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Department of Climate Change, Energy, the Environment and Water  
GPO Box 3090  
CANBERRA ACT 2601

**By email only:** [PackagingReform@dcceew.gov.au](mailto:PackagingReform@dcceew.gov.au)

Dear Sir/Madam,

**Re: Submission to Reform of Packaging Regulation Consultation Paper**

Thank you for the opportunity to provide comment on the Department of Climate Change, Energy, the Environment and Water's (DCCEEW) *Reform of Packaging Regulation* Consultation paper (the Consultation paper).

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.

AMA member companies play a vital role in Australia's food production, agricultural trade and biosecurity preparedness, as well as ensuring 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 across Australia in our 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.

The animal health sector is keen to engage and work collaboratively with the Government to improve packaging waste management in Australia. Animal Medicines Australia is pleased to provide the following comments on the Discussion paper for consideration by the DCCEEW.

## General comments

This reform process has broad implications for the animal health sector in Australia and the animals and community it serves. A thorough, meaningful approach to consultation and engagement with key stakeholders is required to ensure an inclusive, evidence-based process.

The timeframe for consultation of just 4 weeks was, however, insufficient to allow for thorough consideration and the provision of meaningful feedback by relevant stakeholders, undermining the effectiveness of the consultation process.

The Consultation paper highlights three key areas that have been identified as priority areas for consideration:

- Improve packaging design
- Improve recyclability labelling
- Recycled content thresholds

AMA agrees that action in these three areas has potential for improving packaging recycling and waste management in Australia. We encourage extensive consultation with stakeholders, particularly those with highly specialised products subject to rigorous regulation that covers packaging, prior to the introduction of broad regulatory oversight. The animal health sector is highly regulated and is required to comply with strict packaging and disposal labelling requirements to ensure product stability, safety and efficacy. Any additional, duplicative or contradictory regulatory requirements may have unintended consequences for the supply of veterinary medicines, with consequent impacts on animal health, biosecurity, public health and food availability.

## Animal health product waste management

AMA and our members are committed to reducing the use of unnecessary plastic packaging throughout the animal health product supply chain. The unique requirements for safe storage, transport and use of veterinary medicines necessitate careful consideration of all potential options for replacement of specific packaging types. For example, the requirements for shipping fragile, temperature- and light-sensitive veterinary medicines under variable environmental conditions and lack of suitable alternatives mean that, in some cases, the continued use of moulded Expanded Polystyrene (EPS) packaging is necessary.

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.

This complex regulatory framework reflects the unique aspects of the animal health sector and recognises the importance of product stability and efficacy, human and animal safety, and environmental responsibility – including waste management.

Any modification to packaging for veterinary pharmaceuticals, such as transitioning to alternative materials, requires a comprehensive testing to ensure the product's safety and effectiveness over time. This process can take several years.

Compounding these challenges, the capability of existing production equipment to accommodate changes in packaging materials or formats is a significant factor in the animal health sector's ability to change packaging materials. Implementing new packaging solutions can require substantial investments in new equipment and facilities, which have both financial and operational impacts.

The Consultation paper notes that exemptions or transitional arrangements could be considered for essential packaging where it cannot meet the proposed requirements without compromising its functional requirements – including packaging required to meet pharmaceutical safety standards. AMA supports exemptions be applied to primary packaging and applicator devices for animal health products necessary to ensure the stability, efficacy and safety of these important products.

## Recyclability of animal health product packaging

AMA members are committed to the stewardship of their products throughout their lifecycle and are long-term participants in the **drumMUSTER** and ChemClear® industry stewardship programs. Administered by Agsafe Ltd, **drumMUSTER** collects and recycles empty and eligible agricultural chemical and veterinary medicine containers into new products, including new chemical drums – creating a circular solution for eligible agricultural and veterinary containers, where appropriate.<sup>1</sup>

Participation in the voluntary **drumMUSTER** stewardship program demonstrates the animal sector's commitment to extended producer responsibility across the lifespan of veterinary medicine products. Under a fee-for-service arrangement, AMA members contribute financially to the recovery and recycling of eligible packaging through a per-litre payment system.

Since the program's introduction in 1999, more than 43.5 million containers have been collected, equating to nearly 46,000 tonnes of material diverted from landfill. Any mandatory regulatory requirements for packaging should consider existing arrangements and associated financial contributions, including **drumMUSTER**, when determining producer responsibilities.

AMA estimates that around 970 tonnes of plastic packaging is generated by the animal health sector per year for use in livestock, equating to less than 1% of all plastic waste material generated on Australian farms each year (excluding fisheries).<sup>2</sup> Of this, around one-third are eligible for recycling via the **drumMUSTER** program. The remaining veterinary medicine plastic waste generated on-farm is generally not recyclable via existing infrastructure, due to the unique and specialised nature of the products and packaging required to safely store, transport and administer them.

