Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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

18 November 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 and Aged Care (the **Delegate**) pursuant to regulation 42ZCZR;
- the reasons for those final decisions; and
- the date of effect of those decisions

# 2 Final decisions on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #37, March 2022)

## 2.1 Final decision in relation to azelastine and fluticasone propionate

### *Proposal*

The applicant proposed amendments to the current Schedule 2 Poison Standard entries for azelastine and fluticasone propionate to include additional specific entries for fixed-dose combination (FDC) products containing both these substances for use up to 6 months duration (the **Proposal**). The Proposal is made in the context that FDC products containing these substances that are not indicated for a limited period of use are currently included in the Australian Register of Therapeutic Goods (ARTG) as prescription-only medicines.

### *Final decision*

Pursuant to regulation 42ZCZR of the Therapeutic Goods Regulations 1990 (Cth) (the **Regulations**), a delegate of the Secretary of the Department of Health and Aged Care (the **Delegate**) has made a final decision to not amend the current Poisons Standard in relation to azelastine and fluticasone.

### *Materials considered*

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

- The application to amend the current Poisons Standard with respect to azelastine and fluticasone propionate (the **Application**);
- The 25 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The 5 public submissions, with 4 written submissions, received in response to the Interim decision consultation under regulation 42ZCZP of the Regulations (the **Submissions**);
- The advice received from the 37th meeting of the Advisory Committee on Medicines Scheduling (the **Committee**);
- 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**); 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 not amend the current Poisons Standard with respect to azelastine and fluticasone propionate. My reasons for making this final decision are those set out in the interim decision.

In making my final decision, I have taken into account the Submissions, 2 of which were fully supportive of my interim decision, 2 partially supportive and one opposed. Of those responses that were not fully supportive, only the 2 that were partially supportive were written; my consideration of the one response in opposition is limited to noting it, due to the lack of a written component.

The 2 expressions of partial support were indicated by survey buttons, with the written components of these submissions clarifying that the interim decision was not opposed or there were several reasons for supporting the interim decision. These reasons included the potential for misdiagnosis and associated misuse of the substances, leading to worsening of disease state and overlooking more severe illnesses such as pneumonia, were the scheduling to be amended to permit Schedule 2 FDC products with open-ended durations of use.

As such, the written comments lend weight to my interim decision and there are no compelling reasons presented to depart from my interim decision. I have therefore made a final decision that affirms my interim decision to not amend the current Poisons Standard in relation to FDC products containing azelastine and fluticasone.

# 3 Final decisions on proposed amendments referred to the Advisory Committees on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS meeting #30, March 2022)

## 3.1 Final decision in relation to cannabis and tetrahydrocannabinols

### *Proposal*

The applicant proposed the creation of new Schedule 7 and Appendix J entries for cannabis and tetrahydrocannabinols (THCs) for use specifically in analytical and scientific research (the **Proposal**). This would allow use of cannabis and its derivatives in research without the controls imposed under Schedule 9, which can include specific approval from State and Territory health departments.

### *Final decision*

Pursuant to regulation 42ZCZR of the Therapeutic Goods Regulations 1990 (Cth) (the **Regulations**), a delegate of the Secretary of the Department of Health and Aged Care (the **Delegate**) has made a final decision to not amend the current Poisons Standard in relation to cannabis and THCs.

### *Materials considered*

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

- The application to amend the current Poisons Standard with respect to cannabis and THCs (the **Application**);
- The 56 public submissions, with 4 written submissions, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**);

- The 5 public submissions, with four 4 written submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the **Submissions**);
- The advice received from the 30th meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the **Committee**);
- 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**); 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 not amend the current Poisons Standard with respect to cannabis and THCs. 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 Submissions, one out of 5 of which was opposed to my interim decision.

I recognise the evidence base of the individual constituents of cannabis is growing and note that cannabidiol is included in Schedules 3 and 4 of the Poisons Standard. I acknowledge that alternative scheduling options for specific cannabinoids may be considered in future and that a Schedule 9 entry may be problematic for researchers. However, the benefit of increased access for use in research does not outweigh the risk to public health.

