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23 March 2022

Mr Michael Brennan
Chair, Productivity Commission
Australian Government
Canberra ACT

Dear Mr Brennan,

Re: Productivity Commission Inquiry

Animal Medicines Australian (AMA) welcomes the opportunity to provide comments to the Productivity Commission's review of Australia's productivity performance.

AMA is the peak industry association representing the registrants and approval holders of veterinary medicines and animal health products in Australia. They include Australian and global animal health companies that innovate, manufacture, formulate and register essential veterinary medicines and animal health products. These products are critical to supporting Australia's $28 billion dollar livestock industry and $30 billion pet industry. Our members represent more than 90% of registered veterinary medicine sales in Australia.

AMA supports the Inquiry's mandate to review Australia's productivity performance and recommend an actionable roadmap to assist governments to make productivity-enhancing reforms.

Productivity growth is reliant on regulation that is effective, efficient and fit for purpose, and consistent with government principles of best practice regulation.

Thank you for your consideration of AMA's comments. If I can provide any further information to assist, please do not hesitate to contact me.

Yours Sincerely,

(unsigned for electronic submission)

Ben Stapley

Executive Director

SUBMISSION TO THE

Productivity Commission Inquiry

23 March 2022

Animal Medicines Australia

Introduction

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 per cent.[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 per cent increase in the demand for food by 2030[2] and a substantial increase in demand for animal protein from meat, eggs or dairy.[3]

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.

Pet ownership in Australia is booming, with an estimated 30.4 million pets found in 69 per cent of households.[4] Pet ownership has been demonstrated to contribute to improved physical and mental wellbeing[5] 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]

Globally, the animal health sector invests nearly $3 billion per year in the development of new preventative, diagnostic and treatment options.[7] 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.

The importance of scientifically sound, risk-based regulation

AMA promotes the responsible and judicious use of veterinary medicines in animals for the benefit of animal health and welfare, agricultural productivity and sustainability, and public health. We seek to ensure that the regulatory environment for veterinary medicines in Australia is robust, proportionate, risk-based and scientifically sound.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is almost entirely cost-recovered, funded by application and registration fees and levies from the regulated industry. The APVMA has only recently emerged from a prolonged period of disruption and poor performance associated with its relocation. Since 2020, AMA has observed a significant improvement in corporate culture and performance, with on-time application completion rates rising steadily from around 70% in 2017, to 99.1 per cent in the last reported quarter (Oct-Dec 2021).

[1] WPP2019_10KeyFindings.pdf (un.org)
[2] Growing consumption | Knowledge for policy (europa.eu)
[3] Options for the livestock sector in developing and emerging economies to 2030 and beyond | International Livestock Research Institute (ilri.org)
[4] Pets and the Pandemic: a social research snapshot of pets and people in the COVID-19 era – Animal Medicines Australia
[5] 2016 Pet Owners Survey | HABRI
[6] AMAU005-PATP-Report21_v1.41_WEB.pdf (animalmedicinesaustralia.org.au)
[7] Environment, Health, and Communities (healthforanimals.org)

The recent *Independent review of the pesticides and veterinary medicines regulatory system in Australia*[8]provided an opportunity to make course corrections to the regulatory framework, recognising that "*reducing the level of unnecessary or poorly designed regulation will contribute to improved productivity and future living standards for all Australians*."[9] **Disappointingly, this opportunity was missed – with many of the recommendations of the review likely to significantly reduce regulatory rigour and oversight, with potential negative impacts on product safety, consumer trust and trade facilitation.** AMA contends that the rigour of the findings of the review could have been enhanced through adherence to the Government's guidance and principles regarding best practice regulation.

AMA strongly supports the Governments Principles of Best Practice Regulation[10] and the concept of '*minimum effective regulation'* described by the Productivity Commission to guide how regulation should be approached.[11] The discipline and rigor provided by these principles encourages regulation that is appropriate, justified, properly targeted and proportionate.[12] AMA expects adherence to the Principles of Best Practice Regulation wherever there is an expectation of compliance by the regulated community. Similarly, AMA supports the *Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies* by the Office of Best Practice Regulation (Department of Prime Minister and Cabinet).[13] Scientific, risk-based regulation that adheres to these principles is key to maximising productivity growth. The Government is encouraged to ensure that all regulatory activities, reviews, reforms and policy developments comply with these principles.

