Australian Government
Department of Health
Therapeutic Goods Administration

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

23 May 2022

TGA Health Safety Regulation

Contents

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

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

- the decisions made by a delegate of the Secretary of the Department of Health (the **Delegate**) pursuant to regulation 42ZCZR;
- the reasons for the final decisions; and
- the date of effect of the decisions.

2 Final decisions on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #36, November 2021)

2.1 Final decision in relation to astodrimer sodium

Proposal

The applicant proposed amendments to the existing Appendix F and Appendix H entries for astodrimer to include new warning statements for preventative use, and to remove existing restrictions on advertising for preparations containing the substance

Final Decision

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

Appendix F, Part 3 – Amend Entry

POISON	WARNING STATEMENTS	SAFETY DIRECTION
ASTODRIMER SODIUM		
a) For the treatment and relief of bacterial vaginosis	63, 64, 69, 75, 109, 110	
b) For the prevention of recurrent bacterial vaginosis	63, 75, 109, 110	

Appendix H – Amend Entry

ASTODRIMER SODIUM for the treatment and relief of bacterial vaginosis and for the prevention of recurrent bacterial vaginosis.

Materials considered

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

- The application to amend the current Poisons Standard with respect to astodrimer sodium (the **Application**);
- The 41 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations.
- The advice received from the 36th meeting of the Advisory Committee on Medicines Scheduling (the **Committee**);
- The ten public submissions, including two written submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;

- Subsection 52E(1) of *the Therapeutic Goods Act 1989* (Cth) (the **Act**), in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (f) any other matters considered necessary to protect public health;
- The Scheduling Policy Framework 2018 (the **SPF**), pursuant to paragraph 52E(2)(a) of the Act; and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

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

I have made a final decision to confirm my interim decision to amend Appendix F, Part 3 of the current Poisons Standard with respect to astodrimer sodium, and in addition to alter my interim decision concerning Appendix H. In making my final decision, I have taken into account the material detailed in the interim decision and the responses after the second call for public submissions, published on 11 March 2022 under regulation 42ZCZP of the Regulations. I note that two written submissions were received, one supportive and one partially supportive of the interim decision.

The partially supportive submission raised issues with the inclusion of warning statement 75 ("Do not use for more than 7 days unless a doctor has told you to.") and the decision not to amend the Appendix H entry to remove restriction by indication.

I acknowledge that astodrimer is a topical treatment with a low risk of harm itself. However, I find the risks to individual and public health presented by the absence of a prompt to seek advice from a medical practitioner before using the substance for more than seven days outweigh the benefits at this time. I consider that medical oversight plays an essential role in the long-term use of this medicine and the conditions that it is intended to treat, and seven days is a suitable period of use before consultation with a medical professional should be sought.

The partially supportive submission also proposed an alternative Appendix H entry, which I have considered and adopted in my decision to amend Appendix H as indicated above. Although any new warnings on the label would not undergo pre-market review (as the product is classified as a medical device), "bacterial vaginosis" is a restricted representation and would require approval from the TGA. Furthermore, the amended Appendix H entry would restrict advertising to *the treatment and relief of bacterial vaginosis and for the prevention of recurrent bacterial vaginosis* only, thereby ensuring that there are adequate controls over advertising of astodrimer sodium as indicated in my interim decision.

Implementation date

1 June 2022.

2.2 Final decision in relation to flurbiprofen

Erratum

The interim decision contained a transcription error regarding the matters considered by the Advisory Committee on Medicines Scheduling under subsection 52E(1)(d) of the Act that is indicated in red as follows:

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

– Flurbiprofen 8.75mg/0.54mL solution pump actuated metered dose aerosol

– Maximum 5 sprays per day

– Proposal max 15mL as a Class IIb medical device, noting that the placement of new warnings on the labelling would not undergo pre-market review and could lead to confusion at the point-of-sale and point-of-use.

This text was mistakenly included but did not affect the Delegate's interim decision with respect to flurbiprofen.

Proposal

The applicant proposed that the Schedule 2 entry for flurbiprofen be amended to exclude preparations presented in containers of 15 mL or less, that contain 0.25% or 10 mg or less per dose of flurbiprofen and are labelled for the treatment of adults over 18 years, so that these preparations are not scheduled.

Final Decision

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

Schedule 2 – Amend Entry

FLURBIPROFEN in preparations for topical oral use when:

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

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

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

b) in undivided preparations containing 0.25 percent or less or 10 mg or less per dose of flurbiprofen **except** when:

   i) in a primary pack containing not more than 15 millilitres; and

   ii) labelled only for the treatment of adults over 18 years.