With respect to meeting the Scheduling Factor criteria, I acknowledge that the toxicity data for this substance meets the Schedule 7 scheduling factors. However, given the current evidence for the benefits of the substance weighed against the risk of diversion, abuse and misuse, and Australia's obligation when a substance is included in Schedule IV to the United Nations Single Convention on Narcotic Drugs, 1961, my current view is the substance is better aligned with the Schedule 9 factors.

## 3.2 Final decision in relation to lead

***Proposal***

The applicant proposed the following changes to the entries for lead and lead compounds (the **Proposal**) that they stated would prohibit the presence of lead in any of the specified products:

- the entries in Schedules 4, 5 and 6 be removed;
- preparations including medicines and cosmetics that contain lead be captured in an expanded Schedule 10 entry; and
- amendments aimed at reducing or eliminating lead in consumer products are made to Appendix A for printing inks or ink additives, Appendix B for metallic lead, and the entries for lead compounds in Appendices E and F.

### *Final decision*

Pursuant to regulation 42ZCZR of the Therapeutic Goods Regulations 1990 (Cth) (the **Regulations**), a delegate of the Secretary of the Department of Health and Aged Care (the **Delegate**) has made a final decision to amend the current Poisons Standard in relation to lead as follows:

**Schedule 10 – Amend entry**

LEAD COMPOUNDS:

a) in anti-fouling or anti-corrosive paints except in preparations containing 0.1 per cent or less of lead calculated on the non-volatile content of the paints; or
b) in paints (other than anti-fouling or anti-corrosive paints), tinters, inks or ink additives **except** in preparations containing 0.009 per cent or less of lead calculated on the non-volatile content of the paint, tinter, ink or ink additive; or
c) for human therapeutic use **except** in preparations containing 10 mg/kg or less of lead.

**Schedule 6 – Amend entry**

LEAD COMPOUNDS **except**:

a) ~~when included in Schedule 4;~~when included in, or expressly excluded from, Schedule 10;
b) ~~in paints, tinters, inks or ink additives;~~
c) in preparations for cosmetic use containing ~~100~~10 mg/kg or less of lead;
d) in pencil cores, finger colours, showcard colours, pastels, crayons, poster paints/colours or coloured chalks containing ~~100~~25 mg/kg or less of lead;
e) in ceramic glazes when labelled with the warning statement:

CAUTION – Harmful if swallowed. Do not use on surfaces which contact food or drink.

written in letters not less than 1.5 mm in height.

**Schedule 4 – Delete entry**

~~LEAD for human therapeutic use.~~

**Appendix A – Amend Entry**

PRINTING INKS or INK ADDITIVES **except**:

a) when containing a pesticide; or
b) preparations containing more than ~~0.1~~0.009 per cent of lead calculated on the non-volatile content of the ink or ink additive.

**Appendix F, Part 3 – Amend Entry**

LEAD COMPOUNDS

a) in hair cosmetics: Warning statement 25 (Do not use on broken skin. Wash hands thoroughly after use.)

b) when in Schedule 6 preparations that are not hair cosmetics: Safety directions 1 (Avoid contact with eyes), 4 (Avoid contact with skin) and 8 (Avoid breathing dust (or) vapour (or) spray mist.)

**Index – Delete entry**

~~**LEAD**~~
~~cross reference: GLAZING PREPARATIONS, PRINTING INKS or INK ADDITIVES, SELENIUM~~

~~Schedule 4~~

### *Materials considered*

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

- The application to amend the current Poisons Standard with respect to lead (the **Application**);
- The 28 public submissions, including 6 written submissions, that were received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The 6 public submissions, all written submissions, that were received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the **Submissions**);
- The advice received from the 30th meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the **Committee**);
- Australian/New Zealand Standard AS/NZ 2904:1995 *Damp-proof courses and flashing*;
- The 2022 edition of the National Construction Code;
- The Trade Practices Act 1974, Consumer Protection Notice No. 1 of 2009;
- The Health Canada Guidance on Heavy Metal Impurities in Cosmetics;
- The United States Food and Drug Administration Guidance on Lead in Cosmetic Lip Products and Externally Applied Cosmetics;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989* (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 lead. 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 Submissions as follows.