AMA agrees with the view presented in the Principles of Best Practice Regulation that regulators should aim to improve their performance, capability and culture while remaining flexible and responsive to changing circumstances. The willingness of the APVMA to consult with industry to develop mutually acceptable solutions to address disruptions arising from the pandemic is commendable. For example, COVID-related travel restrictions significantly disrupted manufacturing audit schedules, requiring a collaborative approach by APVMA with industry to maintain assurance of product quality standards under alternative audit arrangements, thereby ensuring the availability of critical animal health products during the pandemic.

AMA would encourage the Government and all regulatory agencies to recommit to the principles and practices of best practice regulation and minimum effective regulation.

[8] Independent review of the pesticides and veterinary medicines regulatory system in Australia - DAWE
[9] porter_e.ppt (live.com)
[10] Australian Government Guide to Regulatory Impact Analysis | OBPR (pmc.gov.au)
[11] 'Minimum effective regulation' and the mining industry - Speeches and Presentations - Productivity Commission (pc.gov.au)
[12] Regulator Performance Guide and supporting material | Deregulation (pmc.gov.au)
[13] Best Practice Regulation: A guide for Ministerial Councils and National Standard Setting Bodies | Department of the Prime Minister and Cabinet (pmc.gov.au)

Harmonisation and streamlining across and between regulatory systems

While veterinary medicines are regulated primarily by the APVMA, there are many regulatory systems that interact with the APVMA throughout the registration process. These include:

- Therapeutic Goods Administration
- Food Standards Australia New Zealand
- Dangerous Goods Transport
- Dangerous Goods Storage
- Chemicals of Security Concern
- Diversion to Illicit Drugs
- Retail storage
- Chemical Scheduling
- Biosecurity import permits
- Globally Harmonised System of Classification and Labelling of Chemicals (GHS)
- Environmental impacts
- Workplace health and safety
- Australian Packaging Covenant
- Waste management
- National Pollutant Inventory
- International treaties and conventions
- International trade agreements
- State and territory legislation
- Federal legislation
- Office of the Gene Technology Regulator

These interactions are responsible for many of the inefficiencies associated with the regulation of veterinary chemicals in Australia. Ensuring consistency between these regulatory schemes will greatly improve the efficiency of the regulatory framework in Australia and ensure that livestock producers have access to the products they need for efficient productivity in a timely manner.

Where possible, Australia should seek to align its regulatory requirements with international standards and best practice to improve consistency and minimise the need for Australia-specific requirements. The Australian market is small by global standards and seemingly minor differences in requirements, such as labelling, can have a significant impact on the commercial decision to bring a new product to the Australian market.

An illustrative example of duplicative and inappropriate regulation in this industry concerns the labelling of veterinary chemicals.

The APVMA has the legislated authority to set the labelling requirements for veterinary medicines. These requirements are specified in the APVMA Veterinary Labelling Code[14] and compliance with these requirements is enforced by APVMA.

As part of its expert risk assessment process, the APVMA examines the risks to people's health and safety associated with a veterinary chemical product by taking into account the hazard and the potential for exposure, using a risk assessment approach that:

- identifies and characterises any potential hazards associated with the use of a substance, to determine whether the substance has the potential to cause adverse effects;
- evaluates potential routes and duration of exposure to the substance; and
- characterises the risk or probability that the adverse effect will occur under the defined exposure conditions.

Based on the outcome of the risk assessment, risk mitigation measures can be implemented to reduce human health risks to an acceptable level where necessary, including safety directions, use of

[14] Labelling codes | Australian Pesticides and Veterinary Medicines Authority (apvma.gov.au)

personal protective equipment or restraints on use. This information must then be included on the registered label of that veterinary chemical product.

The *Work Health and Safety Act 2011* imposed a requirement for many veterinary chemical products to also carry hazard and precautionary statements defined by the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The GHS was established as a means of classifying chemicals by the type of hazard (i.e. the potential to cause harm) and communicating hazard to the user via pictograms and Safety Data Sheets.

