

The Animal Health Industry in Australia





About Animal Medicines Australia

Animal Medicines Australia (AMA) is the peak industry body representing the leading animal health companies in Australia. AMA member companies are the local divisions of global innovators, manufacturers, formulators and registrants of a broad range of veterinary medicines. These companies work at the cutting edge of animal health science to prevent, control and treat illness and injury across the livestock, equine and companion animal sectors.

Products from our members account for more than 90% of all animal health product sales. In the livestock sector, which contributed \$34.6 billion to Australia's

agricultural export market in 2021-2022, AMA members' medicines increase farm productivity and deliver significant and sustainable improvements in environmental, safety and health outcomes. Animal medicines underpin the high quality and safety of animal products for local consumption and for export.

In the companion animal pet sector, animal medicines facilitate healthier, longer and better-quality partnerships between people and animals. Data from *AMA's Pets in Australia: a national survey of pets and people* found there are almost 29 million pets in Australia with 61% of households owning one or more.

AMA Members



















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Introduction

Australia's animal health industries provide veterinary medicines and animal health products that are essential to support the health and welfare of our pets, livestock and other animals within our care. Healthy animals provide benefits to all Australians. Healthy animals:

- · Are less susceptible to disease and infection,
- Protect human health by preventing transmission of zoonotic diseases,
- · Are more productive, providing economic benefits for livestock producers and rural communities,
- Are more sustainable, requiring less land, water and feed resources, and
- Provide enduring and rewarding pet ownership experiences

Australia's animal health industries include the leading companies supplying high-quality, safe and effective vaccines, parasiticides, antimicrobials, pain relief and other products. Innovative and highly regulated, consumers can have confidence in the quality and safety of veterinary medicines, facilitating many benefits.

Community confidence is underpinned by an effective regulatory scheme. The Australian Pesticides and Veterinary Medicines Authority rigorously assesses each product prior to registration or sale in Australia.

This independent process confirms that there are no unacceptable risks to users, consumers, the environment or trade.

Veterinary medicines and animal health products are essential inputs that support Australia's \$34.6 billion livestock and \$30.7 billion pet industries.

Improving the health of our animals is often one of the most efficient mechanisms to addressing many of society's current and emerging challenges. Whether it be addressing global food security, the emergence of zoonotic diseases, mitigating and responding to climate change impacts, meeting community expectations on animal health and welfare or facilitating personal health benefits through meaningful pet ownership experiences, animal health industries are working to supply new innovations to help meet these challenges.

On behalf of our member companies, Animal Medicines Australia welcomes opportunities to inform policy making that reflect the benefits better animal health brings and celebrates the contribution towards more sustainable communities that will subsequently accrue.

Industry snapshot

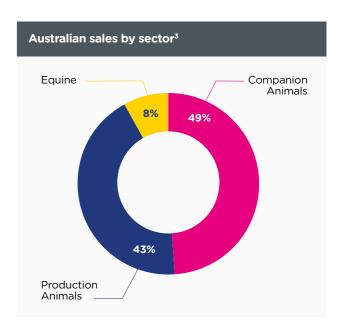
Veterinary medicines and animal health products include parasiticides, vaccines, antibiotics, nutritional supplements and analgesics that protect the health and welfare of animals.

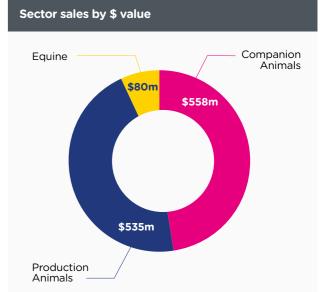
These products are critical inputs to Australia's \$34.6 billion¹ livestock industries. Producers rely on animal health products to prevent and treat animal diseases and to safely conduct necessary animal husbandry and management practices responsibly and ethically. By optimising animal health, producers improve productivity, profitability, food safety and sustainability.