Existing regulatory requirements for disposal of veterinary medicine products takes into account the nature of the final product and complexity of associated packaging. Due to the presence of product residues and the size and specialised packaging types (small bungs, applicators etc) required to safely and accurately dispense the products, primary animal health product packaging is generally not considered recyclable via kerbside bins. AMA and our members would welcome improvements in Australia's recycling infrastructure that would facilitate more responsible disposal options for these packaging types, including processing and recycling capacity. In particular, improved infrastructure and access to facilities is urgently required in rural and regional areas – as highlighted recently by the Regional Australia Institute.<sup>3</sup>

AMA recommends that any mandatory requirements related to recyclability specifically exclude primary packaging for regulated industries such as veterinary pharmaceuticals, where product efficacy and safety regulations take precedence. Highly specialised and regulated industries like the animal health sector have much greater flexibility regarding secondary and tertiary packaging, compared with primary

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<sup>1</sup> Agsafe Drums to Drums; available at <https://agsafe.ac-page.com/Drums-to-Drums>

<sup>2</sup> Agrifutures Australia. Pre-farm gate waste management: Baseline waste data for the agriculture, fisheries and forestry sector; Available at <https://agrifutures.com.au/product/pre-farm-gate-waste-management-baseline-waste-data-for-the-agriculture-fisheries-and-forestry-sector/>

<sup>3</sup> Regional Australia Institute. Circular economy in Action: Regional perspectives. Available at <https://www.regionalaustralia.org.au/common/Uploaded%20files/Files/2024/Circular%20Economy/Circular%20Economy%20in%20Action%20-%20Regional%20Perspectives.pdf>

packaging that has a functional role in product efficacy, stability and safety. AMA suggests that efforts to improve waste management outcomes focus on packaging that does not come into direct contact with the product and does not have a functional role in ensuring the stability, efficacy and safety of the product.

The Consultation paper highlights that chemicals of concern will be phased out to improve recyclability of plastic packaging – while noting that Australia has existing regulatory frameworks to protect human health and the environment from risks associated with chemical use. The Consultation paper further notes that any new regulatory requirements would not duplicate existing requirements. The highly specialised nature of animal health products means that various chemicals are at times required to ensure the stability and safety of the product during storage, transport and use – for example to prevent leakage of product through plastic containers or maintain the physical properties of a product. These chemicals provide a necessary function or benefit to the veterinary medicine and, in many cases, alternatives are not available. AMA recommends the Government engage in extensive consultation with specialised sectors, including the animal health sector, and issue exemptions or transitional arrangements to ensure continued access to these important products and avoid any unintended negative consequences related to product stability, efficacy, safety or availability.

### **Labelling requirement for disposal of animal health products**

The Consultation paper highlights a lack of mandatory disposal statements in Australia, noting that the Australasian Recycling Logo (ARL) is voluntary and only available to APCO members. The animal health sector; however, has legislative requirements regarding product disposal labelling, which is regulated by the APVMA. The *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code)<sup>4</sup> requires that all registered animal health product labels include disposal instructions for packaging.

The Agvet Code states that the APVMA must have regard to certain matters or details in order for it to satisfy itself that a label meets the labelling criteria and approve the label (sections 5D and 14).

As outlined in Part 2, Section 7(1A)(f) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*,<sup>5</sup> the functions and powers of the APVMA include:

- (f) in co-operation with Governments and authorities of the Commonwealth, the States and the participating Territories, to develop codes of practice, standards and guidelines for, and to recommend precautions to be taken in connection with, the manufacture, export, import, sale, handling, possession, storage, disposal and use of chemical products in the States and participating Territories;

Section 5D(1) stipulates that the definition of “meets the labelling criteria” includes:

- (1) A label for containers for a chemical product meets the labelling criteria if the label contains adequate instructions relating to such of the following as are appropriate:
  - (g) the disposal of the product when it is no longer required;
  - (h) the disposal of containers of the product;

The Veterinary Labelling Code (VLC) outlines the requirements for label instructions relating to the appropriate disposal of veterinary medicine containers.<sup>6</sup> These disposal statements reflect the nature of the products, complexity of packaging and practicalities regarding recycling in rural and remote areas.

Any proposal to implement mandatory recycling labels for all packaging in Australia would replicate these existing requirements and add to already crowded product labels. Animal health product labels

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<sup>4</sup> Federal Register of Legislation: Agricultural and Veterinary Chemicals Code Act 1994; available at <https://www.legislation.gov.au/C2004A04723/latest/versions>

<sup>5</sup> *Agricultural and Veterinary Chemicals (Administration) Act 1992* ([legislation.gov.au](https://www.legislation.gov.au))

<sup>6</sup> APVMA. Label content – veterinary products; available at [https://www.apvma.gov.au/registrations-and-permits/labelling-codes/veterinary-labelling-code/label-content#Disposal\\_statements](https://www.apvma.gov.au/registrations-and-permits/labelling-codes/veterinary-labelling-code/label-content#Disposal_statements)

contain important information relating to the safe and efficacious use of the product. Increasing labelling requirements has the potential to distract from this important information and have negative unintended consequences for product efficacy, human and animal health and environmental protection.

