ready-to-use syringe (2mL) and that systemic effects from the toxic impurities are expected at higher doses and longer duration of exposure. This risk is considered no greater than the current use of polyacrylamide in preparations for injection or implantation in human subjects. No exposure to the public is anticipated following use. Furthermore, these risks have been adequately addressed by the veterinary medicines regulator (APVMA) in its application (52E(1)(a)).
- The purposes and extent for which the substance is to be used has been adequately outlined by Applicant. The current application to Scheduling indicates that the veterinary medicines regulator is considering the registration application for a product designed specifically for the treatment of lameness in horses. I have considered that future veterinary medicine preparations containing the substance could also be used for similar indications in other animal species. This is not considered to increase the risk significantly to humans from exposure to the substance,

and therefore further risk mitigation measures through the Poisons Standard are not considered necessary (52E(1)(b)).

- There has been no substantive change in the information available regarding the toxicity of the substance since it was last considered for Scheduling, which would warrant a change to its Scheduling Classification in Schedule 4 of the Poisons Standard based on the criteria set out under the scheduling factors for Schedule 4 substances in the SPF (2018). The diagnosis, management or monitoring of lameness in horses is such that it requires veterinary intervention before the substance is used. Furthermore, it is noted that the substance is currently available for use in various human therapeutic products, including listed medicines (52E(1)(c)).
- The dosage, formulation, labelling, packaging and presentation of the substance from its currently approved uses in humans for tissue augmentation and cosmetic use, will change as a result of its proposed use in veterinary medicines preparations. The Applicant is responsible for ensuring appropriate labelling, including: directions for use; first aid instructions; safety directions; any precaution or restraint statements and safe storage directions. The Applicant has demonstrated that appropriate risk mitigation measures will be put in place should the proposed product containing the substance be registered for use in Australia. As a result, no additional measures are required in the Poisons Standard. Further use of the substance in other veterinary medicine products will be addressed by the veterinary medicines regulator (APVMA) in any future applications to the regulator. The proposed amended entry for the substance in the Poisons Standard will not affect polyacrylamide-containing ingredients listed under the ARTG (52E(1)(d)).
- There is no information to indicate that the substance could pose a risk to humans from abuse of the substance. There is the potential for the diversion of preparations containing the substance into the human population, but listing the substance for veterinary use under Schedule 4 will subject it to the compliance obligations of the applicable Commonwealth, State and Territory jurisdictions (52E(1)(e)).
- Previous consideration by the National Drugs and Poisons Schedule Committee (NDPSC) on various occasions, affirmed the Schedule 4 classification of the substance in preparations for injection for tissue augmentation and cosmetic uses. Moreover, the NDPSC recognised that such uses would require administration and management of potential adverse effects by medical professionals. Similarly, the proposed use in veterinary medicine preparations will require appropriate diagnosis, administration and management by veterinarians. Therefore, the inclusion of veterinary medicine preparations containing polyacrylamide under Schedule 4 is deemed appropriate (52E(1)(f)).

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