Australian Government
Department of Health
Therapeutic Goods Administration

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

TGA Health Safety Regulation

views expressed in the opposing submissions, I consider that the public health risks of kambo significantly outweigh the claimed benefits.

In making my decision, I have also considered the three written responses that were in favour of the scheduling proposal. I found the concerns raised in these submissions are highly pertinent:

- The Pharmacy Guild noted that the effects of kambo are induced by individual bioactive components/peptides rather than an overreaction of the immune system. This means that even a minimal dose may induce pharmacological effects that can pose a significant health risk.
- The Australian Medical Association outlined that the act of blistering the skin and applying kambo could lead to other health risks such as infection. The submission also raised concerns that using kambo may prevent patients from seeing a medical practitioner, and that there is currently insufficient evidence for its intended therapeutic effects.
- The NSW Poisons Information Centre described the three calls that they had received regarding kambo use since 2018. One patient had complications of infection at the burn sites of application; the second presented to hospital with melaena and persistent vomiting; and the third was diagnosed with oesophageal rupture that required surgical repair.

Having considered the significant risks to users and the lack of established therapeutic benefit, I am of the view that kambo should be included in Schedule 10 of the Poisons Standard.

I agree with the Committee's advice that, in order to provide a simple and enforceable definition, kambo should be regulated as a secretion rather than a list of its component substances. The new entry should include the specific frog species *P. bicolor* in the index as a cross reference.

Proposed implementation date

1 October 2021

3.2 Interim decision in relation to lidocaine

Proposal

The applicant proposed an amendment to expand the current Schedule 5 entry for lidocaine to include specifically targeted injectable solutions, at up to 2% concentration, for the pain relief of lambs or calves undergoing animal husbandry procedures.

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made an interim decision to amend the scheduling of lidocaine in the current Poisons Standard as follows:

> **Schedule 5 – Amend Entry**
>
> LIDOCAINE
>
> a) in aqueous gel preparations containing 4.5 per cent or less of lidocaine, for the dermal spray-on administration to the wounds of animals; or

b) in injectable preparations containing 2 per cent or less of lidocaine when packaged in a bottle with a tamper resistant cartridge which can only be dispensed through a rubber ring applicator for tail docking and castration of lambs; or castration of calves.

Materials considered

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

- The application to amend the current Poisons Standard with respect to lidocaine;
- The 91 public submissions, including 29 written submissions, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the meeting of the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #27);
- Subsection 52E(1) of the *Therapeutic Goods Act 1989,* in particular (a) the risks and benefits of the use of a substance; (b) the purpose 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;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Summary of Joint ACMS-ACCS advice to the Delegate

The Committee advised that the Schedule 5 entry for lidocaine be amended as follows:

Schedule 5 – Amend Entry

LIDOCAINE

a) in aqueous gel preparations containing 4.5 per cent or less of lidocaine, for the dermal spray-on administration to post-surgical wounds associated with 'mulesing' of sheep; tail docking and castration of lambs; or castration and disbudding/dehorning in calves[19]; or

b) in injectable preparations containing 2 per cent or less of lidocaine when packaged in a bottle with a tamper resistant cartridge which can only be dispensed through a rubber ring applicator for tail docking and castration of lambs; or castration of calves.

The Committee also recommended an implementation date of **1 October 2021**.

Members agreed that the relevant matters under Section 52E(1) of the *Therapeutic Goods Act 1989* included (a) the risks and benefits of the use of a substance; (b) the purpose 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.

The reasons for the advice included:

a) the risks and benefits of the use of a substance

[19] Changes to the Schedule 5 entry for lidocaine were incorporated in the 1 February 2021Poisons Standard. These changes are reflected in the delegate's current interim decision.

- Significant benefit to animal welfare for routine animal husbandry measures. The improvement of animal welfare will also benefit the mental health and wellbeing of humans in contact with those animals.

b) the purposes for which a substance is to be used and the extent of use of a substance

- Use is for pain relief for wounds associated with rubber ring applicator for tail docking and castration of lambs; castration of calves.

c) the toxicity of a substance

- Formulated product has low oral and dermal toxicity.

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

- New packaging of an existing product that reduces the risk of inappropriate use.
- The injection of lidocaine can only occur during the application of a rubber ring, which prevents accidental injection or needle stick injury.
- If unintended exposure occurs, the dosage is metered, and is sufficiently low that it would not present a major health concern.

e) the potential for abuse of a substance

- Minimal potential for abuse; less risk than some existing products.

f) any other matters that the Secretary considers necessary to protect public health

- Nil

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

I have made an interim decision to amend the current Schedule 5 entry for lidocaine to include specifically targeted injectable solutions, at up to 2% concentration, for the pain relief of lambs or calves undergoing animal husbandry procedures.

In considering the proposal, I have taken into account the 91 public submissions received in response to the pre-meeting consultation. I note that 29 written submissions were received, 27 fully supportive of the proposed amendment, one partially supportive and one opposed. Supporting submissions addressed the safety of the product, the benefits to animal welfare, and the need for increased access by farmers. I have considered each of these arguments in my interim decision to amend the Poisons Standard, and specifically addressed the opposing submission, as set out below.

I agree with the Committee's finding that the relevant provisions of section 52E of the *Therapeutic Goods Act 1989* are: (a) the risks and benefits of the use of a substance; (b) the purpose 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.