AMA notes that veterinary pharmaceuticals are specifically identified as out of scope of the GHS. In the GHS document's 534 pages, the only reference to "veterinary" is the following:

> *"At other stages of the life cycle for these same chemicals, the GHS may not be applied at all. For example, at the point of intentional human intake or ingestion, or intentional application to animals, products such as human or veterinary pharmaceuticals are generally not subject to hazard labelling under existing systems. Such requirements would not normally be applied to these products as a result of the GHS (it should be noted that the risks to subjects associated with the medical use of human or veterinary pharmaceuticals are generally addressed in package inserts and are not part of the harmonisation process)."*[15] *(underlining added)*

The inclusion of GHS label elements on veterinary chemical products is inconsistent with international best practice. All equivalent international regulators exclude veterinary products from GHS labelling requirements, as intended by the GHS itself. Notably, and appropriately, the GHS is also not applied to *human* therapeutic goods in their finished form in Australia.

Further, the placement of both "hazard" (GHS) and "risk" (as assessed by the APVMA) information on veterinary product labels represents regulatory duplication with contradictory information, risking confusion and subsequent mis-use by consumers. Overlaying the APVMA expert risk assessment with GHS hazard elements does not improve user safety and contributes to label clutter on already crowded labels. The APVMA also does not approve GHS label content as GHS is regulated by Safe Work Australia.

Following considerable industry advocacy, the model work health and safety legislation was amended in 2017 to provide an exclusion for veterinary chemical products *if* they are listed on Schedule 4 (if supplied in a form and packaging consistent with direct administration to animals) or Schedule 8 of the Poisons Standard. Veterinary chemicals listed on other Poison Schedules, including parasiticides, antibiotics, analgesics and anaesthetics, are still required to include GHS element on the label.

To have effect, the amendment to exclude some veterinary chemicals needed to be adopted in all jurisdictions. State and territory governments adopted this amendment as written, however the Commonwealth work health and safety regulator, Comcare, inserted a sunsetting clause to the amendment so that the veterinary exclusion from GHS would cease and all veterinary chemicals would need to be brought under GHS requirements on 31 December 2023. If this sunset clause is not removed from the Commonwealth legislation, it could lead to the peculiar situation in which a veterinary product would be legally labelled according to all relevant state legislation, yet would be considered non-compliant whilst being transported by a freight company or used on a premises that is licensed by Comcare.

[15] GHS (Rev.7) (2017) | UNECE

Regulatory requirements should not extend to industries where they were never intended to be applied, as in the case of GHS labelling of veterinary medicines in Australia. Imposition of inappropriate requirements creates unique and expensive burdens for industry and is an important barrier that limits access to the Australian market, to the detriment of animal health and welfare, public health, agricultural productivity and competitiveness, food safety and security, and environmental protection.

Supporting Innovation

The Australian market for veterinary medicines is approximately 2.2% of global sales and compared to market size, the regulatory costs are significant. A characteristic of the business operating environment has been the long-term decline, or stagnation, of livestock numbers. For instance, the Australian national sheep flock dropped from 170.3 million head in 1990, to a low of 63.5 million head in 2020 during drought conditions, with a small rebound in 2021-22 to around 74 million head following the end of the drought[16]. Pet ownership, however, is increasing, with almost 70% of Australian households having a pet.

Animal health products are critical inputs to Australia's livestock production systems. They are intrinsically linked to livestock production, markets, weather and climate, technology, farming systems and other variables.

In December 2019, Animal Health Australia published a report on *Megatrends, Opportunities and Challenges Facing Australian Livestock Industries*.[17] This report highlighted that the opportunities for veterinary medicines in Australia are tied to the successes, or otherwise, of our livestock enterprises:

> "*Rapid and transformative changes in the way livestock farmers do business and the way consumers select products – driven by increasing demand, advances in technology, ecological considerations and climate variability – calls for a long-term, holistic approach to animal health and biosecurity policy in order to safeguard our investment in our herds and flocks and our adoption of new technologies."*

Australia's business operating environment has important ramifications for innovation in veterinary medicines, which could include new chemical entities, new formulations, delivery mechanisms, packaging, compliance aids and other platforms to assist in the delivery of healthcare for animals.

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 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 and other incentives that support commercial decision-making, will encourage investment in Australia. Policy and processes must support efficient and appropriate evaluation of

[16] Meat and Livestock Australia www.mla.com.au
[17] Industry publications - Animal Health Australia

new technologies and encourage the adoption of innovations across broad areas to address animal health challenges, such as genetics, remote sensing, management systems, information technology and robotics. Such actions could also boost the potential value of Australian-developed technologies in international economies.

