Guidelines for determining a minor use - APVMA consultation

Submission of the
Australian Veterinary Association Ltd

15 June 2023

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The Australian Veterinary Association (AVA)

The Australian Veterinary Association (AVA) is the national organisation representing veterinarians in Australia. Our members come from all fields within the veterinary profession. Clinical practitioners work with companion animals, horses, livestock and wildlife. Government veterinarians work with our animal health, public health and quarantine systems while other members work in industry, research and teaching. Veterinary students are also members of the Association.

Guidelines for determining a minor use - APVMA consultation.

Submission from the Australian Veterinary Association.

Background

The APVMA has requested stakeholder input in relation to the guidelines for determining a minor use.

Minor use permits are issued to allow for the legal use of AgVet chemicals in situations where registration of the product would not produce sufficient economic return. A minor use may include use on a minor crop, animal or non-crop situation, or limited use on a major crop, animal or situation.

Issues

Definition of 'Minor Use'

The minor use guidelines are heavily targeted to the agricultural sector rather than the veterinary sector.

The current guidelines are principally related to agricultural usage with extensive lists of various crop species. There is a list of major animal species and discussion that if the use is in a non-major species or the treatment is in less than 10% of the number of animals, it can be classified as a 'minor use'.

It can be very difficult to assess animal disease incidence in Australia as there are very few national requirements for disease reporting, apart from for notifiable diseases, and thus it is difficult to confirm a disease incidence of less than 10%.

There are many more current agricultural permits compared to veterinary permits; on the APVMA website permit search function there are almost 1000 current agricultural permits and only around 120 current veterinary permits.

The need for 'Supply Permits' or similar

In the past there was the possibility for a 'supply permit' for Veterinary products as part of the 'minor use' permit system. These permits covered supply during the registration process, which often takes 3-5 years. This was a very useful type of permit for low value, schedule 4 veterinary medicines for companion animals, including horses.

There is an increasing use of compounded veterinary medicines, which require no registration, and at the same time, an increasing regulatory burden for registration of products. The APVMA is moving towards being equivalent to International Regulatory Authorities, such as the CVM (FDA) and the EMA, with resultant higher requirements for quality, efficacy and safety studies, and an associated much higher regulatory cost and longer assessment times. As such it is difficult for veterinary pharmaceutical companies to justify the registration costs when veterinarians can compound an identical product to a registered product.

If a supply permit can be issued for these low value products this would allow sales and income revenue during the lengthy registration process.

Currently there is very little incentive for registration of such products and Australian veterinarians are missing out on being able to use registered products and are relying on compounded products, which have no requirement for proof of efficacy, safety or stability, these products should ideally be niche products for situations where there is no suitable registered product (due to species, formulation, route of administration etc), however they are becoming first line treatments for many species and many diseases.

In addition, the Australian market is very small in comparison with the US and EU markets, and it is difficult for pharmaceutical companies to justify the registration costs and timeframes for a registration in Australia. Typically, these products have already been approved by an overseas regulatory authority and yet the information needs to be re-assessed by the APVMA, with resultant increased costs and delays.

If a supply permit could be issued for innovative or novel products this would allow sales and income revenue during the lengthy registration process and make the registration of these products more appealing.

Similar to the situation for low value products, there is little incentive for registration for some innovative products which are approved overseas resulting in lack of access to these products for Australian veterinarians.

The AVA recommends that the guidelines for 'minor use' should be expanded to include 'supply permits' and include Schedule 4 Veterinary Medicines, for supply only to registered veterinarians for companion animals, including horses.

The products could not include anthelmintics, nor antimicrobials if there are different sensitivity patterns for Australia compared with countries where the products are approved.

The products would need to be novel, either by active or route of administration and not similar to any existing registered product.

The requirements for approval of the permit should be reduced so that these permits can be approved rapidly with a minimum data requirement of, for example -

GMP manufacture

- Reduced shelf life based on minimum of 6m accelerated data.
- Scientific argument supporting efficacy and safety with a commitment to full registration. The APVMA could request a statement such as 'The efficacy and safety of this product has not been approved by the APVMA.'
- Relevant human safety statements as per overseas approval if unscheduled with a commitment to scheduling as part of full registration.

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