## **Recycled content**

The materials used for the immediate packaging of veterinary medicines undergo extensive testing to ensure there are no interactions between the packaging and product that could jeopardise the quality or efficacy of the product and are safe for people administering the product and the environment.

In some cases, alternative packaging including recycled content may not be available or appropriate – for example, where the physical properties of recycled materials are inferior to virgin material and can cause leakage through the packaging or interact with the medicinal product, which can pose a contamination risk to the product. Recycling of Polyolefines (PE and PP) results in a blend of different polymer types, where every batch of recycled material has a different composition, and the properties of the materials can vary substantially between batches. Finally, materials used to produce e.g. blister film compositions are not commercially available as recycled materials because the technology to produce them is not available.

The incorporation of recycled content into existing animal health product packaging would require significant product testing to ensure the product remains safe and effective for use and satisfies the regulatory requirements for product stability, quality and safety.

Packaging materials are considered to be part of the registered animal health product, such that any changes to packaging materials must be considered by the APVMA to ensure the new materials continue to satisfy the registered specifications for safety, quality and efficacy. To generate the necessary data 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. This is particularly the case for low volume product lines with global supply chains.

A mandatory requirement for inclusion of recycled content in animal health product packaging in Australia may result in products being withdrawn from the market if it is not economically viable for manufacturers to invest in sourcing new packaging materials and generating the data required to ensure product stability and seek regulatory approval.

Ensuring access to animal health products and maintaining their viability and efficacy during transport, storage and use across Australia in our 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.

AMA notes that the Consultation paper indicates that exemptions may be considered where specific packaging types or functions may not be suited to recycled content. AMA urges the DCCEEW to implement an exemption for animal health products for the reasons noted above.

## **National and global harmonisation of packaging regulations**

Consideration of international supply chains and global packaging and traceability/reporting requirements should be prioritised. 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.

Nationally consistent packaging requirements are essential for ensuring rapid, reliable transport nationwide to address animal health and welfare concerns and ensure that food safety and biosecurity threats can be appropriately managed.

Changes to the use of plastics in the veterinary pharmaceutical supply chain, including packaging or disposal requirements, in a single jurisdiction could have detrimental impacts on the national supply chain as veterinary medicines are regulated at the federal level and distributed across state and territory borders. Products may become unavailable if new regulations are imposed in one jurisdiction and not

others, posing significant risks to animal health and welfare, agricultural production, biosecurity, human health and food safety. To ensure the costs and benefits associated with any new regulations on plastics are shared across the Australian marketplace and do not result in unintended negative consequences, regulations that affect the pharmaceutical supply chain must be consistent nationwide and informed by significant industry consultation.

National and global consistency regarding the inclusion of recycled content in packaging should be prioritised. In the case of veterinary pharmaceutical products, harmonisation 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.

AMA recommends consideration of specific regulatory requirements that currently exist for different commodity sectors and comprehensive consultation with affected industries, including the veterinary pharmaceutical sector, when making recommendations regarding packaging regulations, to avoid regulatory contradictions and any unintended negative impacts on product supply.

## **In Summary:**

Animal Medicines Australia is looking forward to further engagement with the Government regarding packaging waste management in Australia.

- Veterinary medicines are crucial tools used by veterinarians to support the health, welfare and wellbeing of livestock, pets, and other animals under human care.
- Packaging regulations 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 and low volume product lines with global supply chains).
- National consistency should be prioritised.
- Consideration of global requirements and supply chains is essential.

## **AMA supports:**

- AMA supports the proposed exemptions for essential packaging where it cannot meet the proposed requirements without compromising its functional requirements – including packaging required to meet pharmaceutical safety standards such as animal health products.
- AMA supports the proposed exemptions to recycled content requirements where packaging types or functions that are not suited to recycled content, including animal health products.
- AMA supports national harmonisation of packaging regulations to ensure unintended adverse consequences are avoided.

## **AMA does not support:**

- AMA does not support broad implementation of regulatory requirements relating to recyclability, including packaging design and phase-out of specific chemicals in packaging. Animal health products are highly regulated products with legislated requirements relating to packaging and product stability. A mandatory requirement for packaging design and composition may jeopardise the availability, efficacy or safety of important veterinary medicines.
- AMA does not support the implementation of mandatory requirements for recycled content in packaging for animal health product packaging or the introduction of a tax for products where the packaging does not include recycled content. Animal health products are highly regulated products with legislated requirements relating to packaging and product stability. A mandatory requirement for recycled content in packaging materials may jeopardise the availability, efficacy or safety of important veterinary medicines.

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

Yours Sincerely,

A handwritten signature in black ink, appearing to read 'Katie', followed by a horizontal line extending to the right.

Dr Katie Asplin

Director, Animal Health Policy and Engagement