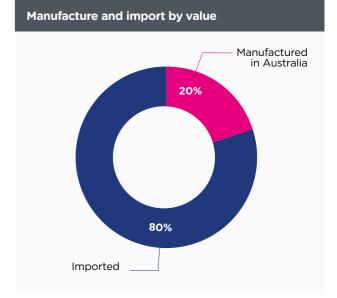
Similarly, animal medicines protect and treat Australia's 30.4 million pets from illness, injury and disease. Responsible pet ownership relies on access to safe, affordable veterinary medicines and animal health products.











¹ AWE Agricultural forecasts and outlook June quarter 2021: daff.ent.sirsidynix.net.au/client/en_AU/search/asset/1032181/0 2 AMA Pets and the Pandemic 2021: animalmedicinesaustralia.org.au/wp-content/uploads/2021/08/AMAU005-PATP-Report21_v1.41_WEB.pdf 3 AMA Sales Audit Data MAT 2020

What are veterinary medicines and what do they do?

Parasiticides



Parasiticides protect and treat animals for internal and external parasites including worms, fleas, flies and ticks. Parasite infections are often entirely preventable but if not treated or managed will result in decreased production or health and can be fatal. Some examples of parasites are heartworm, tapeworm, ticks, lice and fleas.

Antibiotics



Like humans, animals can sometimes get sick with a bacterial infection. When this occurs, antibiotics are often the only effective tool to treat the disease. Bacterial infections that are treated with antibiotics include salmonella, leptospirosis and staphylococcus. Many antibiotic products are unique to animal health. No antibiotic used to treat human diseases is used for growth promotion in animals.

Analgesics



An analgesic drug is a pain relieving medication given to prevent, relieve and manage pain in animals. Providing pain relief to animals when conducting necessary animal husbandry practices, or to provide comfort to pets suffering painful injuries or illnesses helps contribute to ethical and responsible animal care practices.

Nutrition & metabolism



Registered animal health products include vitamin, mineral and nutritional supplements, growth promotants, dietary/therapeutic pet foods, and digestive enzyme supplements. Whether food producing livestock or a family pet, nutrition plays a significant part in animal health and welfare.

Immunotherapy (Vaccines)



Vaccination is an effective, inexpensive way to prevent deadly disease. Vaccinations also go beyond protecting the health of a single animal, by preventing spread of the disease. Vaccinations prevent a wide spectrum of animal diseases such as canine parvovirus, feline calicivirus, anthrax, tetanus and pulpy kidney and the use of vaccines in animals is an important step in decreasing the need to use antibiotics. Immunotherapy products also include antisera and antivenom, which can be used to counteract poisonous and toxic substances, such as snakebite venom.

Other products



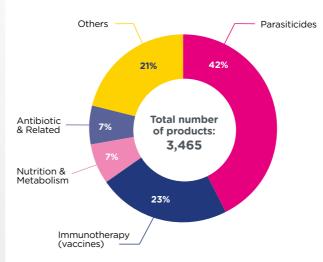
Other categories of animal health medicines include musculoskeletal (anti-inflammatory agents, muscle relaxants), dermatological preparations (antiseptics, diagnostic agents), endocrine system (sex hormones, trophic hormones & insulin preparations), cardiovascular system, alimentary system and ear, nose and throat preparations.

What is a registered product?

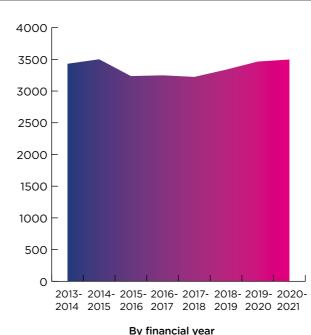
If an animal health product has a defined clinical medical use or a therapeutic effect, it must be registered prior to being sold, whether manufactured locally or imported. The Australian Pesticides and Veterinary Medicines Authority (APVMA) is Australia's independent regulator. The APVMA approves the importation, supply and sale of every veterinary medicine and formulated product after a risk assessment of appropriate scientific data has demonstrated the product is efficacious and not unduly hazardous to human or animal health or the environment, and that it will not adversely affect trade. More information is available at www.apvma.gov.au

