



Animal Medicines Australia
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Department of Climate Change, Energy, the Environment and Water

Online submission only

Dear Sir/Madam,

Re: Developing a national framework for recycled content traceability

Thank you for the opportunity to provide comment on the proposal to develop a national framework for recycled content traceability (the Proposal).

Animal Medicines Australia (AMA) is the peak industry association representing the registrants and approval holders of veterinary medicines and animal health products in Australia. They are the local divisions of global innovators, manufacturers, formulators and registrants that supply essential veterinary medicines and animal health products that are critical to supporting Australia's \$34 billion livestock industry and the \$33 billion pet industry. Our members represent more than 90% of registered veterinary medicine sales in Australia.

Animal Medicines Australia commends the Government's commitment to providing guidance regarding the implementation of traceability systems for recycled content in supply chains and is pleased to provide the following comments for consideration.

AMA member companies play a vital role in Australia's food production, agricultural trade and biosecurity preparedness, as well as ensuring that veterinarians have access to the animal health products they require to maintain and improve the health and wellbeing of our pets, wildlife and competition animals. AMA members develop, register and supply innovative new medicines including vaccines and anti-infection medicines to prevent and control outbreaks of animal disease, as well as medicines and treatments that enable good health and wellbeing, and the production of food and fibre products that are safe for human consumption and use. Healthy animals are much less susceptible to disease and infection, and good animal health is essential to good animal welfare.

Ensuring access to animal health products and maintaining their viability and efficacy during transport, storage and use in Australia's unique and often extreme environmental conditions is vital to maintaining not only the health and wellbeing of the animals in our care, but also Australia's rigorous biosecurity systems, public health and access to safe, nutritious, affordable food. Consequently, the materials used to package animal health products have a functional role in maintaining the stability and efficacy of the product, which go far beyond simple containment. This is particularly relevant for fragile products and those with specific light or cold-chain storage and transport requirements.

Animal health product packaging and disposal pathways are subject to rigorous regulatory requirements, administered by the Australian Pesticides and Veterinary Medicines Authority (APVMA). To ensure the viability of registered products, the APVMA requires that stability data be generated using the same containers (packaging material) and with the same closure system as that proposed in the application for registration of the product.

The incorporation of recycled content would, therefore, require significant product testing to ensure the product remains safe and effective for use and satisfy the regulatory requirements for product stability, quality and safety. In addition, APVMA authorisation is required prior to the introduction of any new packaging for veterinary medicines. Packaging materials are considered to be part of the registered product, such that any changes to packaging materials must be assessed by the APVMA to ensure the new materials continue to satisfy the registered specifications for safety, quality and efficacy. To accommodate these regulatory requirements, as well as production lead times, several years are generally required to introduce new packaging materials for registered veterinary medicines, particularly for low volume product lines.

As highlighted in the Discussion Paper, national consistency regarding the traceability of recycled content should be prioritised. In the case of veterinary pharmaceutical products, national consistency is essential for ensuring continued access nation-wide to address animal health and welfare concerns and ensure that biosecurity threats can be appropriately managed, regardless of packaging type.

Similarly, consideration of international supply chains and global packaging and traceability/reporting requirements should be considered. Australian animal health products are commonly sourced from global manufacturing facilities, which are part of complex global supply chains with equally complex requirements regarding packaging requirements for product stability, quality and safety.

In Summary:

- Veterinary medicines are crucial tools used by veterinarians to support the health, welfare and wellbeing of livestock, pets, and other animals under human care.
- Any traceability systems should consider and accommodate unique circumstances for specialty supply chains, including the animal health sector, with specific regulatory and product stability requirements (particularly fragile, light-sensitive and temperature-sensitive products).
- National consistency should be prioritised.
- Consideration of global requirements and supply chains is essential.

If we can provide further information at any time, please do not hesitate to contact me.

Yours Sincerely,

Dr Katie Asplin

Director, Animal Health Stewardship