Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Notice of final decision to amend the current Poisons Standard in relation to bromoxynil

17 April 2024

Confidentiality

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

Contents

1. Notice of final decision made under Regulation 42ZCZV of the *Therapeutic Goods Regulations 1990*

This document constitutes a notice a notice for the purposes of regulation 42ZCZX of the *Therapeutic Goods Regulations 1990* (the **Regulations**). This notice sets out:

- the final decision made by a delegate of the Secretary of the Department of the Health and Aged Care (the **Delegate)** under Regulation 42ZCZW in relation to proposed amendments to the current Poisons Standard which were not referred to an expert advisory committee[1]
- the reasons for the decision
- the date of effect of the amendment (in circumstances where the final decision is to amend the current Poisons Standard).

The final decision follows an application to amend the Poisons Standard in relation to bromoxynil received on 8 February 2024 (the **Application**).

Pursuant to r 42ZCZV of the Regulations, on 2 April 2024, the Delegate:

(a) made an interim decision on the application having regard to the information provided by the applicant, and

(b) provided the applicant a written notice setting out the interim decision and the reasons for the decision, and advised that they may, within the period specified in the notice (not being less than 10 business days after the date of the notice), make a written submission to the Delegate about the interim decisions.

A response to the interim decision was received from the applicant on 11 April 2024. After considering this response, the Delegate is making their final decision to confirm their interim decision in relation to bromoxynil in accordance with r 42ZCZW of the Regulations. In accordance with r 42ZCZX of the Regulations, this notice provides a publication of the Delegate's decision, and the reasons for the decision.

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**)
- the Therapeutic Goods Administration (the **TGA**).

Note: additional terms are also be defined for individual decisions.

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

2. Final decision on proposed amendment not referred to an expert advisory committee

Final decision in relation to bromoxynil

Pursuant to r 42ZCZW of the Regulations, the Delegate has made a final decision to amend the current Poisons Standard in relation to bromoxynil as follows:[2]

Schedule 7 – New Entry

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

Schedule 6 – Amend Entry

BROMOXYNIL in preparations containing 1.5% or less of bromoxynil.

Index – Amend Entry

BROMOXYNIL

Schedule 7
Schedule 6

Implementation date

1 February 2025

Materials considered

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

- the Delegate's final decision dated 4 September 2023 (the **2023 Final Decision**) to amend the current Poisons Standard with regards to bromoxynil
- the application to amend the current Poisons Standard with respect to bromoxynil as specified in 2023 Final Decision but to defer the date of implementation (the **Application**)
- 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 applicant's response to the interim decision, received on 11 April 2024
- the Scheduling Policy Framework 2018 (the **SPF**), and
- the Scheduling handbook: Guidance for amending the Poisons Standard (the **Handbook**).

[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.

Proposal

Currently bromoxynil is included in the Poisons Standard as a Schedule 6 substance. In November 2022, the Delegate received a proposal to create a new entry in Schedule 7 of the Poisons Standard for preparations containing greater than 1% of bromoxynil. On 4 September 2023, after due consideration pursuant to the Act and the Regulations, the Delegate made a final decision to amend the Poison Standard with regards to bromoxynil. The 2023 Final Decision was to:

- create a new Schedule 7 entry for preparations containing more than 1.5% bromoxynil, and
- amend the existing Schedule 6 entry to capture all other bromoxynil preparations.

The Delegate decided that the amendments will come into effect on 1 June 2024.

On 8 February 2024, the Delegate received an application to defer the implementation date for the amendment specified in the 2023 Final Decision with regards to bromoxynil to 1 January 2025.

Interim decision

Pursuant to regulation 42ZCZV of the Regulations, I made an interim decision to amend the current Poisons Standard in relation to bromoxynil as specified in the 2023 Final Decision but with an implementation date of **1 February 2025**. The interim decision was provided to the applicant on 2 April 2024.

My 2023 Final Decision agreed with the advice of the Advisory Committee on Chemicals Scheduling (ACCS 36, March 2023). Further, I did not receive any submissions opposing the proposal or my interim decision to up-schedule bromoxynil (including the implementation date) during the two rounds of public consultation.