In my view, the relevant parts of the Scheduling Policy Framework (SPF 2018) are the scheduling factors for Schedule 5:

- Lidocaine, in the proposed formulation, has a low oral and dermal toxicity, and has a low potential for causing harm.
- Lidocaine presents a low hazard from repeated use and is unlikely to produce significant toxicity.

- The packaging of the product can appropriately mitigate the risks of injury in handling, storage and use. The product design specifically prevents needle-stick injury and accidental exposure.
- During use in castration and tail docking, lidocaine is capable of causing only minor adverse effects to humans (through accidental exposure).
- Lidocaine has a low potential for causing harm, demonstrated by its long history of safe veterinary use in Australia.

I note that lidocaine is a local anaesthetic with a low toxicity and a long history of safe use in Australian veterinary products. The current proposal relates to a new veterinary use of the substance – as a specifically targeted injectable solution for pain relief during animal husbandry procedures. Though this is a new method of administration, veterinary lidocaine products have had only three reported adverse events[20] [21] since the Australian Pesticides and Veterinary Medicines Authority approved the first product in 2005. These reports are consistent with the known low toxicity of lidocaine, which has been extensively covered in past decisions and committee meetings. The most recent decision on the substance, made in 2020, was to expand the Schedule 5 entry for topical lidocaine products, referencing a low toxicity and low risk to human health. In my view, lidocaine has a favourable safety profile that is consistent with its inclusion in Schedule 5.

While lidocaine does not require specific professional oversight in topical formulations, I acknowledge that injectable substances present a unique set of risks that depend on product packaging. These include a potential for needle-stick injury and accidental exposure that would usually necessitate the presence of a registered practitioner. I also note that the Joint ACMS-ACCS have previously expressed concern that bulk injectable lidocaine could be diverted for inappropriate use. I consider that the application adequately addressed each of these issues, with reference to a specific product design, noting the Committee's findings that:

- The cartridge size is small, and enclosed within a tamper-resistant device. Accessing the solution would take a complex deliberate effort, and require separate equipment for injecting the solution. The potential for diversion for inappropriate use is negligible.
- The injection of lidocaine can only occur during the application of a rubber ring, which precludes use in humans or at sites other than those targeted. The product presents a negligible risk of needle-stick injury or accidental exposure.
- The product dosage is metered. If an accidental human injection occurred, the dosage would be sufficiently low that it would not present a major health concern.

Having considered the applicant's product design against the SPF 2018, I have decided that certain injectable lidocaine products are appropriate for inclusion in Schedule 5. The intent of my interim decision is to capture products with the abovementioned safety features in Schedule 5, while keeping all other forms of injectable lidocaine in Schedule 4. As part of my decision, I have also decided to accept all minor amendments to the applicant's wording that were suggested by the Committee. I consider that these changes will give a more accurate description of the product and reduce ambiguity in interpretation of the schedule entry. In particular, I note that the product is better classified as 'tamper resistant' rather than 'tamper proof'.

I note concerns raised by the Australian Veterinary Association that the lack of tamper proofing, and potentially high availability, may allow inappropriate use that could cause harm to humans

[20] According to: Adverse Experience Reporting Program annual reports | Australian Pesticides and Veterinary Medicines Authority (apvma.gov.au)

[21] The applicant noted that all of these adverse events appear to be caused by other substances in the product.

and animals. However, I consider that the product's tamper resistant packaging sufficiently mitigates risks of diversion, especially given the small cartridge size. I also reiterate that the decision relates to a specific product design with a different safety profile to other injectable anaesthetics. In light of the opposing public submission, I remain of the view that the risks of the substance and product are consistent with their inclusion Schedule 5.

In making my decision, I note that there are growing consumer expectations that farmers minimise animal suffering during castration and tail docking. The use of injectable anaesthetics may provide an effective solution, but currently requires the presence of a veterinarian. Since farmers or contractors tend to administer husbandry procedures themselves, this requirement may lead to increased costs and logistical difficulties that reduce uptake. These challenges may be especially complex for larger operations that castrate or dock hundreds of animals in a day, or for those that live in remote areas without access to well-resourced veterinary clinics. Allowing non-prescription access to injectable lidocaine could reduce these barriers and lead to a significant increase in animal welfare; in doing so, the change may help satisfy consumer expectations and reduce the burden on farmers. In my view, expanding the Schedule 5 entry for lidocaine in this form may significantly benefit Australian farmers and their livestock.

Proposed implementation date

1 October 2021

3.3 Interim decision in relation to hemp seed oil

Proposal

The applicant proposed an amendment to the existing Schedule 9 entries for cannabis and tetrahydrocannabinols to exclude hemp seed oil for oral consumption from scheduling when compliant with the Food Standards Code.

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made an interim decision to amend the scheduling of hemp seed oil in the current Poisons Standard as follows:

CANNABIS

Schedule 9 – Amend Entry

CANNABIS (including seeds, extracts, resins, and the plant and any part of the plant when packed or prepared), **except**:

a) when separately specified in these Schedules; or

b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols and hemp fibre products manufactured from such fibre; or

c) ~~when in~~ hemp seed oil ~~for purposes other than internal human use~~ containing ~~50~~ 75 mg/kg or less of cannabidiol ~~cannabinoids, including~~ and ~~20~~ 10 mg/kg or less of tetrahydrocannabinols.~~, when labelled with either of the following warning statements:~~

~~i) Not for internal use; or~~

~~ii) Not to be taken.~~