I note that with regard to the submissions on Schedule 4 entry being moved to Schedule 10 that the change applies only to preparations for human therapeutic use. As currently there are no Schedule 4 products containing lead on the ARTG, it is expected that there will be no impact on currently available products by moving this entry to Schedule 10. Further and as noted in my interim decision, an exemption to the Schedule 10 entry for human therapeutic use for preparations containing 10 mg/kg or less of lead aligns with the *Therapeutic Goods (Permissible Ingredients) Determination (No. 3) 2020*, which allows the presence of lead as an active homeopathic ingredient at a concentration of no more than 0.001%. A value of 10 mg/kg is equivalent to 0.001% w/w or 10 ppm. This value would also account for the adventitious presence of lead in some therapeutic ingredients.

With regards to the submission on anti-fouling paints, I acknowledge the comments received regarding the potential issues with implementation of this decision (which was published in September 2021). I note that 2 rounds of consultation on this matter have already been conducted in 2021 and further information as provided by industry. Given the breadth of changes and as noted in my interim decision, the implementation of these amendments to the Poisons Standard will not come into force until 1 October 2023.

***Proposed implementation date***

**1 October 2023**

## 3.3 Final decision in relation to meloxicam

***Proposal***

The applicant proposed the creation of a new Schedule 6 entry for oral transmucosal preparations of meloxicam, at concentrations of up to 1 per cent for pre-surgical treatment and pain management during routine animal husbandry procedures (the **Proposal**). This would enable access to certain preparations of meloxicam, for use in animals, without a prescription.

***Final decision***

Pursuant to regulation 42ZCZR of the Therapeutic Goods Regulations 1990 (Cth) (the **Regulations**), a delegate of the Secretary of the Department of Health and Aged Care (the **Delegate**) has made a final decision to amend the current Poisons Standard substantially in line with the Proposal as follows:

**Schedule 6 – New Entry**

MELOXICAM in oral transmucosal preparations containing 1 per cent or less meloxicam for pre-surgical treatment and pain management in livestock during routine animal husbandry procedures.

**Schedule 4 –Amend Entry**

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

**Index – Amend Entry**

**MELOXICAM**

Schedule 6
Schedule 4

### *Materials considered*

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

- The application to amend the current Poisons Standard with respect to meloxicam (the **Application**);
- The 393 public submissions, with one hundred and 143 including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The 87 public submissions, with 79 written submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the **Submissions**);
- The advice received from the 30th meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the **Committee**);
- 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**); 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 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 Submissions.

I acknowledge the variety of opinions presented in both sets of public submissions. My overall conclusion is that the benefits from increased access to meloxicam in *oral transmucosal* preparations through a specific Schedule 6 entry outweigh the risks. The Schedule 6 entry may encourage a greater uptake and wider use of meloxicam for animal husbandry procedures, particularly to those who find that the current scheduling of meloxicam is a barrier to providing adequate pain relief measures to their livestock. It will enable reasonable access to a relatively safe medication. I consider that the risks associated with greater access to this substance through this amended scheduling will be mitigated by the various Schedule 6 controls, such as limiting it to oral transmucosal preparations and child resistant packaging. Furthermore, the veterinary medicine regulator will stipulate any specific labelling information including the directions for use, safety directions and any applicable warning statements deemed appropriate, when such products are considered for registration.

### *Implementation date*

**1 February 2023**

## 3.4 Final decision in relation to lidocaine

### *Proposal*

The applicant proposed that the existing Schedule 5 entry for lidocaine be amended to exclude injectable formulations for veterinary use in certain husbandry procedures (the **Proposal**). The proposal effectively sought to reverse the scheduling decision on lidocaine published in September 2021.

### *Final Decision*

Pursuant to regulation 42ZCZR of the Therapeutic Goods Regulations 1990 (Cth) (the **Regulations**), a delegate of the Secretary of the Department of Health and Aged Care (the **Delegate**) has made a final decision to not amend the current Poisons Standard in relation to lidocaine.

