Animal Medicines Australia

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Australian Packaging Covenant Organisation
PO Box Q1523
Queen Victoria Building
SYDNEY NSW 1230

Submission via online survey only

Dear Sir/Madam,

Re: Consultation on a strengthened industry-led EPR approach for packaging

Thank you for the opportunity to provide comment on the APCO Member Consultation Paper, *From Collective Action to System Impact: Strengthening packaging EPR to build social license and achieve Australia's National Packaging Targets* (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 rapidly expanding 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 APCO and governments to improve packaging waste management in Australia. Animal Medicines Australia is pleased to provide the following comments on the Consultation paper for consideration by APCO.

Key points:

- Animal Medicines Australia looks forward to further engagement with APCO 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.
- EPR stewardship schemes 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).
- The implementation of broad EPR requirements relating to recyclability, including the inclusion of recycled content in packaging should be avoided.
- Consideration of global requirements and supply chains is essential.

General comments

This review 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.

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.

AMA urges APCO to avoid making broad recommendations that do not fully consider the needs of sectors that supply highly specialised products subject to rigorous regulation regarding waste management. The animal health sector is highly regulated and is required to comply with strict packaging and disposal requirements to ensure product stability, safety and efficacy, as well as ensuring the safety of people, animals and the environment. The introduction of Extended Producer Responsibility (EPR) mechanisms that do not adequately consider the unique regulatory and supply environment that the animal health sector operates within may have unintended consequences for the supply of veterinary medicines, with consequent impacts on animal health, biosecurity, public health and food availability.

While the Consultation paper makes reference to niche packaging types, including pharmaceuticals and agricultural products, it is not clear how these sectors will be exempted or accommodated in the proposed scheme. Further information regarding how niche packaging types and sectors with unique regulatory or product stability requirements for packaging will be considered by APCO when implementing the proposed scheme is required.

Regulation of animal health product disposal

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.

Ensuring product stability and safety

AMA notes the proposal in the Consultation paper to provide modulating discounts to incentivise changes to packaging design. The ability for the animal pharmaceutical sector to access these benefits and accommodate amendments to packaging design is highly dependent on external factors, such as regulatory requirements and global supply chains, as well as costly, lengthy stability and safety trials to ensure that any new packaging material is fit for purpose and meets existing regulatory conditions. AMA recommends that APCO consider the unique regulatory requirements for niche product types when determining both negative and positive incentives for adopting new technologies relating to packaging. Providing incentives where companies can demonstrate that efforts are being made to meet EPR parameters, such as the commencement of safety and stability testing and/or applications to the regulator to amend packaging types would be welcome.

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.

Consequently, 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.

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 materials such as blister film compositions are not commercially available as recycled materials because the technology to produce them is not available.

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. Implementing new packaging solutions can require substantial investments in new equipment and facilities, which have both financial and operational impacts.

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.

Labelling requirements for the disposal of animal health products

The animal health sector is subject to legislative requirements regarding product disposal labelling, which is regulated by the APVMA. The *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code)[1] 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).

[1] Federal Register of Legislation. Agricultural and Veterinary Chemicals Code Act 1994: https://www.legislation.gov.au/C2004A04723/latest/versions

As outlined in Part 2, Section 7(1A)(f) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*,[2] 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.[3] These disposal statements reflect the nature of the products, complexity of packaging and practicalities regarding recycling in rural and remote areas.

In most cases, it is considered inappropriate for veterinary pharmaceutical product packaging to be recycled via kerbside recycling services, due to the nature of both the packaging (small, niche components) and product residues. The relatively small volume of veterinary pharmaceutical packaging is also generally not suitable for the implementation of specific collection or return schemes – especially in regional and rural areas. Significant investment in and development of infrastructure, including collection, transport and processing facilities that can safely dispose of veterinary pharmaceutical packaging, particularly in rural and regional areas is urgently required to facilitate veterinary pharmaceutical waste management.

Stewardship 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 ***drum****MUSTER* and ChemClear® industry stewardship programs. Administered by Agsafe Ltd, ***drum****MUSTER* 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.[4]

Participation in the voluntary ***drum****MUSTER* stewardship program demonstrates the animal sector's commitment to EPR 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 44 million containers have been collected and diverted from landfill. Any mandatory regulatory requirements for packaging should consider existing arrangements and associated financial contributions, including ***drum****MUSTER*, 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).[5] Of this, around one-third are eligible for recycling via the

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[2] Federal Register of Legislation. Agricultural and Veterinary Chemicals (Administration) Act 1992: Federal Register of Legislation - Agricultural and Veterinary Chemicals (Administration) Act 1992

[3] APVMA. Label content – veterinary product: https://www.apvma.gov.au/registrations-and-permits/labelling-codes/veterinary-labelling-code/label-content#Disposal_statements

[4] Agsafe Drums to Drums: https://agsafe.ac-page.com/Drums-to-Drums

[5] AgriFutures Australia. Pre-farm gate waste management: Baseline waste data for the agriculture, fisheries and forestry sector: https://agrifutures.com.au/product/pre-farm-gate-waste-management-baseline-waste-data-for-the-agriculture-fisheries-and-forestry-sector/

drum*MUSTER* 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.[6]

Highly specialised and regulated industries like the animal health sector have much greater flexibility regarding secondary and tertiary packaging, compared with primary 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.

Complex international and local supply chains

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 nation-wide 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.

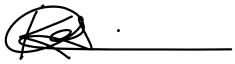
National and global consistency regarding the inclusion of recycled content in packaging should be prioritised and exemptions implemented for highly regulated, specialty packaging such as animal health products. In the case of veterinary pharmaceutical products, harmonisation is essential for ensuring 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 stewardship, to avoid regulatory contradictions and any unintended negative impacts on product supply.

[6] Regional Australia Institute. Circular economy in Action: Regional perspectives: https://www.regionalaustralia.org.au/common/Uploaded%20files/Files/2024/Circular%20Economy/Circular%20Economy%20in%20Action%20-%20Regional%20Perspectives.pdf

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

Yours Sincerely,



Dr Katie Asplin

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