Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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

15 December 2023

Contents

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

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

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

Defined terms

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

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

Note: additional terms are also defined for individual decisions.

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

Final decisions on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #42, June 2023)

Final decision in relation to bisacodyl

Proposal

The applicant proposed the creation of a new Schedule 2 entry for bisacodyl for oral use except in divided preparations in packs containing 20 tablets or less (the **Proposal**). Bisacodyl is a laxative that is not currently scheduled. The proposed amendment would restrict all oral preparations of bisacodyl to pharmacy sale, except packs of 20 tablets or less which would still be available for purchase from supermarkets and convenience stores.

Final decision

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

Schedule 2 – New entry

BISACODYL:

a) in divided preparations for oral use **except** in a primary pack containing 20 dosage units or less containing 5 mg or less of bisacodyl per dosage unit; or

b) in divided preparations for rectal use **except:**

(i) in a primary pack containing 12 dosage units or less suppositories containing 10 mg or less of bisacodyl per dosage unit; or

(ii) in a primary pack containing 25 dosage units or less enemas containing 10 mg or less of bisacodyl per dosage unit.

Index – New entry

BISACODYL
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 bisacodyl (the **Application**)

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

- the 9 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 42nd meeting of the Advisory Committee on Medicines Scheduling (the **Committee**)[3]
- the interim decision relating to bisacodyl and the materials considered as part of the interim decision, as published on 5 October 2023
- the 2 public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the **Submissions**)
- subsection 52E(1) of the 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 (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to bisacodyl. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material in the interim decision and the 2 public submissions, which were both in support of the interim decision, which were received in response to the interim decision consultation.

As outlined in my interim decision, I acknowledge the concerns in relation to the potential public risks associated with senna and other stimulant laxatives. There is insufficient evidence before me at present to consider changes to the scheduling of these substances. I welcome any application to amend the Poisons Standard in relation to other stimulant laxatives if supported by sufficient scientific and clinical evidence.

I have considered the requests for a delay to the implementation date for this decision and also an additional transition period, similar to the supply arrangements that were enacted for the re-scheduling of codeine in February 2018. I note that the decision on codeine affected a significantly greater number of products in the Australian market compared to this decision on bisacodyl. Further, the continuation of supply of bisacodyl-containing products in response to a scheduling change is regulated by the legislation of individual states and territories, and the Poisons Standard is not the appropriate mechanism to implement a transition period. However, I acknowledge the implementation date of 1 October 2024, which provides a period of approximately 10 months from the date of publication, may cause disruption to the supply of bisacodyl-containing products due to the implementation of packaging changes in response to the decision. As such, I have made a final decision to extend the implementation date to 1 February 2025.

Implementation date

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

1 February 2025

Final decision in relation to olopatadine

Proposal

The applicant proposed the creation of a new Schedule 2 entry for olopatadine when combined with mometasone in aqueous nasal sprays with limitations on dose per actuation and maximum recommended daily dose, for the short-term treatment of allergy conditions in patients aged 12 and over (the **Proposal**). Olopatadine is an antihistamine that is currently available by prescription only (Schedule 4).

Final decision

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

Schedule 4 – Amend Entry

OLOPATADINE **except** when included in Schedule 2.

Schedule 2 – New Entry

OLOPATADINE in preparations for nasal use delivering 600 micrograms or less of olopatadine per dose when the maximum recommended daily dose is no greater than 4,800 micrograms for the treatment of allergic rhinitis or rhinoconjunctivitis for up to 6 months in adults and children 12 years of age and over.

Index – Amend Entry

OLOPATADINE
Schedule 4
Schedule 2

ANTIHISTAMINES
cross reference: ASTEMIZOLE, AZELASTINE, BILASTINE, CETIRIZINE, DESLORATADINE, FEXOFENADINE, LORATADINE, OLOPATADINE, TERFENADINE

Schedule 4
Appendix F, clause 4

[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.

Appendix F, clause 4 – Poisons that must be labelled with warning statements and safety directions		
Item	Poison	Warning statement item number
23	Antihistamines not separately specified in this Appendix **except** the following: (a) dermal, ocular, parenteral and paediatric preparations; (b) oral preparations of astemizole, azelastine, bilastine, cetirizine, desloratadine, fexofenadine, loratadine or ternadine; (c) nasal preparations of azelastine or olopatadine; (d) preparations for the treatment of animals	**39** – This medication may cause drowsiness. If affected, do not drive a vehicle, or operate machinery. Avoid alcohol. Or **40** – This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.

Materials considered

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

- the application to amend the current Poisons Standard with respect to olopatadine (the **Application**)
- the 8 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 42nd meeting of the Advisory Committee on Medicines Scheduling (the **Committee**)[5]
- the interim decision relating to olopatadine and the materials considered as part of the interim decision, as published on 5 October 2023
- the 2 public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the **Submissions**)
- the Australian Register of Therapeutic Goods (ARTG)
- 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; and (d) the dosage, formulation, labelling, packaging and presentation of a substance.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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

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

I have made a final decision to vary my interim decision and amend the current Poisons Standard to include rhinoconjunctivitis (the simultaneous presentation of allergic rhinitis and allergic conjunctivitis) as a permitted indication in the manner detailed above. I have also revised the proposed Appendix F entry to exclude nasal preparations of olopatadine instead of oral preparations to align with the new Schedule 2 entry. Consistent with my interim decision, I have decided to create a new Schedule 2 entry which will allow supply of olopatadine as a 'Pharmacy Only' medicine (Schedule 2) in certain formulations for patients 12 years of age and over.

In reaching my final decision, I have considered the 2 written public submissions received in response to the interim decision consultation. I note that both submissions partially supported the interim decision.

