



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**

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26 November 2021

Senator Susan McDonald
Chair
Rural and Regional Affairs and Transport Legislation Committee
Parliament House
CANBERRA ACT 2600

via rrat.sen@aph.gov.au

Dear Senator

The Australian Pesticides and Veterinary Medicines Authority (APVMA) provided the Rural and Regional Affairs Transport (RRAT) Legislation Committee a response at the Supplementary Senate Estimates hearing 26 October 2021, in relation to a recent Therapeutic Goods Administration (TGA) scheduling decision on lidocaine (also known as lignocaine).

To assist the Committee, the APVMA offers the following background information.

Lidocaine products are local anaesthetics. Currently, the only injectable lidocaine products available for sale are included in Schedule 4, and are therefore only available for use by a veterinary surgeon, or on prescription from a vet. Other forms of lidocaine for use in animal husbandry are already included in Schedule 5 and are available without prescription or advice from a veterinary surgeon.

The recent decision by the TGA to amend the Poisons Standard will allow the sale of certain injectable products to users directly without the requirement to seek advice from a veterinary surgeon. While there may be no statutory impediment to the distribution of the products through a range of retail outlets, owing to the specific nature of the products the APVMA does not expect them to become available for sale in supermarkets.

The TGA decision follows application for an amendment to update the entry for lidocaine (also known as lignocaine) in Schedule 5 of the Poisons Standard to include an injectable form of lidocaine.

The Schedule 5 entry now reads:

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 container 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 recent amendment added part 'b' to this entry, which previously included only the aqueous gel preparations. Other forms of injectable lidocaine for animal treatment remain in Schedule 4.

The APVMA has a role in the scheduling of substances as part of the assessment of applications made to the APVMA. The APVMA assesses information supplied by the applicant and considers whether a proposal to reschedule the substance can be supported in accordance with the Scheduling Factors established by the TGA. That consideration is referred to the TGA for decision.

All decisions on the appropriate schedule for active constituents are taken by the Scheduling Delegate in the TGA, who may seek advice from an advisory committee.

Applications for scheduling referred to the advisory committee are provided for public comment, and all comments received are taken into account by the Scheduling Delegate.

Currently, there are no registered Schedule 5 injectable products containing lidocaine/lignocaine.

When any products that meet the definition of the Schedule 5 entry (including the packaging requirements and appropriate directions for use) are registered, the products will be made available only for the uses allowed in the amended scheduling entry (in this instance, for tail docking and castration of lambs or castration of calves). It is therefore anticipated that these products will be available through livestock or rural stores, in a similar manner to other Schedule 5 products used to treat a range of conditions in livestock and which do not require veterinary intervention.

The APVMA remains satisfied that all registered products meet the statutory criteria as set out in the *Agricultural and Veterinary Chemicals Code Act 1994*.

The APVMA would be pleased to provide a briefing or further information should you require it.

I trust this information is of assistance.

I have provided a copy of this letter to Senator McMahon, noting the Senator's interest in this matter.

Yours faithfully

Ms Lisa Croft
Chief Executive Officer