23 June 2023

Director, Permits and Minor Use
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Submitted via email: enquiries@apvma.gov.au

RE: Updating the guide for determining a minor use Discussion paper February 2023

To whom it may concern,

WoolProducers Australia (WoolProducers) and Sheep Producers Australia welcome the opportunity to provide a submission on the discussion paper, "*Updating the guide for determining a minor use*".

WoolProducers and Sheep Producers Australia are the national peak industry bodies representing Australian wool growers and sheep meat producers respectively. Representation spans a broad range of issues, including, but not limited to animal health and welfare, biosecurity, natural resource management, emergency animal disease outbreak preparedness, market access and assurance and industry development. WoolProducers and Sheep Producers Australia appreciate the role that APVMA plays in regulating AgVet chemicals to support continued safe and efficient agricultural production systems.

WoolProducers and Sheep Producers Australia are satisfied that the criteria for determination of minor use under Schedules 1 and 2 of the "*Guide for determining a minor use"* are reasonable with regards to sheep. Being classed as a *major animal species* within Schedule 1, only schedule 2 is applicable to sheep, whereby classification as a minor use would require less than 10% of the eligible sheep population to be treated per annum.

WoolProducers and Sheep Producers Australia understand that this review is not seeking to inform an amendment of the applicable legislation, however we do believe that the "*Guide for determining a minor use"*, which provides interpretation and guidance on the administration of the applicable legislation, could be amended to better serve the needs to Australian farmers, while continuing to allow the APVMA to fulfill their regulatory functions.

In raising opportunities to enhance the administration of Minor Use Permits, WoolProducers and Sheep Producers Australia wish to draw the APVMAs attention to the Custom R Pilus footrot vaccine, which has been subject to multiple representations to the APVMA, the Department of Agriculture and numerous federal ministers over the past decade. To date the Minor Use Permit pathway has failed to deliver on the needs of Australian wool growers and sheep meat producers in relation to the management and eradication of footrot. The Custom R Pilus footrot vaccine is a serotype specific sheep vaccine that has proven its efficacy and safety under (now unavailable) Emergency Use Permits. The inability to access the vaccine via a Minor Use Permit is continuing to compromise sheep health and welfare, and consequently the sustainability of Australia's wool and sheep meat

industries, owing the current onerous and prohibitive bureaucratic processes associated with permitting and registration of the vaccine.

Availability of equivalent registered product

WoolProducers and Sheep Producers Australia understands that the APVMA has a policy of refusing to grant Emergency Use Permit and Minor Use Permits in instances where 'equivalent' registered products are available. We understand that this policy exists to protect the commercial interests and investment associated with products undertaking the product registration process. This has been the basis for the APVMA refusing to issue either of these two permit types for the Custom R Pilus footrot vaccine.

The APVMA has stated that the serotype-specific Custom R Pilus footrot vaccine is equivalent to the registered Footvax® vaccine (which became available to Australian producers following its successful re-registration in July 2020). The fact is that the assumption of equivalence is ill informed based on outdated assumptions that are no longer fit for purpose (i.e. based exclusively on host x pest). While both products target the footrot (*Dichelobacter nodosus*) in sheep, there are many points of difference between the two products, some of which are listed below:

- The Footvax® vaccine is an 'off the shelf' product that can be accessed and used by producers with little more than a basic visual diagnosis.
- The Custom R Pilus vaccine requires producers to undertake extensive swabbing and serotyping to determine the strains of footrot present in a given flock. This allows determination of the appropriateness to use the custom vaccine and informs formulation to the vaccine to target the strains present within a given flock. The cost of this serotyping often varies between $1500 and $3000, depending on numbers and logistics.
- The Custom R Pilus vaccine, while being limited to one or two serogroups of footrot, has been proven many times (through levy funded research) to have a longer 'effective period' than the Footvax® vaccine.
- The Footvax® vaccine is effective against all serotypes other than M, whereas the Custom R Pilus vaccine can be formulated for various serotype combinations, including M.

Taking the above points into account the Footvax® is a readily accessible broad-spectrum product, whereas the Custom R Pilus vaccine is a specialised product that requires significant producer investment (serotyping) to determine its suitability for inclusion in a control programme.

Schedule 3 - Inadequate determination of "sufficient economic return"

The concept that "sufficient economic return" can be determined with the simple information outlined in the current guidelines is flawed and unlikely to provide sufficient information for the APVMA (a regulator) to reliably distinguish what would yield a sufficient economic return to a commercial entity.

The current considerations within Schedule 3 fail to consider product research and development costs up until the APVMA permit application or registration process commences. With this being the

case, it is not possible to establish what the return on investment is, as the only "investment" costs being considered are the product registration costs.

Schedule 3 fails to take into consideration the opportunity cost to manufacturers or distributors in pursuing full registration. Companies that are willing to pursue products that are of a minor use (as defined by Schedule 1 and 2 of the guidelines) are generally likely be smaller in size and have less resources to support licensing activities and regulatory affairs. As a consequence, such companies need to make decisions as to which products these finite resources are allocated to. These will typically be products that deliver a greater return on investment and are therefore more likely to be excluded from the Minor Use Permit pathway.

Schedule 3 also fails to assess the potential opportunity costs to industry and producers of not having product available to producers. Such costs could be either financial, in terms of decreased production or profitability, or reputational through compromised environmental or animal welfare outcomes. While such costs would not provide a direct return to the manufacturer / distributors of AgVet chemicals, they must be considered when determining "sufficient economic return" at a national level.

The issues above in relation to Schedule 3 assessment criteria will only become more prevalent in the coming years. This will largely be driven by the transition away from traditional broad spectrum and generic chemistry and management approaches to more targeted and bespoke solutions in response to supply chain demands for decreased chemical usage and reduced off-target impacts. With increased usage of these bespoke and targeted products, the current Schedule 3 considerations will only drive AgVet chemicals away from the Australian market, which will obviously lead to undesirable animal health and welfare outcomes and have an overall detrimental impact on Australia's livestock production sector.

WoolProducers and Sheep Producers Australia thank you for the opportunity to provide this submission and look forward to a Minor Use Permit process that better serves the needs of Australian wool and sheep meat producers.

Should you wish to discuss our submission further, please contact WoolProducers' General Manager, Adam Dawes on 0455 442 776, or gm@woolproducers.com.au

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