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Members of the joint ACCS-ACMS
Therapeutic Goods Administration

NSW Poisons Information Centre
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Re: Proposed amendments referred for scheduling advice to the Joint ACMS-ACCS #21

PARACETAMOL - request to create a new Schedule 6 entry for paracetamol for animal treatment

The NSW Poisons Information Centre (NSWPIC) provides a phone-based advice service on suspected poisonings to the public and health professionals calling from NSW, TAS and ACT on a near full-time basis and a shared after-hours service to the remainder of Australia. This results in approximately half of Australia's poisons-related calls being received by our Centre.

The NSWPIC opposes the addition of paracetamol to Schedule 6 of the Poisons Standard as a treatment for animals.

Paracetamol is responsible for the single largest number of calls to Poisons Centres nationally¹. Widespread community use and ease of access means it is also very commonly involved in deliberate self-poisonings. The NSW PIC alone received 2778 calls regarding deliberate self-poisoning with single ingredient paracetamol products in 2018.

Paracetamol is potentially toxic in doses greater than 200mg/kg or 10g (whichever is less) requiring investigations and potential antidote treatment due to the risk of hepatotoxicity.

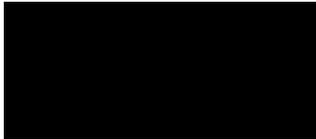
Approval of a veterinary formulation of paracetamol in schedule 6 would allow purchase of a product of undefined strength/concentration with no restrictions on sale. Products indicated as available overseas by the applicant, are of much greater concentration of paracetamol (up to 400mg/ml) than is currently available in Australia for human use. This concentrated product could easily result in an accidental exposure to a toxic dose of paracetamol (25ml) with just a mouthful of product. 5ml of such a concentrated product would be a toxic dose in a 10kg toddler.

Easy access to such a concentrated product would be very dangerous in cases of deliberate self-poisoning. Just 75ml of a 40% solution would result in a massive paracetamol exposure. Difficulties in management of massive paracetamol exposures have been well documented by Chiew et al².

Should paracetamol be deemed appropriate for animal treatment in Australia, we suggest it be placed in Schedule 4 along with other analgesics for animal use. This will allow for appropriate safety warnings, packaging and restriction on sale to minimise the risk of both acute accidental and deliberate self-poisoning in humans. In addition, there are safety concerns relating to dosing errors and off-label use in other species where paracetamol can be highly toxic in small quantities.

This would be consistent with regulations in the UK where paracetamol is only available for veterinary use with a prescription.

Regards



1. Alanna Huynh, Rose Cairns, Jared A Brown, Ann-Maree Lynch, Jeff Robinson, Carol Wylie, Nicholas A Buckley and Andrew H Dawson, on behalf of the Synthesis of the Network of Australian Poisons Services' Health Outcomes and Treatment (SNAPSHOT) investigators. Patterns of poisoning exposure at different ages: the 2015 annual report of the Australian Poisons Information Centres
Med J Aust 2018; 209 (2): 74-79. || doi: 10.5694/mja17.01063
2. Angela L. Chiew, Geoffrey K. Isbister, Katharine A. Kirby, Colin B. Page, Betty S. H. Chan & Nicholas A. Buckley (2017) Massive paracetamol overdose: an observational study of the effect of activated charcoal and increased acetylcysteine dose (ATOM-2), Clinical Toxicology, 55:10, 1055-1065, DOI: [10.1080/15563650.2017.1334915](https://doi.org/10.1080/15563650.2017.1334915)