How regulatory authorities determine the appropriate schedule for pain medications

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REDCAP SOLUTIONS

The regulators

APVMA

- Australian Pesticides and Veterinary Medicines Authority.
- Responsible for the registration of all veterinary medications.
- The scheduling of a pain relief medication will depend on the classification of the active drug in the Poisons Standard.

Department of Health

- Therapeutic Goods Administration (TGA)
- Responsible for maintaining the Poisons Standard

The Poisons Standard

- Is a record of all decisions regarding the classification of medicines and chemicals by the Department of Health.
- Some of these decisions were made 30 to 40 years ago.
- Includes both human and veterinary medicines.
- A drug may be included in more than 1 schedule for different purposes.
- Updated three times a year.


AUSTRALIA

Poisons Standard October 2020

I, Avi Rebera, as delegate of the Secretary of the Department of Health, make the following Poisons Standard.

Dated 29 September 2020

Schedule 1	Not in use
Schedule 2	Pharmacy Medicine
Schedule 3	Pharmacist Only Medicine
Schedule 4	Prescription Only Medicine or Prescription Animal Remedy
Schedule 5	Caution
Schedule 6	Poison
Schedule 7	Dangerous Poison
Schedule 8	Controlled Drug
Schedule 9	Prohibited Substance
Schedule 10	Substances of such danger to health to warrant prohibition of sale, supply and use

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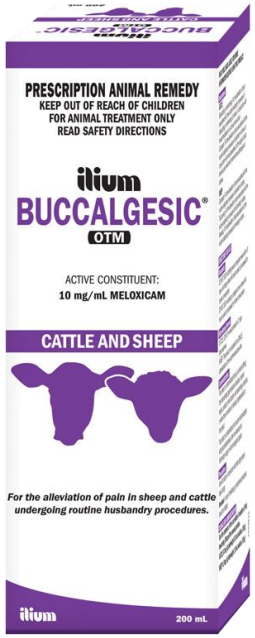
Schedule 4
PRESCRIPTION ANIMAL REMEDY

- Substances which are only available from a veterinarian.
- The prescribing veterinarian must have a *bona fide* relationship with the owner of the animals for which they supply S4 drugs.
- Can be problematic for sheep and cattle producers, particularly in remote areas.



Factors for classifying a drug as Schedule 4

- The ailment or symptoms that the substance is used for requires medical or veterinary intervention.
- The use of the substance requires adjunctive care or specialised handling for administration.
- The use of the substance may produce dependency with a moderate propensity for misuse, abuse or illicit use.
- The seriousness, severity and frequency of adverse events are such that monitoring or intervention by a medical or veterinary practitioner is required to minimise the risk of the substance.
- The margin of safety between the therapeutic and toxic dose is low.
- The use of the substance may contribute to communal harm (e.g. antibiotic resistance).

Scheduling of pain medications

- Historically pain medications were S4 drugs as they were prescribed or administered by doctors or vets, usually by injection. e.g
- Lignocaine
  - Bupivacaine
  - Non-steroidal anti-inflammatory drugs such as Meloxicam
- More recently these drugs have become available in products that can be administered by farmers and contractors without the need for veterinary attendance on farm:
  - Topical sprays for application to wounds (lignocaine/bupivacaine in Tri-Solfen)
  - Oral liquids for pain relief (meloxicam in Buccalgesic)
  - Rubber ring applicator devices with pain relief (lignocaine in Numocaine used with the Numnuts applicator)
- Raises the question: should these substances still be in Schedule 4 or is a different Schedule more appropriate to improve access to pain relief and improve welfare outcomes in livestock?

Schedule 5 CAUTION

Factors for S5 classification:

- The substance has a low health hazard.
- The substance is capable of causing only minor adverse effects to humans in normal use.
- The likelihood of injury in handling, storage and use can be mitigated through appropriate packaging and simple label warnings.
- Non-corrosive and low toxicity
- Low potential for causing harm

Schedule 5 substances can be sold over-the-counter in rural retail stores greatly improving access to the medications.

CASE STUDY – TRI-SOLFEN

- First registered in 2008
- Schedule 4 as it contains lignocaine and bupivacaine (both S4 drugs)
- An application was subsequently submitted to the Department of Health to change the scheduling of the two local anaesthetics to S5.
- The Scheduling Committee considered whether the use of the drugs in this product met the Schedule 5 criteria.
- Successful outcome!

CASE STUDY: TRI-SOLFEN
Bupivacaine – Poison Standard (Oct 2020)

Schedule 4 entry

- BUPIVACAINE except when included in Schedule 5

Schedule 5 entry

- BUPIVACAINE in aqueous gel preparations containing 0.5 % or less of bupivacaine, 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 of calves

CASE STUDY: TRI-SOLFEN
Lignocaine – Poison Standard (Oct 2020)

Schedule 4 entry

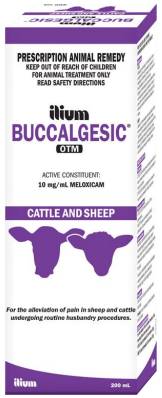
- LIDOCAINE except:
  - when included in Schedules 2 or 5;
  - In dermal preparations containing 2% or less of total local anaesthetic substances per dosage unit; or
  - In lozenges containing 30 mg or less of total anaesthetic per dosage unit

Schedule 5 entry

- LIDOCAINE in aqueous gel preparations containing 4.5% 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 of calves

Into the future:

Other pain relief medications for farm animals may prove to be good candidates for rescheduling?



Thank you

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