In October 2023, a peak body representing stakeholders in the agricultural industry voiced concerns regarding the implementation date of 1 June 2024 for the up scheduling of bromoxynil. These concerns were described in detail in the Application. Other major industry stakeholders have also communicated similar concerns posed by the implementation date of 1 June 2024. The key issues are summarised below:

- Bromoxynil agricultural products are essential to control weeds in key crops such as wheat, oats, barley, rye, linseed and lucerne. The use of bromoxynil is critical in maintaining a reliable, quality supply of sustenance for all Australians.
- Approximately 80–90% of the bromoxynil agricultural products are supplied, purchased and used between May and July. This represents a volume of 800,000 to 900,000 litres (for each of the major suppliers) and the implementation date of 1 June 2024 falls in the middle of the peak use period.
- Compliance with the storage requirements for a Schedule 7 poison poses significant challenges. There are numerous sites around Australia for each of the major suppliers. Each site needs to be evaluated by a safety officer to determine the changes required for storage. The construction or expansion of secure storage facilities required to house the large volume of bromoxynil used during the peak period, is unlikely to be completed by 1 June 2024. This is a human health risk due to potential for unsecured storage of bromoxynil on distribution and/or retail sites.
- Industry noted that the logistics are also complicated by distance, with the majority of bromoxynil agricultural products manufactured on Australia's east coast, while most products are supplied to Western Australia.
- In addition, despite marketing programs that encourage early seasonal purchase of bromoxynil agricultural products for holding on farms, timeframes for purchasing decisions are strongly linked to factors such as favourable weather which contributes to the intensity of supply required during the peak purchase period.

- Other obligations of commercial stakeholders under the relevant state and territory legislation for the storage of Schedule 7 substances, if any, must also be considered. Lack of compliant storage facilities, and transport distances, will have flow on effects on the warehousing, supply and transport across Australia and may lead to product shortage or unavailability during the peak use period.

I also noted that the application did not raise any objections to the 2023 Final Decision to up schedule bromoxynil and only sought to defer the implementation date of that decision. Therefore, I decided not to refer the application to an expert advisory committee.

While it is irregular to alter any final decision to amend the Poisons Standard after it has been published, I recognised the extenuating circumstances in this case should the 2023 Final Decision and its original implementation date of 1 June 2024 be allowed to stand. Therefore, I decided to amend the Poisons Standard with regards to bromoxynil as specified in the 2023 Final Decision, but with an implementation date of 1 February 2025.

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

Pursuant to regulation 42ZCZW of the Regulations, I have made a final decision to confirm my interim decision to amend the Poisons Standard with regards to bromoxynil as specified in the 2023 Final Decision with an implementation date of 1 February 2025.

I have considered the applicant's response dated 11 April 2024 which agrees with my interim decision. I am aware that some suppliers have progressed arrangements to implement product changes in anticipation of the original implementation date of 1 June 2024. I appreciate these efforts and acknowledge that disruptions to work plans that may occur from a deferral. However, in view of the new evidence of the substantial impact of the original implementation date for the up-scheduling of bromoxynil on industry, I have decided to defer the implementation date. While there are no changes from the 2023 Final Decision with regards to the amendments to the entry for bromoxynil, the implementation date of 1 June 2024 will be superseded and deferred to **1 February 2025**.

My decision to delay the implementation of the 2023 Final Decision does not negate the hazards associated with bromoxynil. I retain the concerns raised in the 2023 Final Decision, in particular, the increasing association of bromoxynil with incidents of self-harm. I encourage all holders of bromoxynil products to exercise caution in storing, supplying, and using bromoxynil products in the interim. I encourage suppliers and retail outlets to continue plans to phase out home and garden products containing bromoxynil that will not be consistent with the forthcoming change to the Poisons Standard.

I also encourage all stakeholders affected by scheduling decisions to engage with the public consultations conducted as part of the scheduling of medicines and chemicals. While every effort is made by the decision maker to independently acquire information that inform scheduling decisions, feedback from stakeholders, peak bodies and the wider community is crucial to the decision-making process.

Therapeutic Goods Administration

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