Proposed amendment to the Poisons Standard - 3.4 Lidocaine

Submission of the Australian Veterinary Association Ltd

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The Australian Veterinary Association (AVA)

The Australian Veterinary Association (AVA) is the national organisation representing veterinarians in Australia. Our 8,500 members come from all fields within the veterinary profession, including companion animal and livestock clinical practice, and roles in government, public health, industry and academia.

Summary

Re: Proposed amendments to the Poisons Standard – meetings, March 2022.

Section 3.4 Lidocaine: proposes that the existing Schedule 5 entry for lidocaine be amended to exclude injectable formulations for veterinary use in certain husbandry procedures. The proposal effectively seeks to reverse the scheduling decision on lidocaine published in September 2021.

The AVA **supports** the amendment, and a return to a prescription-only Schedule 4 categorisation of all forms of injectable lidocaine. A summary of reasoning follows:

- The AVA was deeply concerned by the decision to make the injectable anaesthetic drug lidocaine available as an over-the-counter product on the S5 Schedule, effective 1.10.21.
- The TGA committee based much of their approval on the assumption that the drug was *"in a bottle with a tamper resistant cartridge which can only be dispensed through a rubber ring applicator"* and thus not a threat to public health.
- The AVA contends that this argument is flawed, as the product is in fact NOT sufficiently tamper-resistant to meet the criteria for Schedule 5:
    - We have provided video evidence separately demonstrating that the cartridge that is applied to the NumOcaine bottle can be easily twisted off by hand or removed with a teaspoon.
    - Alternatively, the lidocaine can be dispensed independently of ring application by activating the pump on the applicator and dispensing the liquid into another receptacle.
- These risks were considered manageable by the veterinary profession when lidocaine was restricted through S4 scheduling. The recent S5 scheduling opens the door for unrestricted access to lidocaine, placing animal welfare and public health at risk. These risks are detailed in the submission and include:
    - risks of toxicity in target and non-target species
    - animal welfare risks due to inappropriate use by lay operators, for example to perform illegal acts of veterinary science (target and non-target species)
    - diversion of use to mask pain and injury in performance animals eg horses and greyhounds
    - use to perform illegal procedures on humans eg illegal body "modifiers"
    - addition to illegal human street drugs such as cocaine
    - use in human suicide.
- The AVA also refutes the statement in the September 2021 scheduling decision that the need for veterinary prescription may lead to "logistical difficulties" and "reduced uptake of the product". There is no impediment to supply by veterinarians, nor was this substantiated by the former applicant.
- A third flaw in the September 2021 scheduling decision was the argument that "*Allowing non-prescription access to injectable lidocaine could …lead to a significant increase in animal welfare*". It does not appear that the TGA committee consulted with animal welfare experts to assess the veracity of that claim. In fact, the research and field experience to-date suggest the pain relief offered by this system is modest and short-lived at best. Given the nature and extended duration of pain associated with use of rubber rings, it can be argued that other methods of castration and tailing are preferable from an animal welfare perspective.

Discussion

We address the relevant matters mentioned in section 52E of the *Therapeutic Goods Act 1989,* on which the TGA is likely to base their decision:

The risks and benefits of the use of a substance

Lidocaine is an important drug to assist in the short-term local anaesthesia in animals undergoing procedures. However, there are known risks associated with its use in humans and in animals. These include overdosage, incorrect administration, toxicity, and diversion to use in other species, including humans (expanded below). For animal patients, veterinary knowledge, training and oversight are required to prescribe appropriately and mitigate these risks.

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

Injectable lidocaine can be used to provide short-term local anaesthesia during some husbandry procedures in animals. Veterinarians fully support and encourage increased use for this purpose, and it is AVA policy that this should occur under veterinary direction.

In the recent TGA decision to reschedule lidocaine to S5, a key argument used to justify the change was the need to make the drug more accessible to farmers. The AVA believes this argument is flawed, and that the former applicant did not demonstrate a gap or any impediment to supply by veterinarians.

