6 September 2024

By Email

Submission on behalf of the New Zealand Veterinary Association regarding the Agricultural and Horticultural Products Regulatory Review

The New Zealand Veterinary Association Te Pae Kīrehe (NZVA) is the largest membership organisation representing veterinarians in Aotearoa New Zealand. We support members through leadership, education, guidance and support.

The NZVA is making this submission on behalf of its members in response to the Agricultural and Horticultural Products Regulatory Review.

You will find a summary of our feedback on the following pages.

Yours sincerely,

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NZVA summary of feedback

Purpose of regulation

The purpose of the Agricultural Compounds and Veterinary Medicines Act 1997 and the associated regulations is to manage the risk that agricultural compounds and veterinary medicines pose to:

- trade in primary produce
- agricultural security
- public health
- animal welfare.

There are also additional purposes of regulation, such as to protect food safety for consumers and protect the environment from potential damaging impacts from the use of some chemicals.

What are the costs?

- The regulations present a barrier to market due to the costs and complexity of getting an agricultural compound registered and maintaining registration.
- Applicants and companies will charge a premium to recover the costs of bringing a product to market and maintain registration, potentially making them more expensive.
- Applicants registering agricultural compounds must evaluate whether the costs to market outweigh the returns from sales of the compound. Combined with New Zealand's small market for veterinary medicines, this can mean that the costs associated with registration and marketing can reduce the likelihood that novel and innovative compounds become available here.
- Production and companion animals may receive a lower standard of care compared to other countries due to some veterinary medicines being unavailable in New Zealand.
- There is the potential that New Zealand may not be as internationally competitive with its farming systems due to reduced access to innovative compounds.

What are the benefits?

- That the risks associated with the use of an agricultural compound (see above) are well managed and minimised.
- Veterinarians, farmers and the public can have confidence that the products they use on their animals are safe and effective every time.
- Farmers, international markets and consumers can have confidence that residues from veterinary medicines will be at safe levels when used according to the labelled instructions.
- New Zealand's agricultural exports are more easily traded with other countries due to our adoption of international Organisation for Economic Co-operation and Development (OECD) guidelines on manufacturing, efficacy, safety and residues.
- New Zealand's international trade in agricultural products (diary, meat and wool) is worth $34.3 billion (MPI, March 2024) and, without tight regulatory controls on the approval and use of agricultural compounds in the sector, other countries could use our relaxed regulations as a barrier to their markets, jeopardising our primary industries.

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Are the regulations working in NZ compared to other countries?

- In general, the regulatory process functions well in New Zealand, but specific issues are highlighted below in the next section.
- The regulatory process is complex to manage multiple risks and sets a high quality threshold for approval for valid reasons.
- The New Zealand regulatory system is comparable to other English speaking OECD countries and shares similar internationally-recognised guidelines with similar expectations on the data required to demonstrate quality manufacturing, animal efficacy, safety and tissue residues.
- Although the registration of veterinary medicines can be seen as the primary barrier to market in New Zealand, the registration requirements are largely identical to other countries and in many cases the same data can be used in New Zealand as overseas.
- The registration system in New Zealand employs independent data assessors to review regulatory dossiers prior to ACVM review. In theory, this reduces the workload of the ACVM group in the review process.

Issues and potential solutions associated with the current regulatory system

- **Approval times:** In recent years approval has been slow, taking months to years. While approval times have improved in 2024, it is important that applications for new veterinary medicines are approved in a timely manner. ACVM needs to be well-resourced (funding, people, IT infrastructure) to maintain approval timelines within the 40 working days as legislated.
- **Barriers to market:** The complexity of the application process and the costs associated with maintaining registration can reduce the likelihood that innovative veterinary medicines are available to New Zealand veterinarian's, farmers and consumers. The ACVM group should consider how to incentivise applicants to bring novel and innovative products to the New Zealand market.
- **Fewer veterinary medicines available in NZ:** There are veterinary medicines available in other English-speaking OECD countries with very similar registration requirements and similar use patterns that are not registered in New Zealand. For therapeutic areas and species where there is minimal difference between countries (for example companion animals and equine) greater acceptance of international registration packages should be encouraged and a system of co-registration developed to bring more medicines to the NZ market.
- **Complexity of the information required by applicants:** For applications with generic compounds with well understood chemistry the necessary data required for approval may be excessive and costly. A more pragmatic approach to the approval of generic veterinary medicines should be taken where possible.
- **ACVM communication:** Applicants can have difficulty determining exactly what data is required for registration in New Zealand particularly for novel products. The ACVM group should provide clear written feedback about the data required to gain approval early in the process when requested so there are no surprises at later stages.
- **ACVM data assessors:** Applicants have expressed concern that regulatory dossiers are being reviewed again in detail by the ACVM group after review by data assessors. The ACVM group should work more closely with the data assessors to ensure sufficient training and knowledge of the approval requirements and minimise duplication where possible.

Market failures – example

- **Disease outbreak:** The source of the 2017 *Mycoplasma bovis* outbreak in New Zealand has yet to be determined, but several potential routes were identified including bull semen, cow embryos, animal feed and illegal vaccines. Relaxing the regulations around veterinary medicines, particularly biologicals like vaccines, increases the risk of a major disease incursion. A disease outbreak would have far-reaching impacts on trade, our primary industries, the economy and the country.

Market successes – example

- In 2023, phenobarbitone, a medication used to control seizures in animals, became unavailable in New Zealand. The regulator (New Zealand Food Safety) worked closely with veterinary groups (veterinarians, wholesalers, pharmaceutical companies) to find a solution and re-establish a supply quickly and minimise disruption.

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