Animal Medicines Australia

Animal Medicines Australia
ABN 76 116 848 344 / ACN 116 848 34
15 National Circuit
Barton ACT 2600, Australia

T +61 2 6257 9022
E enquiries@animalmedicines.org.au
W animalmedicines.org.au

6 June 2025

National Competition Analysis 2025
Productivity Commission
Melbourne VIC 8003

Online submission via https://www.pc.gov.au/inquiries/current/competition-analysis-2025

Dear Sir/Madam,

RE: National Competition Policy analysis 2025

Thank you for the opportunity to provide comment on the National Competition Policy analysis 2025.

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 growing pet industry. Our members represent approximately 80% of registered veterinary medicine sales in Australia.

AMA welcomes the opportunities that were first identified in the 2024 Productivity Commission report '*National Competition Policy: modelling proposed reforms'* and put forward for further modelling and analysis in this study – specifically, to adopt trusted overseas standards and address regulatory barriers related to emerging technologies, to support the competitiveness and productivity of our sector.

The global population is expected to increase from the current 7.7 billion to 9.7 billion by 2050, with the population in Australia and New Zealand projected to increase by 28%.[1] At the same time, the global middle class is expected to expand to 5.3 billion people. Collectively, these changes in population metrics are expected to generate a 35% increase in the demand for food by 2030 and a substantial increase in demand for animal protein from meat, eggs or dairy.[2,3]

[1] WPP2019_10KeyFindings.pdf
[2] Growing consumption | Knowledge for policy
[3] Options for the livestock sector in developing and emerging economies to 2030 and beyond

To continue to meet the growing demands for animal protein, both domestically and for our important export markets, Australian livestock farmers will be required to not only improve productivity, but also their efficiency – that is, improving productivity while simultaneously reducing their environmental impact and ensuring their operations remain economically viable. The National Farmers Federation's ambitious goal of Australian agriculture being a $100 billion sector by 2030 will only be realised by maintaining the health and welfare of Australia's livestock.[4] Healthy animals produce more meat, milk and eggs, enabling farmers to meet the increasing demand for animal protein with fewer animals, more sustainably.

Australia's strong biosecurity and industry-led disease preparedness and response processes, including access to disease prevention tools such as vaccines, are central to agricultural productivity by keeping devastating animal diseases out of Australia. Fewer animals lost or suffering from disease will improve food security, food safety and trade, whilst reducing pressure on natural resources and lowering emissions associated with animal production.

Pet ownership in Australia is booming, with an estimated 28.7 million pets found in 6.9 million households.[5] Pet ownership has been demonstrated to contribute to improved physical and mental wellbeing and a recent survey commissioned by AMA found that 70 per cent of respondents reported that being pet owners improved their lives during the COVID-19 pandemic.[6,7]

Globally, the animal health sector invests nearly $3 billion per year in the development of new preventative, diagnostic and treatment options.[8] Having ready access to the tools necessary to keep animals healthy is key to a productive, sustainable and resilient society in Australia, with subsequent environmental, economic and social benefits. It is vital that Australian farmers and pet owners have timely access to the critically important animal health products that AMA's member companies provide.

Regulation to support productivity

AMA strongly supports the Government principles of best practice regulation[9] and the concept of 'minimum effective regulation' described by the Productivity Commission, to guide how regulation should be approached.[10] The discipline and rigor provided by these principles encourages regulation that is appropriate, justified, properly targeted and proportionate. Scientific, risk-based regulation that adheres to these principles is key to maximising productivity growth. To maximise potential productivity benefits, it is essential to ensure that all regulatory activities, reviews, reforms and policy developments comply with these principles.