Indeed, whenever use is indicated, veterinarians are able to supply S4 medications such as lidocaine by telemedicine or other remote means, once an initial relationship with the client and knowledge of their flock has been established. The NumOcaine preparation is used for routine procedures that are planned well in advance, allowing producers to obtain the correct amount of product from a veterinarian who has knowledge of the farmer's property and business. With effective transport services the rapid provision of product is possible even for the most remote properties.

Prior knowledge of the farmer's flock or herd is important to ensure the drug is being obtained for legitimate purposes, and then ongoing supply by the veterinarian allows for some oversight and monitoring of quantity and use; this is not at all onerous or any impediment to access by the farmer, but is an important safety measure to reduce risk of misuse of the drug or diversion into inappropriate use (for example in humans).

The toxicity of a substance

Injectable lidocaine has a high potential to cause harm with inappropriate administration. Unintentional administration of lidocaine into a blood vessel (intravenously or intraarterially) or administering an excessive dose locally, can lead to toxicity.

The product label on the NumOcaine bottles indicates maximum dose for a sheep is 60mL and does not indicate a safe dose rate for different weight ranges. Lidocaine is toxic to sheep at doses as low as 5mg/kg bodyweight (Morishima et al, 1981) and NumOcaine is 2% lidocaine (20mg/mL), therefore 60mL would be potentially toxic for all sheep weighing less than 240 kg, which is all sheep in Australia.

Inadvertent excessive or repeated dosing of lambs causing lidocaine toxicity could easily occur with NumOcaine. This is because lamb marking in Australia typically occurs when lambs are 2-12 weeks of age and a large proportion are less than 12 kg in weight. The 1.5 mL dose dispensed by the product applicator contains 30mg lidocaine. Therefore, a single dose injected into the scrotum for castration is potentially toxic in lambs up to 6kg.

A double dose of NumOcaine (60mg) where 1.5mL is additionally injected into the tail (for docking) is therefore potentially toxic in lambs up to 12 kg (12kg x 5mg = 60mg).

Also, be aware that Tri-Solfen, a ~4% lidocaine-containing spray-on gel, is sometimes used at lamb marking for pain relief when the Mules operation is performed. Additional topical application of Tri-Solfen to a mulesing wound at lamb marking may potentially increase risk of lidocaine toxicity when used simultaneously with NumOcaine.

NumOcaine and the delivery device are not registered in goats, and field trials on efficacy and safety have not been carried out for goats. There is a testimonial on the product website where someone has used it on their calves and goats. Toxicity can occur with lidocaine in goats (Venkatachalam et al, 2018) as with sheep; however, there is an increased risk as many goats in Australia are miniature and may be less than 6kg when being castrated as kids.

Furthermore, if the NumOcaine bottle has been tampered with or altered to be used for goat disbudding at the same time as castration, this will increase the risk of lidocaine toxicity.

The dosage, formulation, labelling, packaging and presentation of a substance

Note comments above on labelling, dosage and risks of toxicity.

The packaging of the substance is of significant concern, given that the non-reusable, plastic, quick-change cartridge that is applied to the NumOcaine bottle can be easily twisted off by hand or removed with a teaspoon.

Furthermore, the lidocaine can be dispensed independently of ring application by activating the pump on the applicator and dispensing lidocaine into another receptacle.

The TGA have based much of their decision to schedule this as S5 on the assumption that the device is tamper-resistant and thus not a threat to public health. This is NOT the case, and the AVA has separately supplied video evidence of this to the TGA in our application.

Essentially the product is a stand-alone bottle of lidocaine once the cartridge is removed. The wording of the current S5 entry requires that the lidocaine may only be dispensed *through* a rubber-ring applicator. Clearly this product does not meet that criterion.

