To: ACVM team: ACVM.Consultation@mpi.govt.nz

Submission: Second round of Consultation on the Update of Veterinary Medicine Adverse Event Guidance Documents & Reporting Form

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Submitted Information
The information supplied is what is available by 14 October 2021. Further information may be provided in future to inform ACVM.

1. Introduction

Agcarm welcomes the opportunity to provide feedback on the second round of Consultation on the Update of the Veterinary Medicine Adverse Event Guidance Documents & Reporting Form.

This submission represents the views of the animal health industry members of Agcarm which encompasses the majority of animal health products registered in NZ.

Agcarm notes the revisions made in response to our comments made during the first round of consultation. Our feedback in this round of consultation covers a few key outstanding points and we have also raised some issues that need further clarification.

2. Key points and recommendations

Agcarm recommends:

a. Changing 'human exposure' to 'human adverse outcomes following exposure' in the Adverse event report Veterinary Medicines ACVM 25.
b. Revision of Section A of the Guidelines for registrants to allow for exchange of full information between ACVM and registrant should ACVM be provided with new information from a reporter.
c. Reviewing the introduction to Section B to ensure it reflects the purpose of managing trade risks from residues.
d. Adding the equivalent of Section B on Risk Area Management Notifications to the Guidelines for veterinarians and animal owners. Not having this would appear to be a major gap.

e. Extending the proposed timeline of 5 working days from first notification for possible residues or interference with disease diagnosis to 20 working days to align with AER timeframes.
f. Extending the timeframe for providing feedback to voluntary reporters to 20 working days.
g. Convening an industry workshop on the new system before it comes into effect, so it is well understood by all stakeholders.

3. Adverse event report Veterinary Medicines ACVM 25 (September 2021)

3.1 Adverse event definition: *'Any observation in animals that is unfavourable and unintended, and that occurs after the use of a veterinary medicine. This may include side effects, target animal safety issues, residue issues, human exposure, lack of efficacy or alleged interactions with other products.'*

Comment: We note the need for consistency with the definition in the guide for registrants. Instead of 'human exposure', we suggest this should be 'human adverse outcomes following exposure'.

3.2 Reporter's and Animal Owner's contact details sections: For registrants *"state withheld if consent refused and state at minimum city or district.'*

Comment: We note that not all adverse event reports have addresses collected. In some cases, only phone number (usually cell phone is provided) without location. Is it required that we must determine each caller's location to have a valid AE report? Is it possible for the caller to reply "withheld" to this location information if they choose?

4. ACVM Guideline for Registrants Section A

4.1 Provision of reporter details

Reasoning from ACVM is *'situations where information of a sensitive nature is required such that directing the question via the product registrant is inappropriate, or where urgent contact is required'. Location was required for identifying possible geographical "clusters".*

Comment: It should be considered that the ACVM may be able to extract different or additional information from a reporter due to their independence from product registrants and also their authority. In some cases, reporters may be motivated to provide more compelling information to the ACVM. In these cases, how will registrants get this new information and will there be the opportunity to reassess the case file? This section needs revision to allow for this exchange of full information between ACVM and registrant. Also, where a phone number has been provided, an address is not always collected (especially in minor flea AE/SLEES).

5. ACVM Guideline for Registrants Section B: Risk Area Management Notifications (to include in the adverse event reporting program)

We note the ACVM reasoning for inclusion is:

Although the preference of those making comments on the matter was for the two concepts to have entirely different management systems, for the reasons outlined above a new system specific to RMNs is not proposed. Instead, the following changes have been made to the registrant guidelines:

- *Renamed "Veterinary Medicines Pharmacovigilance Programme: Adverse Event Reporting and ACVM Act Risk Area Management Notifications".*
- *Purpose section added that describes the risks that need to be managed for veterinary medicines and confirms that the Pharmacovigilance Programme includes Adverse Event Reporting and ACVM Act Risk Area Notifications components.*
- *The Adverse Event Reporting and ACVM Act Risk Area Management Notifications components are sectioned off from each other.*
- *A dedicated information requirements section has been included in the ACVM Act Risk Area Management Notifications section.*

In the guideline document it states: '*NZ is an exporting nation that places emphasis on animal welfare and has a geographical remoteness that means animal diseases endemic in many parts of the world remain exotic to our shores. In consequence, there is a need to proactively respond to information relating to the use of a vet medicine that has not resulted in an adverse event but may result in unacceptable ACVM Act risk area management if not appropriately managed.'*

Comments: Agcarm generally supports the revisions made to separate the ACVM RMN system from AER in the guideline for registrants, however, the introduction above is confusing and does not align with our understanding about the main purpose of the ACVM RMN system being to respond to residue issues. The only defined issue that this introduction may apply to is when issues arise that have resulted in interference with disease diagnosis or control. The introduction needs to be reviewed to ensure it is applicable to the information requested in this programme as potential residue issues and most illegal off label product use are not likely to result in exotic diseases on our shores.

Importantly, we note there is no equivalent of Section B on ACVM Risk Area Management Reporting for Veterinary Medicines in the guidelines for veterinarians and animal owners. This would appear to be a significant gap as in most cases we expect Risk Management Notifications will involve the farmer or veterinarian engaging directly with ACVM in managing an event. It will be important to make the distinction between adverse events reporting and RMN reporting clear to veterinarians and farmers to avoid confusion.

The summary of Reporting Timelines in Appendix 1 is a helpful addition. However, the proposed timeline of 5 days for possible residues or interference with disease diagnosis is problematic. This would mean notification outside of AE reporting programs which will poses difficulties with information accuracy and the quality checks that would normally occur. Harmonisation of

timelines to 20 working days would mean meeting these reporting requirements would be much more achievable.

6. Feedback to voluntary reporters

We note that the timeline for feedback to voluntary reporters has been extended to 10 working days. This is an improvement on the initially proposed 5 working days but we are still of the view that this timeline should be the same as the routine AE reporting timeline to keep the count simple and possible to achieve (20 working days).

7. Further briefing/workshop on the new Veterinary Medicines Pharmacovigilance Programme

Our members have requested the opportunity for further discussion with ACVM on the new system before it is in place, so it is well understood. To this end, we would like to request an industry workshop on the new system be convened before it comes into effect.

8. About Agcarm

Agcarm is the industry association for manufacturers and suppliers of animal health and crop protection products. For further information and a full list of members, see www.agcarm.co.nz.

Agcarm member products protect public health, improve animal welfare, and help environmental management. They:

- Play a pivotal role in growing high yield, sustainable food, and fibre products.
- Help supply healthy, nutritional, and affordable food.
- Keep New Zealand's agriculture, horticulture, and forestry sectors internationally competitive.

Our members are committed to safety, innovation, and product stewardship.