---

[4] 2030 Roadmap - National Farmers' Federation

[5] Pets in Australia: A national survey of pets and people - Animal Medicines Australia

[6] Survey of U.S. Pet Owners | HABRI

[7] Pets and the Pandemic: a social research snapshot of pets and people in the COVID-19 era - Animal Medicines Australia

[8] Environment, Health, and Communities (healthforanimals.org)

[9] Australian Government Guide to Policy Impact Analysis | The Office of Impact Analysis

[10] 'Minimum effective regulation' and the mining industry - Productivity Commission Chairman's Speech - Productivity Commission

Global harmonisation

AMA considers that there are significant productivity benefits to be realised in our sector from greater adoption of trusted international standards and guidelines, that could deliver lower costs of compliance for businesses, increasing product choice and availability for consumers, faster and consistent regulation of emerging technologies, lower costs for regulatory agencies (such as APVMA, TGA and FSANZ) and the replacement of outdated standards.

There are considerable adaptive costs to register an animal health product to Australia due to unique Australian regulatory requirements. AMA member companies invest significant resources over many years to research, develop and register veterinary medicines that support animal health and welfare, farm productivity and sustainability. Products are often developed for global markets, with every Australia-specific requirement (such as requirements for additional residue trials to determine Export Slaughter Intervals, or unique labelling requirements) increasing the time, cost and complexity to bring innovative new products to our farmers.

To maximise the productivity benefits derived from veterinary medicines, harmonisation with existing global regulatory standards and systems is critical. The Australian market is small by global standards and seemingly minor differences in regulatory requirements, such as labelling or packaging, can have a disproportionate impact on the commercial decision to bring a new product to the Australian market.

For the veterinary medicines sector, global harmonisation includes the implementation of VICH guidelines on technical requirements for registration[11], using existing pharmacopoeial standards for actives (rather than creating a new Australian pharmacopoeia), and adopting trade and food safety standards and requirements set out by Codex, JECFA and the WTO. Closer alignment of labelling and packaging requirements with other major markets would be welcomed.

Important productivity benefits for Australian producers could also be obtained by leveraging multilateral opportunities (APEC, ASEAN) and free trade agreements (FTAs) to address trade barriers and align import tolerances for animal-derived commodities in global markets.

Trans-Tasman harmonisation

The New Zealand and Australian markets are highly interrelated, with many companies operating joint Australia-New Zealand businesses, with shared manufacturing, supply chains and regulatory teams that manage their product portfolios across both markets. AMA notes that many New Zealand product lines (especially therapeutics), and a number of Australian products, may not be commercially viable for local release without the additional scale generated by the two markets combined.

Measures that support closer regulatory alignment between Australia and New Zealand will encourage innovation and investment in our region and confer significant animal health and welfare benefits to both Australia and New Zealand.

[11] https://vichsec.org/

Regulatory barriers to competition and trade

Trade barriers

Unique Australian regulatory requirements that diverge from global norms create significant barriers to competition and productivity. An illustrative example in the veterinary medicines sector is the use of Export Slaughter Intervals (ESIs). Australia is the only country that sets two separate 'withdrawal periods' for the use of veterinary medicines prior to slaughter – the withholding period (WHP) for the domestic market and the Export Slaughter Interval (ESI) for export markets. The WHP is concerned with human food safety, while ESIs are solely a tool for mitigating potential risks to trade from the presence of veterinary medicine residues (it has no human food safety relevance).

Livestock producers manage a complex set of factors to ensure their animals are healthy, their farms are productive, their businesses are efficient and their produce meets export market specifications more competitively than their overseas competitors. Although ESIs provide trade assurance, they reduce the competitiveness of Australian producers. ESIs limit the ability of Australian producers to use certain veterinary medicines as intended and restrict Australian producers from obtaining important animal health, sustainability and productivity benefits that are available to their competitors who export to the same markets.

A new approach to managing trade risks is needed that moves away from a sole focus on market analysis to also consider animal health and welfare, resistance management, market competitiveness, agricultural productivity and sustainability, and reduce the barriers to bringing innovative new veterinary medicines to Australia.

Emerging technologies

AMA recognises the important role that emerging technologies may provide in delivering health and welfare benefits to the livestock, companion animal and agricultural sectors. Promising new medical technologies include monoclonal antibodies, mRNA and multi-strain vaccines, and gene technologies.