These risks were considered manageable by the veterinary profession when the lidocaine was restricted through S4 scheduling, and the responsibility for correct use to minimise the animal welfare and public health risk sat with the prescribing veterinarian. The rescheduling to S5 gives unrestricted access to lidocaine, placing animal welfare and public health at risk.

The potential for abuse of a substance

Potential for abuse in animals:

Under the current S5 scheduling, with loss of veterinary oversight, it is highly likely that lidocaine will be used inappropriately by lay persons, placing animal welfare at risk:

1. There is evidence of this occurring already in target species - the product frequently asked questions page includes discussion of NumOcaine use in calves up to 3 months of age, which is considered unacceptable practice from an animal welfare perspective, and contravenes guideline G6.16 in the Cattle Animal Welfare Standards and Guidelines that use over 2 weeks in calves is not recommended.

   In fact, there is footage online for promotional purposes, showing use of this applicator on very mature calves up to 178kg – this is completely unacceptable from an animal welfare perspective.

2. The AVA is very concerned about diversion for use by lay persons to illegally perform painful acts of veterinary science, for example:
   - cattle producers attempting epidurals to correct the commonly occurring vaginal prolapse in Bos indicus cattle;
   - horse owners attempting to desensitise testicles in unsedated colts to castrate them
   - owners attempting invasive surgeries such as caesarians in farm animals (with a recent example of this prosecuted in the Victorian courts)
   - owners of a range of species suturing wounds (for example, dogs used in pig hunting).

3. There is also a very real risk of this drug being used as a masking agent in performance animals (eg horses, greyhounds). Masking a prior injury such as a fracture could result in catastrophic accidents for both the animal and rider in the case of horses.

Potential for abuse in humans:

Diversion of the drug for use in humans poses public health risks, with some examples being:

1. Use as a local anaesthetic by illegal 'body modifiers': Ref: One dead-ABC News- Sep 21
2. Use to dilute cocaine by illegal drug dealers: Ref: Two deaths-NSW Health Aug 21

   Even topical human lidocaine formulations have been recorded as being used to "cut" cocaine by illegal drug suppliers: Ref: How Cutting Drugs Became Big Business. While ever NumOcaine remains available as an S5 drug this illegal activity will be even easier for the black-market trade, given its relatively pure formulation, compared to topical sprays and ointments.

3. As a method of suicide. There are numerous references of fatal lidocaine poisoning in the literature, eg.
   - Acute Lidocaine Toxicity; a Case Series
   - Suicide due to oral ingestion of lidocaine: a case report and review of the literature
   - Fatal Lignocaine Poisoning: Report of Two Cases and Review of the Literature

In conclusion, management of potentially dangerous medications through prescription by veterinarians means that medicines are dispensed for appropriate reasons, to the correct animals, at the correct dose rates, with appropriate advice and labelling, to prevent adverse events, misuse, resistance, and chemical residue issues. Veterinary oversight also allows for investigation of side-effects and adverse events should they occur. With rescheduling to allow unrestricted access, veterinary oversight is lost, posing an unacceptable risk to animals and the public. **We therefore strongly support the proposal to remove injectable lidocaine from the Schedule 5 entry in the Poisons Standard.**

References

1. Victorian woman prosecuted for performing illegal caesareans on sheep_2019
2. Ref: One dead-ABC News- Sep 21
3. Ref: Two deaths-NSW Health Aug 21
4. Acute Lidocaine Toxicity; a Case Series
5. Suicide due to oral ingestion of lidocaine: a case report and review of the literature
6. Fatal Lignocaine Poisoning: Report of Two Cases and Review of the Literature
7. Morishima et al., 1981. Toxicity of lidocaine in adult, newborn and fetal sheep. Anesthesiology 55:57-61.
8. Venkatachalam et al, 2018. Toxicity and Pharmacokinetic Studies of Lidocaine and Its Active Metabolite, Monoethylglycinexylidide, in Goat Kids. Animals 2018: 8, 142.

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