### *Materials considered*

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

- The application to amend the current Poisons Standard with respect to lidocaine (the **Application**);
- The 479 public submissions, including 183 with a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The 75 public submissions, with 67 written submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the **Submissions**);
- The advice received from the 30th meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the **Committee**);
- Subsection 52E(1) of *the Therapeutic Goods Act 1989* (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 not to amend the current Poisons Standard with respect to lidocaine. My reasons for making the final decision are those set out in the interim decision.

I have taken into account the Submissions, 6 of which were in support of the interim decision, one was in support with caveats and 68 were opposed.

I acknowledge the variety of opinions presented in both sets of public submissions and recognise the strong advocacy by the veterinary profession to ensure optimal animal care and welfare in Australia, irrespective of their support or otherwise for the proposed amendment to the Poisons Standard. In coming to my final decision, I have given greater weight to the reasons (as outlined in my interim decision) related to the risk to public health and safety, than the potential risk to animals from greater non-veterinary access to lidocaine-based treatments.

I would also like to stress two important aspects of the scheduling of substances under the Poisons Standard. Firstly, the Poisons Standard does not provide for the approval or registration of any particular product containing a scheduled substance. Rather, it can provide for the access to a substance according to the impacts of the presentation or features of a product containing the substance on the risk to users, consumers or patients. For example, presentation of cockroach baits in plastic labyrinths, over the counter medicines packaged in limited pack sizes, low dose dermal gel preparations. In the case of the new Schedule 5 entry for lidocaine, the entry allows for a lidocaine-containing device (product) that meets the product presentation indicated in Schedule 5, to be considered by the veterinary medicine regulator when assessing its registration application.

Secondly, the regulator will be responsible for assessing the overall efficacy, quality and safety of any product as part of its risk assessment. The regulator, the Australian Pesticides and Veterinary Medicines Authority (APVMA) will, as part of its registration process, stipulate any specific labelling information required for the product, including the directions for use, contraindications, safety directions and any applicable warning statements deemed appropriate for such a product. Critically, with respect to the new Schedule 5 entry for a lidocaine-containing device (product), the APVMA will also consider whether it meets the definition of this Schedule 5 entry including whether, in fact, it is tamper-resistant.

# 4 Final decisions on proposed amendments referred to the Advisory Committee on Chemicals Scheduling (ACCS #33, March 2022)

## 4.1 Final decision in relation to flumioxazin

### *Proposals*

Two (2) scheduling proposals were received with respect to flumioxazin.

- The proposal by the first applicant was to amend the Schedule 6 entry for flumioxazin to include liquid preparations that are currently captured by the Schedule 7 entry (the **first proposal**).

- The proposal by the second applicant was to delete the Schedule 6 and Schedule 7 entries for flumioxazin and create a new Schedule 5 entry for all preparations of flumioxazin except water soluble bags in sealed sachets (the **second proposal**), thereby exempting these preparations from scheduling.

### *Final Decision*

Pursuant to regulation 42ZCZR of Therapeutic Goods Regulations 1990 (Cth) (the **Regulations**), a delegate of the Secretary of the Department of Health and Aged Care (the **Delegate**) has made a final decision to not amend the current Poisons Standard in relation to flumioxazin.

### *Materials considered*

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

- The applications to amend the current Poisons Standard with respect to flumioxazin (the **Applications**);

- There were 16 public submissions received for each of the 2 applications, with a written component provided in one and two instances, respectively, for the first and second applications , received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The 2 written public submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations (the **Submissions**);
- The advice received from the 33rd meeting of the Advisory Committee on Chemicals Scheduling (the **Committee**);
- 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; and (d) the dosage, formulation, labelling, packaging and presentation of a substance.
- 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 not amend the current Poisons Standard with respect to flumioxazin.

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 Submissions. However, I have given the greatest weight to the Committee's findings on the relevant provisions of section 52E of the Act with respect to the risks to human health and safety from exposure to flumioxazin.

While I would welcome a future proposal if greater empirical evidence on the safety of the substance were to be made available, the current body of evidence indicates that the risk of significant, irreversible developmental toxicity remains a major concern for human health safety from exposure to flumioxazin. Therefore, there is no clear or compelling reason to amend the current scheduling of flumioxazin.