Materials considered

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

- The application to amend the current Poisons Standard with respect to flurbiprofen (the **Application**);
- The 35 public submissions, including five written submissions, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the 36th meeting of the Advisory Committee on Medicines Scheduling (the **Committee**);
- The nine public submissions, including two written submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of the *Therapeutic Goods Act 1989* (Cth) (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 Scheduling Policy Framework 2018 (the **SPF**), pursuant to paragraph 52E(2)(a) of the Act; and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

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

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to flurbiprofen. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses after the second call for public submissions, published on 11 March 2022 under regulation 42ZCZP of the Regulations. I note two written submissions were received, one supportive and one opposing the interim decision.

I have considered the matters raised in the opposing submission, in particular that easing restrictions on the supply of flurbiprofen would enable use beyond a period that is considered reasonable for symptoms of a sore throat to resolve and would warrant review by a healthcare professional. Consistent with my interim decision, I am of the opinion that the safety profile and risk of toxicity from low dose flurbiprofen throat spray is comparable to that of flurbiprofen lozenges, which are already available for general sale and present a similar risk to the throat spray in this regard. Therefore, I confirm my interim decision to amend the Schedule 2 entry for flurbiprofen in the Poisons Standard.

Implementation date

1 June 2022.

3 Final decisions on proposed amendments referred to the Advisory Committees on Medicines and Chemicals Scheduling in joint session (ACMS-ACCS #29, November 2021)

3.1 Final decision in relation to cis-jasmone

Proposal

The applicant proposed the creation of new entries in Schedule 5 and Schedule 6 for cis-jasmone for agricultural use.

Final Decision

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

Schedule 5 – New Entry

CIS-JASMONE when prepared and packaged as an agricultural chemical **except** when present as a fragrance.

Index – New Entry

CIS-JASMONE
cross reference: (Z)-JASMONE

Schedule 5

Materials considered

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

- The application to amend the current Poisons Standard with respect to cis-jasmone (the **Application**);
- The 23 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations.
- The advice received from the 29th meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the **Committee**);
- The eight public submissions, including one written submission, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989* (Cth) (the **Act**), in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (f) any other matters considered necessary to protect public health;
- The Scheduling Policy Framework 2018 (the **SPF**); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

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

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to cis-jasmone. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses after the second call for public submissions, published on 11 March 2022 under regulation 42ZCZP of the Regulations. I note that the one written submission received was supportive of the interim decision.

Implementation date

1 June 2022.

3.2 Final decision in relation to meloxicam

Proposal

The applicant proposed the creation of a new Schedule 6 entry for meloxicam that captures injectable preparations, at up to 2 per cent concentration, for the pre-surgical treatment of sheep undergoing husbandry procedures.

Final Decision

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

Materials considered

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

- The application to amend the current Poisons Standard with respect to meloxicam (the **Application**);
- The 333 public submissions, including 232 written submissions, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the 29th Meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the **Committee**);
- The 13 public submissions, including five written submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989* (Cth) (the **Act**), in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health;
- The Scheduling Policy Framework 2018 (the **SPF**); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

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

I have made a final decision to confirm my interim decision that no change be made to the current Poisons Standard with respect to meloxicam. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses after the second call for public submissions, published on 11 March 2022 under regulation 42ZCZP of the Regulations. I note that five written submissions were received: one supportive and four opposed to the interim decision.

I have considered the opposing submissions, in particular comments on the difficulty of timely access to products containing meloxicam and veterinarian advice. However, I consider that currently there is no evidence before me substantiating that barriers to accessing meloxicam for veterinary use are significant so as to outweigh the risks associated with the applicant's proposed amendment to the Poisons Standard. Furthermore, the removal of the oversight (including appropriate advice and counselling) from a veterinarian has the potential to increase the number of adverse events associated with the use of injectable meloxicam in a veterinary setting. Therefore, I confirm my interim decision to not amend the Poisons Standard with respect to meloxicam.

3.3 Final decision in relation to choline salicylate

Proposal

The applicant proposed the creation of a new Schedule 3 entry for choline salicylate for human therapeutic or cosmetic use. Choline salicylate is currently captured in the Poisons Standard as a derivative of salicylic acid, and dermal preparations containing greater than 40 per cent of salicylic acid are captured in Schedule 3. Other dosage forms and lower concentration dermal preparations are not currently scheduled.

