Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Attn: Scheduling & Committee Support Section, MDP 122

Via email: medicines.scheduling@health.gov.au

26 January 2022

Dear Sir/Madam,

Re: Public consultation on proposed amendments to the Poisons Standard - ACMS/ACCS/Joint ACMS-ACCS, March 2022

Sheep Producers Australia (SPA) welcomes the opportunity to comment on the proposed poison standard. SPA seeks to make a comment on two substances:

- Item 2.3 Meloxicam; and
- Item 2.4 Lidocaine.

Item 2.3 Meloxicam

SPA **supports** the proposed reclassification of Meloxicam from an S4 to a S6 product, and agrees with the reasons presented by the applicant that it is of low risk of misuse. SPA specifically refers to the fact that it is widely used by farmers, has appropriate labelling and guidance and is dispensed in single dose packaging.

Item 2.4 Lidocaine (Numocaine)

SPA **opposes** the proposed reclassification of lidocaine, from an S5 (Poison) to S4 (Vet Prescription). The active ingredient lidocaine will be referred to in SPA's submission interchangeably with its product name, Numocaine. SPA queries why the proposed amendments to the Poisons Standard is being reconsidered by the TGA, given the TGA recently made a decision on the current classification, and in light of the submission prompting the amendment providing no new information.

SPA reiterates its view that the availability of effective pain relief products is essential for Australian sheep producers to maintain high animal welfare. Whilst requiring a veterinary prescription may be an effective way of regulating some veterinary chemicals, it has been acknowledged by the TGA that it is not a necessary nor appropriate mechanism to reduce the risk of misuse for the Numocaine product. It is also acknowledged that veterinary chemicals pose a degree of human health risk in many cases, but are managed appropriately through a combination of use-of-product warnings, restrictive dispensing technology and

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distribution via limited rural retailers. The regulations imposed by a S5 poison classification are sufficient to mitigate this risk.

In opposing the reclassification of the Numocaine product to a S4 (Vet Prescription), SPA refers to the reasons for the decision published by the delegate in October 2021.

> *"I have also considered the opposing submission, from the Australian Veterinary Association, which argued that the packaging of the drug is not tamper proof and does not prevent misuse. The submission also raised that veterinarians are well placed to prescribe lidocaine, and that rescheduling to Schedule 5 disallows assessment of risks and therapeutic need by a medical professional. I note that many of these points were raised in the pre-meeting consultation and discussed in the interim decision. I reiterate that, though it is better classified as 'tamper resistant' rather than 'tamper proof', the product design sufficiently mitigates the risks of diversion. It is also used for procedures that are typically performed by farmers or contractors, and do not require consultation with a veterinarian. As such, the rescheduling of lidocaine is appropriate"*[1]

Nothing in the current proposed amendment alters the reasons provided in the October 2021 determination. The risk to human health remains the same as if it were a S4 classification – which is minimal. The only difference in rescinding the S5 scheduling decision is that the product will be dearer and more difficult to access for farmers for pain relief for their livestock. Claims of misuse by the applicant can be addressed as follows:

- *The solution can be dispensed into a vessel, and misused*

The packaging remains 'tamper-resistant', meaning that it is difficult, though not impossible, to dispense the solution in ways not consistent with the Schedule 5 entry. The tamper-resistant nature of the dispenser was considered sufficient to minimise risks of misuse in the October 2021 decision and no further evidence has been provided to suggest this risk has increased.

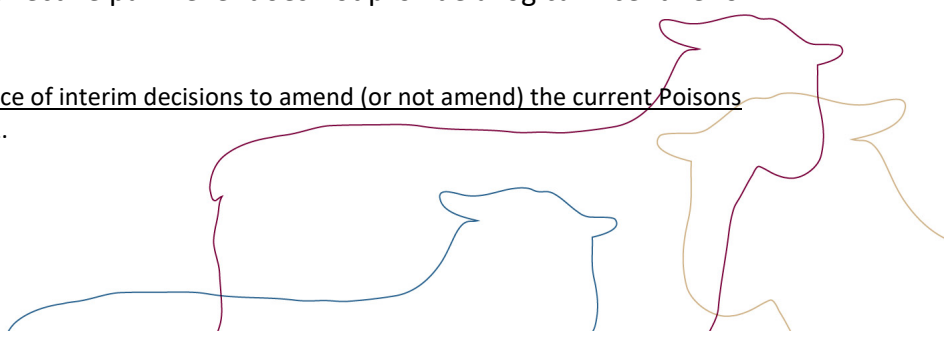
- *The product poses public health risks in the form of being misused for body modification, illicit drug manufacturing, or as a suicide agent*

SPA cannot confirm or deny this particular claim, however, the risk is not changed by virtue of a veterinary prescription. Use of the product for any of these reasons is inconsistent with the regulation, and ought to be managed by law enforcement in the way that any other poison, chemical or drug is. The same claims could be made of household items and other agricultural chemicals that are classified in the S5 regulation.

- *Lidocaine can be used as a masking agent in performance animals or to perform painful acts of veterinary science, with poor animal welfare outcomes.*

Performing complex veterinary surgery on an animal is regulated under animal welfare legislation, and the availability of effective pain relief does not provide a logical incentive for

[1] Therapeutic Goods Administration, Notice of interim decisions to amend (or not amend) the current Poisons Standard (tga.gov.au), October 2021, p12.



individuals to perform such procedures. Moreover, scheduling the product so as to require a veterinary prescription would make no difference to the opportunity that individuals may take to undertake such surgeries. Unless supervised by a veterinarian, which is not required under an S4 classification, it is impossible to know whether the product is being used for lamb marking (as it is intended), complex surgery, or any other reason.

- *Access to lidocaine for use by farmers on livestock is not impeded by the involvement of veterinarians, and veterinary oversight of the quantities and use of the substance is important to mitigate the risks of misuse or diversion.*

Access to pain relief via veterinarians only remains a major impediment for farmers, hence the support by SPA to reschedule the product to an S5 classification last year. Lamb marking does not require veterinary oversight, and farmers require easy access to pain relief chemicals so that they and their contractors can undertake the necessary husbandry procedures to provide for good lifetime welfare outcomes. To effectively manage the risk of misuse, as the applicant has proposed, would involve a veterinary consultation and prescription, the costs of which would be significant. If no consultation is undertaken, then the risks of misuse remain the same, regardless of whether a prescription is sought. To require a prescription only adds unnecessary cost and regulation to what is already a low-risk product.

SPA believes that the TGA made the right decision in October 2021 to reclassify the product to an S5. To reconsider its earlier decision would be detrimental to animal welfare outcomes, while providing no reduction to the risk of misuse. Whilst no risk can be completely eliminated with regards to chemicals and poisons, SPA believes the construction and design of the product and applicator makes the product difficult to abuse.

Should you wish to discuss this submission further, please don't hesitate to contact me on 0412 472 710 or at ceo@sheepproducers.com.au.

Yours sincerely

Bonnie Skinner
Acting Chief Executive Officer
Sheep Producers Australia