I acknowledge the concerns raised by the Pharmacy Guild of Australia, which suggested that a Schedule 3 entry for olopatadine may be more appropriate as the medicine is proposed to be used to treat allergic rhinitis, a chronic condition that may require monitoring by a health professional. However, as outlined in the interim decision, I am not persuaded that the quality use of the medicine cannot be achieved as a 'Pharmacy Only' medicine (Schedule 2). Further, many medicines for the treatment of allergic rhinitis are already available in Schedule 2 preparations.

I have noted the private submission that suggested inclusion of rhinoconjunctivitis as a permitted indication in the proposed Schedule 2 entry. The submission highlighted that consumers can recognise the symptoms of rhinoconjunctivitis as allergic rhinitis co-presents very frequently with allergic conjunctivitis.

Considering these views and pursuant to s 52E(1)(a) and (b) of the Act, I have reconsidered the relative risks of olopatadine when used for rhinoconjunctivitis. As expressed in my interim decision, the risk profile for olopatadine is low and well defined. I note several other Schedule 2 antihistamine substances are already listed on the Australian Register of Therapeutic Goods (ARTG) for the treatment of allergic rhinitis or allergic conjunctivitis, the two aspects of rhinoconjunctivitis.

The availability of a 'Pharmacy Only' medicine (Schedule 2) for rhinoconjunctivitis aligns with the SPF and supports the inclusion of this indication in the new Poisons Standard entry for olopatadine. I am confident that consumers can successfully recognise the symptoms of rhinoconjunctivitis, which is unlikely to be confused with other more serious conditions. Consistent with my interim decision, I am of the view that a Schedule 2 classification will provide opportunity for patients to be screened, assessed, and counselled where necessary. In addition, I affirm my interim decision that it is not unusual for both a first- and second-line treatment to be available in a pharmacy. I have therefore decided to vary my interim decision to include rhinoconjunctivitis in the Schedule 2 entry for olopatadine.

Implementation date

1 February 2024

Final decisions on proposed amendments referred to the Advisory Committees on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #34, June 2023)

Final decision in relation to ibotenic acid

Proposal

The applicant proposed the creation of a new Schedule 4 entry for ibotenic acid for therapeutic use and a new Schedule 7 entry to capture all other use of the substance (the **Proposal**). Ibotenic acid is not currently listed in the Poisons Standard.

Final decision

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

Schedule 9 – New entry

IBOTENIC ACID

Index – New Entry

IBOTENIC ACID
cross reference: MUSCIMOL

Schedule 9

Materials considered

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

- the application to amend the current Poisons Standard with respect to ibotenic acid (the **Application**)
- the 8 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 34th meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the **Committee**)
- the interim decision relating to ibotenic acid and the materials considered as part of the interim decision, as published on 5 October 2023

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

- the 3 public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the **Submissions**)
- subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to ibotenic acid. My reasons for making the final decision are those set out in the interim decision, and where applicable are also noted below.

In making my final decision, I have considered the material in the interim decision and the 3 public submissions received in response to the interim decision consultation.

I have considered the requests in one of the public submissions for a new Schedule 8 entry for ibotenic acid. The submitter proposed that the Schedule 8 entry is intended to facilitate access for research purposes and to accommodate any future applications for registration of medical devices containing the substance as an excipient.

However, Schedule 9 exists within the Poisons Standard to allow access to a substance for research purposes. Inclusion of a Schedule 8 entry for this purpose is therefore not required and inconsistent with the scheduling of other substances which have been deemed to present such risks to human health as to only permit access for research. Furthermore, as there are no registered medical devices containing ibotenic acid as an excipient, there is currently no reason to create a scheduling entry specifically in anticipation of such an application being approved. Should an application for the registration of a medical device or a medicine containing the substance be received by the TGA, there would further opportunity to review the scheduling of ibotenic acid.

Further, I find that the comparison to the Schedule 8 entry for cannabis is not valid. At the time that the Schedule 8 entry for cannabis was introduced into the Poisons Standard, there was emerging evidence of the therapeutic value of cannabis for certain medical conditions. Combined with a relatively limited acute toxicity profile, it was appropriate to include cannabis in Schedule 8 under strict conditions. By contrast, given its neurotoxicity and the lack of clinical evidence demonstrating the therapeutic value of ibotenic acid at this time, the inclusion of ibotenic acid in Schedule 8 is not supported as the risks outweigh the benefits of such a scheduling classification.

Muscimol is the active metabolite of ibotenic acid and is also a psychedelic neurotoxin. I have noted the claim of Generally Recognised As Safe (GRAS) status in the USA is related to a proprietary mushroom (*Amanita muscaria*) extract. This GRAS status does not pertain specifically to muscimol and was not assessed by a government regulatory body. For these reasons, I consider that this information is not relevant to the consideration of ibotenic acid safety under the Poisons Standard.

I have also considered the cross-referencing of ibotenic acid in the Poisons Standard with muscimol. Muscimol is a Schedule 9 substance due to its toxicity, potential for abuse and its lack of therapeutic value. Therefore, muscimol is not permitted for use outside of a research setting. I consider these characteristics to be shared by ibotenic acid, and therefore it is appropriate to cross reference the two similar substances in the Poisons Standard.

Implementation date

1 February 2024

Amendments to the Poisons Standard in relation to NCEs

The NCEs listed below will be included in the new Poisons Standard that will come into effect on 1 February 2024.[7]

Nirsevimab

Schedule 4 – New Entry

NIRSEVIMAB

Index – New Entry

NIRSEVIMAB

Schedule 4

Tislelizumab

Schedule 4 – New Entry

TISLELIZUMAB

Index – New Entry

TISLELIZUMAB

Schedule 4

[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.

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