Final Decision

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

Schedule 2 – New Entry

CHOLINE SALICYLATE for oromucosal preparations.

Index – New Entry

CHOLINE SALICYLATE

Schedule 2

Materials considered

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

- The application to amend the current Poisons Standard with respect to choline salicylate (the **Application**);
- The 28 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the 29th meeting of the Advisory Committee on Medicines and Chemicals Scheduling in joint session (the **Committee**);
- The ten public submissions, including four written submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of the *Therapeutic Goods Act 1989* (Cth) (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 Scheduling Policy Framework 2018 (the **SPF**), pursuant to paragraph 52E(2)(a) of the Act; and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

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

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to choline salicylate. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses after the second call for public submissions, published on 11 March 2022 under regulation 42ZCZP of the Regulations. I note four written submissions were received: one supportive, one partially supportive and two opposing the interim decision.

I have considered the points raised in the opposing and partially supportive submissions, in particular that the scheduling of choline salicylate should be qualified according to indications for use or labelled age restrictions. I note that this approach has recently been considered by the regulator in New Zealand, however I maintain concerns regarding the possible risks presented by this approach. Under a scheduling entry qualified by indications, a product marketed for

mouth ulcers would be available by general sale (such as in supermarket and convenience stores) with different labelling and no instructions for use in teething, in contrast to an identically formulated product indicated for teething pain that is available for pharmacy sale only. I am of the view, consistent with my interim decision, that this situation would lead to consumer confusion and pose an unacceptable risk, due to the likelihood that the product that is not scheduled may be used for teething despite the lack of corresponding instructions. Therefore, I consider that placing all oromucosal preparations containing choline salicylate in Schedule 2 is necessary to protect the safety of consumers.

Any safety concerns regarding products containing levels of choline salicylate above 10 per cent, which are regulated as prescription only medicines in New Zealand, would be mitigated during the evaluation process by the product regulator. I note that there are currently no registered products on the Australian market that contain these levels of choline salicylate.

I agree with the submissions that suggested a longer time period is required to allow for a more orderly and cost-efficient transition, and for this reason I have changed the implementation date to 1 October 2023.

Implementation date

1 October 2023

4 Final decisions on proposed amendments referred to the Advisory Committee on Chemicals Scheduling (ACCS #32, November 2021)

4.1 Final decision in relation to chromates and chromium trioxide

Proposal

The applicant proposed that the Schedule 6 entries for chromates and chromium trioxide be amended to exclude articles where the proportion of chromates (or chromium) does not exceed 0.1% w/w of the article. In this application 'chromates' refers to three hexavalent chromium-containing compounds: dichromium tris (chromate), strontium chromate and chromic acid.

Final Decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate has made a final decision to vary the Appendix A entry from the interim decision and amend the current Poisons Standard as follows:

> **Appendix A – New Entry**
>
> TREATMENT LAYERS OF COATED METAL ARTICLES **except** articles intended for use in the collection of drinking water when not compliant with the health and safety requirements of the Australian Standard AS 4020:2018 *Testing of products for use in contact with drinking water.*

Materials considered

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

- The application to amend the current Poisons Standard with respect to chromates and chromium trioxide (the **Application**);

- The 21 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the 32nd meeting of the Advisory Committee on Chemicals Scheduling in joint session (the **Committee**);
- The seven public submissions, including one written submission, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (f) any other matters considered necessary to protect public health;
- The Scheduling Policy Framework 2018 (the **SPF**), pursuant to paragraph 52E(2)(a) of the Act; and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

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

I have made a final decision to vary the Appendix A entry with respect to treatment layers of coated metal articles in my interim decision to amend the current Poisons Standard. My reasons for making the final decision are those set out in the interim decision and the reasons for the variation are set out below. In making my final decision, I have taken into account the material detailed in the interim decision and the responses after the second call for public submissions, published on 11 March 2022 under regulation 42ZCZP of the Regulations. I note one written submission was received from the applicant that was partially supportive of the interim decision.

I have considered the reasoning provided in this submission to amend the exceptions in the Appendix A entry in my interim decision and agree that the wording be amended as indicated above. As identified in the interim decision, the main health concern regarding these materials is the possible leaching of chromates into rainwater which can then be collected for drinking. The amended wording ensures that coated metal articles that are not intended for the collection of drinking water will be correctly exempted from scheduling considerations, and ensure that articles intended for the collection of drinking water are only exempted from scheduling if they comply with the requirements of Australian Standard AS/NZS 40202 *Testing of products for use in contact with drinking water*.

Implementation date

1 October 2023