"Smart" technologies are increasingly being utilised to improve the diagnosis, treatment and management of disease in both people and animals. There are important productivity opportunities for animal health in a wide range of related areas, such as intellectual property protections, digital record management, data sharing, machine-readable labels, point-of-care diagnostics, wearable monitors, biosensors, artificial intelligence, remote sensing, nanotechnology and robotics (among others).

New technologies do not necessarily require entirely new regulatory systems; many risks can be effectively and efficiently managed through existing regulatory structures and systems. To support effective and efficient regulation whilst maximising productivity benefits from new technology, the general approach to regulation of emerging technologies should be:

- risk-based, where regulation is proportionate to the risk of potential harm,
- technology-neutral, where regulation is focussed on the outcomes, rather than the process or methods used, and is able to accommodate future developments,
- data-driven, where regulation is adaptive and able to respond to actual uses and potential harms as they emerge rather than speculating about harms and pre-empting uses, and

- collaborative, where regulation is developed in collaboration with the regulated community, is aligned nationally and internationally, and builds expertise within the regulatory community.

Work on how to appropriately regulate a number of emerging veterinary medicine technologies, (particularly vaccines and monoclonal antibodies) has been well advanced by other leading global regulatory authorities. To the greatest extent possible, Australia should take its lead from existing, globally trusted, regulatory approaches and only diverge from global principles and practices where a different approach in Australia is justified by science-based risk assessment.

Supporting local manufacturing

The veterinary medicines sector is one of Australia's most highly regulated industries, with significant regulatory requirements regarding quality assurance. The majority of animal health products available in Australia are currently manufactured overseas, alongside local manufacturing which exports to global markets. The capability to manufacture animal medicines locally, while maintaining quality and consistency standards and minimising waste, will provide our members with greater opportunities for local manufacturing.

Australia has a reputation for high quality manufacturing capability. Promoting and advancing Australia's local manufacturing capabilities would assist in protecting local capacity in high-tech, specialised markets, such as animal medicines. This capacity would, in turn, aid in safeguarding Australia's livestock and companion animal sectors against potential supply issues, such as those experienced during the COVID19 pandemic as a result of global supply chain disruptions.

Supporting innovation

Innovation in animal health requires scientific and risk-based approaches and policy settings that aim to eliminate barriers, provide seamless systems between registrations and product uses, incentivise development of local infrastructure and resources, facilitate collaboration, support regulatory innovation, promote unencumbered trade of animals and animal products, support animal welfare of both livestock and companion animals, and meet the challenges of social license. Australia's ability to deliver on sustainability, efficiency, trade (in animals and animal commodities) and economic goals is dependent on the commercialisation and adoption of innovative new technologies.

The Australian market is small, which limits the ability of companies to recover the costs of bringing a new product to the market. Streamlining interactions between industry, stakeholders and government, and recognising areas of intellectual property, data protection and other incentives that support commercial decision-making, will encourage investment in Australia. Policy and processes must support efficient and appropriate evaluation of new technologies and encourage the adoption of innovations across broad areas to address animal health challenges. Such actions could also boost the potential value of Australian-developed technologies in international economies.

The provisions for data protection for veterinary medicines within the current regulatory framework are limited, complicated and inconsistent between agricultural chemicals and veterinary medicines in similar situations. Further, Australian data protection periods are often significantly shorter that those available in comparable regulatory systems overseas. Data protection is a critical element underpinning commercial and investment decisions, and the current situation significantly inhibits investment and innovation in

Australia. The need for data protection reform was acknowledged in the 2024 government response to recent reviews of the APVMA.[12]

AMA would be pleased to discuss any of the issues raised in our submission in more detail. Please feel free to contact me at any time.

Yours sincerely,

Dr Charmian Bennett
Director Science and Policy

[12] Detailed response to the final report on future structure and governance arrangements for the Australian Pesticides and Veterinary Medicines Authority