Facilitating movement of products and labour

In 2015-16, the use of animal health products created an additional 9,898 jobs in Australia and generated more than $578 million in wages[18] – highlighting the important contribution the sector makes not only to Australia's food production but also the national economy and agricultural productivity more broadly.

For some time, the veterinary sector has faced workforce shortages, with both private practices and government agencies struggling to fill positions, particularly in rural and regional areas.[19] These shortages have been exacerbated by the COVID-19 pandemic, which saw a boom in pet ownership and disruption of the movement of veterinarians due to border restrictions, coincident with the end of crippling drought conditions that triggered re-stocking of livestock herds. These factors led to an unprecedented increased demand for veterinary services without corresponding increases in availability. Subsequently, the veterinary sector is facing a workforce crisis that threatens its long-term sustainability and places the mental health and wellbeing of veterinarians under significant strain.

In 2021, the Australian Veterinary Association successfully lobbied the government to have overseas veterinarians included on the Priority Migration Skilled Occupation List (PMSOL), allowing for visas to be fast-tracked for suitably qualified overseas veterinarians. While this will hopefully provide some relief for Australia's over-worked veterinarians, workforce shortages remain, and ongoing staffing and isolation impacts of the COVID-19 pandemic continue to pose challenges for the sector.

Despite the important role veterinarians play in our lives by keeping our pets and livestock healthy, the veterinary industry globally and in Australia is facing a mental health crisis, with veterinarians tragically up to four-times more likely than the general population to die by suicide and twice as likely as other health professionals.[20,21] In a recent survey of Australians working in the veterinary profession, 66.6 per cent reported that they have or are experiencing a mental health condition – 4.8 per cent above the national average during the same time period.[22] High workloads, negative client interactions, staff shortages and a lack of work-life balance were listed as contributing factors to poor mental health.

Similarly, farmers report worse mental health and wellbeing compared with non-farmers, and the suicide rate among farmers is higher than the general population.[23,24] Financial pressures, workload, isolation and a lack of accessible support services, as well as the unique pressures faced by farmers,

[18] Microsoft Word - AMA Economic Contribution Final Report 9 August 2018.docx (animalmedicinesaustralia.org.au)
[19] Veterinary workforce (ava.com.au)
[20] Workplace stress, mental health, and burnout of veterinarians in Australia - PubMed (nih.gov)
[21] AVA short report
[22] ava-sf-veterinary-wellness-report-oct2021.pdf
[23] The health and wellbeing of Australian farmers: a longitudinal cohort study | BMC Public Health | Full Text (biomedcentral.com)
[24] Social factors and Australian farmer suicide: a qualitative study | BMC Public Health | Full Text (biomedcentral.com)

such as drought and bushfires (which are likely to worsen as a result of climate change), are considered contributing factors to poor mental wellbeing among farmers.

Additional resources for veterinarians and farmers are required to prioritise and safeguard the mental and physical wellbeing of the people who care for our pets and livestock, providing us with companionship and ready access to safe, nutritious and affordable food. AMA supports the Australian Veterinary Association's efforts to improve our understanding of the pressures placed on veterinarians and others working within the industry, as well as provide support and identify and implement solutions.[25]

Safeguarding Australia's livestock sectors

The animal health sector plays an important role in safeguarding Australia's livestock industries by ensuring farmers have access to all available tools that they need to improve and maintain the health of their animals, including vaccines, diagnostics and veterinary expertise.

The World Organisation for Animal Health (OIE) estimates that more than 20% of animal production worldwide is lost as a direct result of disease[26]. Without access to animal health products such as vaccines, antimicrobials, parasiticides etc., farm productivity would be reduced due to:

- higher farm input costs per unit of production,
- sick animals are less productive, reducing returns on farm investment,
- higher animal mortality due to illness or disease, and
- more labour-intensive stock management practices to control and manage disease on farm.

The National Farmers Federation's ambitious goal of Australian agriculture being a $100 billion sector[27] will only be realised by maintaining the health and welfare of Australia's livestock. Healthy animals produce more meat, milk and eggs, enabling farmers to meet the increasing demand for animal protein with fewer animals.

