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Director, Permits and Minor Use
Australian Pesticides and Veterinary Medicines Authority

By email only: enquiries@apvma.gov.au

Dear Director,

Re: consultation on draft guidelines for determining minor use

Thank you for very much for the opportunity to provide comments on the draft guidelines for determining minor use.

Animal Medicines Australia (AMA) is the industry association representing the registrants and approval holders of veterinary medicines and animal health products in Australia. They are the local divisions of global innovators, manufacturers, formulators and registrants that supply essential veterinary medicines and animal health products that are critical to supporting Australia's $34 billion livestock industry and the $33 billion pet industry. Our members represent more than 90% of registered veterinary medicine sales in Australia.

AMA supports mechanisms that provide greater access to products where there is a limited market, an infrequent or sporadic need for use, and/or where there are limited or no products available for an important therapeutic need. These minor use situations may not provide sufficient economic returns to support a product registration, but effective treatment of affected animals is essential to deliver important animal health and welfare benefits. A minor use permit is a key mechanism to facilitate access and use of important veterinary medicines when there are limited or no registered products available.

AMA notes that the current guidance material is heavily focussed on agricultural applications. Veterinary medicines are used in different ways and for different reasons to agricultural products,

such that the criteria to determine minor uses in one sector are not necessarily applicable to the other sector. In particular, minor uses cannot be approved in one species and extrapolated to others (as is done with crop groups), as physiology and metabolism varies by species. Minor uses to address animal health and welfare needs may be more effectively supported through veterinary-specific guidance material and AMA would be pleased to support this work.

The draft guideline includes a proposal to classify salmonids as a major species. AMA has no objection to this change.

The requirement to demonstrate insufficient economic return to consider registration of a product in a major species (thereby justifying the granting of a minor use permit) mandates the use of a Tier 2 PAA. The 2025-26 Cost Recovery proposal (currently also under consultation) includes significant increases to the cost of PAAs, such that a Tier 2 PAA could cost around $3000 (up from $770), with an administration fee of $730 (up from $190). Ther minor use permit itself will cost $500 (up from $350). There are no rebates on registration fees available for PAAs when used to obtain minor use permits. This requirement for a Tier 2 PAA will be a significant deterrent to seeking minor use permits for veterinary uses, thereby encouraging more off-label use to address veterinary needs.

AMA would suggest that a minor use determination for veterinary medicines should not rely on a list of major versus minor species, or economic analyses. The test should, instead, consider whether:

a) there is a genuine need; and
b) there are no suitable or insufficient registered options to meet that need.

In any species, uses that do not meet economic return thresholds are not pursued commercially and are not registered, despite there being an unmet need. If producers identify a particular use as a priority for any animal species, the APVMA should focus on the safety and efficacy considerations to enable that use and issue permits when those requirements are satisfied, not because a particular species is identified as major or minor.

Please let me know if AMA can provide further information at any time.

Yours sincerely,

Dr Charmian Bennett

Director Science and Policy