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Agvet Reform Team
Department of Agriculture, Water and the Environment
Canberra ACT 2600

Submitted by email only: agvetreform@agriculture.gov.au

Dear Agvet Reform Team,

Re: Consultation on Manufacturing approval of agricultural and veterinary chemicals

Thank you for the opportunity to provide comment on this proposal.

Animal Medicines Australia (AMA) is the peak industry body representing the leading animal health companies in Australia. AMA member companies are the innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products that prevent, control and cure disease across the companion animal, livestock and equine sectors. Our members represent more than 90% of Australian sales of registered veterinary medicine products.

The discipline and rigour provided by the Australian Government's regulatory impact analysis framework ensures that regulatory responses are appropriate, justified, properly targeted and proportionate. The Australian Government Guide to Regulation (2020)[1] provides an appropriate framework for developing and evaluating regulatory proposals, including the consideration of non-regulatory solutions as the default. The Guide clearly specifies six Principles for Australian Government Policy Makers that apply to any 'rules' where there is an expectation of compliance by the regulated community:

1. Policy makers should clearly demonstrate a public policy problem necessitating Australian Government intervention, and should examine a range of genuine and viable options, including non-regulatory options, to address the problem.
2. Regulation should not be the default option: the policy option offering the greatest net benefit — regulatory or non-regulatory — should always be the recommended option.

[1] https://www.pmc.gov.au/resource-centre/regulation/australian-government-guide-regulatory-impact-analysis

3. Every substantive regulatory policy change must be the subject of a Regulation Impact Statement.
4. Policy makers should consult in a genuine and timely way with affected businesses, community organisations and individuals, as well as other policy makers to avoid creating cumulative or overlapping regulatory burdens.
5. The information upon which policy makers base their decisions must be published at the earliest opportunity.
6. All regulation should be periodically reviewed to test its continuing relevance.

AMA considers that strict compliance with these principles is essential to support effective policy development and regulatory settings that are appropriate, efficient and effective. At this stage, it is not clear to AMA that these policy principles have been properly reflected in this proposal.

AMA considers that greater consideration and discussion structured around these principles would assist better consideration by stakeholders. AMA would welcome further details about the proposal to facilitate an informed and considered assessment of costs and benefits for animal health industries.

Specifically, AMA would request further discussion to address the following concerns:

1. *Clear articulation of the policy problem and its scope:* AMA notes that a general description of the policy problem is included in the consultation document. However, the scope of the problem, including any implications for veterinary medicines and animal health products remains unclear. Clear problem definition is essential to fully consider the merits of any policy or regulatory intervention.
2. *The need for a regulatory response to the problem is not explained or justified*: AMA considers that a regulatory response is one of a range of options that could be implemented. AMA would welcome further discussion on the merits of a regulatory response in comparison to other options.
3. *There is insufficient explanation and contextual information provided to assess the appropriateness or effectiveness of the proposed measure*: In the absence of a clear problem definition or assessment of the need for a regulatory response, it is difficult to assess the appropriateness of any measure. Again, AMA would welcome further discussion on the need for the proposed measure within the veterinary medicines and animal health context.
4. *Only one potential 'solution' has been identified and no other options are presented or evaluated*: AMA would welcome discussion on whether there are additional options that could be evaluated.
5. *The proposal appears to substantially duplicate existing regulatory obligations*: Good Manufacturing Practice standards and the Manufacturers Licensing Scheme administered by APVMA place comprehensive and rigorous obligations on veterinary medicine manufacturers. There is a high risk of incorporating duplication and inefficiency that should be carefully explored in consultation with industry.
6. *The proposed regulation could increase the regulatory burden*: Imposing additional regulatory obligations will increase the regulatory burden on veterinary medicine registrants. The independent checking that could be required to provide the assurance sought under this proposal would likely result in significant additional costs with no concomitant increase in safety, efficacy or availability of veterinary medicines. As a principle, AMA expects that any regulatory option chosen should be that which demonstrates the greatest net benefit to the community. We would welcome further consultation to

demonstrate that the net benefits expected to accrue from this reform would exceed the costs incurred.

Further, AMA notes that the short period allocated to stakeholder consultation has not facilitated a thorough analysis of the likely costs, benefits and implications that this proposal may have on the animal health industry. A carefully considered, thorough analysis of all aspects of this proposal is essential to gathering informed perspectives from industry.

Overlap with Good Manufacturing Practice obligations

AMA notes that this measure overlaps with the GMP (Good Manufacturing Practice) system already in place for veterinary medicines marketed in Australia. GMP certification is a condition of registration in Australia and provides assurance that all steps involved in the manufacture of a finished veterinary product and its constituents are equivalent to Australian standards, regardless of the country of manufacture. Without such evidence, the veterinary product cannot be imported, registered or sold in Australia. According to current government regulations, veterinary manufacturers and registrants already meet the requirements for legal manufacture at overseas sites through the existing GMP system.

The consultation document notes that the proposal is intended to bring Australia into alignment with the *OECD Best Practice Guidance to Identify Illegal Trade of Pesticides*. This document is clearly directed at agricultural products, with limited (if any) relevance to veterinary products. The manufacture, registration and use of veterinary medicines is considerably different to that for agricultural products, such that guidelines developed for agricultural products are generally not applicable to veterinary products. This proposal does not reflect these fundamental differences. Alignment with OECD guidance in this case is likely to mis-align veterinary medicine manufacture with international equivalents.

Potential implementation challenges

An exclusion for veterinary products would not be straightforward:

1. The proposal includes sites of manufacture for active ingredients. In contrast to agricultural actives, veterinary actives currently do not require separate GMP certification as that process is captured by GMP certification for the finished product. If the manufacture of veterinary actives is captured by this measure, it will significantly affect industry's ability to source lesser-used APIs and those that are not used in human medicine.
2. There are multiple active ingredients that are used in both agricultural and veterinary products. Consideration must be given to mechanisms that will clearly and consistently exclude an active when present in a veterinary product, but would capture the same active when present in an agricultural product.

AMA further notes that the proposal would require an applicant to declare that *"the applicant believes on reasonable grounds that the manufacture of the active constituent or chemical product does not infringe the laws of the country of manufacture"*. This language, and the terminology "*lawful manufacture",* are vague and open to interpretation. The proposal provides no clarity on what must be assessed in order for manufacture to be deemed "legal" in another country, which could plausibly include many areas such as employment laws, workplace health and safety laws, competition laws and/or environmental laws. It is unlikely that a registrant would have sufficient visibility on all local laws and bylaws in a given country to be able to sign the proposed self-declaration.

Further, it is hard to see how a self-declaration would achieve the aim of providing greater assurance, nor how APVMA would be able to assess or ensure compliance in the absence of such authority in their governing legislation. Companies that this measure is intended to target will have no hesitation signing such a declaration, yet companies who are already compliant will face substantial issues with signing, with significant resources required to confirm all local country requirements on the manufacture of veterinary actives at overseas sites. Any such measure would also require significant lead-in time (at least 3-4 years) to support compliance.

AMA looks forward to working with the Department with a view to constructively addressing the issues outlined in this submission.

Should you have any questions in relation to our comments, please contact AMA's Director Science and Policy, Dr Charmian Bennett on (02) 6257 9022.

Yours sincerely,

(unsigned for electronic submission)

Ben Stapley

Executive Director