Animal health products are responsible for up to 15 per cent of production in seven key commodity groups in Australia (beef cattle, dairy, sheep meat, wool, pork, chicken meat and eggs), contributing $2,668 million to the Australian economy.[28] The use of animal health products in Australia reduces the average consumption prices for meat, eggs and dairy products by approximately 12.8 per cent, equating to an average annual average household saving of around $270.

Animal disease outbreaks, however, contribute to increased food costs. An outbreak of Foot and Mouth Disease (FMD) in Australia would be devastating for the meat and wool industries, halting exports for at least six to 12 months and costing the industry up to $50 billion over ten years.[29] Such an outbreak would have significant impacts on both food availability and cost.

A 1999 outbreak of Newcastle Disease in Australia resulted in the slaughter of 1.9 million meat chickens and 13,000 laying hens, with a cost to farmers of around $200 million. The eradication program took 3 months, involved 5000 people and cost the government $22 million excluding

[25] Veterinary Wellness Project | AVA
[26] VS-FINAL-EN.pdf (oie.int)
[27] 2030 Roadmap - National Farmers' Federation (nff.org.au)
[28] Microsoft Word - AMA Economic Contribution Final Report 9 August 2018.docx (animalmedicinesaustralia.org.au)
[29] Megatrends, opportunities and challenges facing Australian livestock industries

compensation.[30] There have been no outbreaks of Newcastle Disease in Australia since a vaccination and surveillance program was implemented in 2002.[31]

Australia's strong biosecurity and industry-led disease preparedness and response processes, including access to disease prevention tools such as vaccines, are central to keeping devastating animal diseases out of Australia.

The animal health sector has a strong history of innovation and an ambitious goal of a world where the threat of disease is significantly reduced by improving animal immunity and disease prevention strategies, developing earlier, more specific diagnostic technologies and more accurate, effective treatments. Fewer animals lost or suffering from disease will not only improve food security and safety, but also reduce pressure on natural resources and lower emissions associated with animal production.

Zoonoses prevention

The inter-connected nature and importance of global partnerships in maintaining the global economy has never been more clearly demonstrated than during the COVID-19 pandemic. Emerging infectious animal diseases are spreading more quickly because of greater global travel and trade, putting the livelihoods of farming communities around Australia at increasing risk. It is estimated that around 60 per cent of infectious diseases are zoonotic (meaning they can spread between animals and people).[32]

Vaccination and other disease prevention tools like preventative parasite control medications, along with rigorous biosecurity processes and diagnostic technologies are at the forefront of zoonoses prevention.

While improved animal health management in Australia means that it is rare that zoonotic diseases spread directly to people, indirect transmission does occur – for example, via an insect vector (such as a tick or mosquito bite) or consumption of food contaminated with *Salmonella* or *E.coli* bacteria. The best way to prevent zoonotic diseases spreading from animals to humans is to keep animals healthy and prevent them from becoming ill in the first place.

All livestock and pet owners must have sufficient access to all tools available for improving and maintaining animal health – including veterinary medicines. Greater attention must be placed on detecting and preventing infectious animal diseases from entering Australia and responding to them if they do.

Boom in pet ownership

AMA's *Pets and the Pandemic* report[33] confirmed that Australia experienced a boom in pet ownership during the COVID-19 pandemic, with an estimated 30.4 million pets across the country. Nationally, 69 per cent of households now own a pet, up from 61 per cent just two years ago. In a time of significant

[30] Chicken kill leaves bitter aftertaste (smh.com.au)
[31] Newcastle Disease Management - Animal Health Australia
[32] Preventing the next pandemic - Zoonotic diseases and how to break the chain of transmission | UNEP - UN Environment Programme
[33] Pets and the Pandemic: a social research snapshot of pets and people in the COVID-19 era – Animal Medicines Australia

uncertainty and reduced social interaction, Australians have turned to pet ownership as a source of comfort and joy.

On average, pet owners are spending $3,200 per dog and $2,100 per cat each year— primarily on food, veterinary services, and healthcare products. Extrapolated across the country, dog owners have spent $20.5 billion in the last year, while cat owners have spent $10.2 billion.

With pet ownership now at record levels, policy makers must consider the needs of companion animals and their owners. This should range from rental, strata and body corporate regulations to animals in public places, transport access and holiday accommodation. The pandemic also showed that pet animal welfare must be explicitly protected as an essential service/activity.