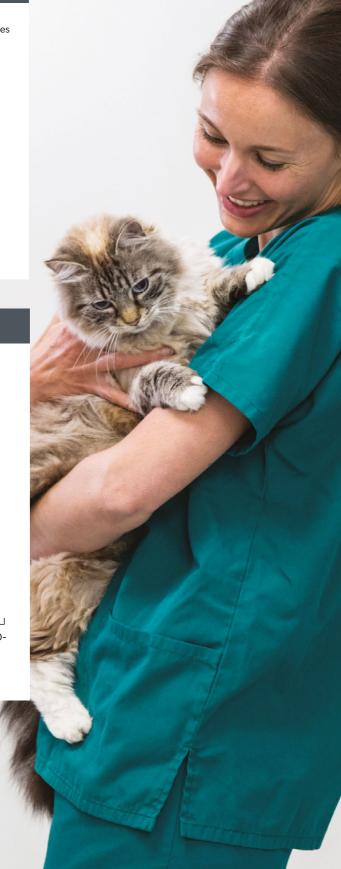
Sales by product category

Major veterinary medicine categories by sales4



Total number of registered products⁴





The Animal Health Industry in Australia

⁴ APVMA Annual Sales Data: apvma.gov.au/node/10756



Quality and safety

Veterinary medicines and animal health products are highly regulated. They are subject to rigorous, independent regulatory systems. These systems work to minimise risks to users, animals, consumers and the environment.

Registration

Before any product can marketed for sale, it must first be registered for use. The Australian Pesticides and Veterinary Medicines Authority (APVMA) is responsible for conducting independent, sciencebased risk assessments prior to registering veterinary medicines. The APVMA assesses risks for:

- Users: to determine whether the proposed use will present any unacceptable risks to users (such as veterinarians, farmers or pet owners) when using the product,
- Animals: to ensure that a product is safe to use on a treated animal,
- Consumers: to determine whether the use will result in any unacceptable residues in animal products, such as meat, dairy or poultry,
- The environment: to consider any potential risk to the environment, including non-target plants, animals and ecosystems,
- Trade: to determine whether potential products may risk access to export markets for animal products.

The APVMA will only register a product if it is satisfied that any identified risks can be managed. This includes approving the label instructions and precautions necessary to inform responsible use practices.

Post-registration control of use

Australia's state and territory governments are responsible for controlling how veterinary medicines are used. This includes ensuring that only appropriately trained and qualified people can access and use certain medicines (especially potentially hazardous products) and establishing licensing and other control systems.

Good manufacturing practice

All manufacturers of registered veterinary medicines need to comply with a rigorous manufacturing licencing scheme. This is similar to the manufacturing licensing scheme for human medicines. The scheme ensures the highest manufacturing standards are applied. To obtain and maintain a licence, manufacturers are regularly audited by independent inspectors who examine every aspect of the manufacturing process, including the source and quality of all ingredients, manufacturing equipment and packaging materials.





Pharmacovigilance

Animal health companies operate detailed pharmacovigilance systems that identify and track examples where a veterinary medicine may appear to be ineffective or related to an adverse reaction. These systems allow a rapid investigation of any product quality or safety issue. Similarly, APVMA's Adverse Experience Reporting Program collects reports from users on reactions or poor outcomes from products. Adverse Event Reporting informs whether product recalls are necessary and can indicate if additional controls are required.

Monitoring, compliance and enforcement

All Commonwealth, state and territory government regulatory schemes involve significant reporting and compliance obligations. Animal health companies take great care to ensure that all regulatory obligations are met, recognising that significant penalties can be imposed for failing to meet legislated standards.

Other regulatory schemes

In addition to APVMA and state and territory dedicated control systems, multiple other regulatory systems also apply to veterinary medicines. These include:

- Gene technology regulation
- Biosecurity and import regulations
- Poisons scheduling
- Maximum residue limits (domestic and export destinations)
- Withholding periods and export slaughter intervals
- Dangerous Goods transport (air, land and sea) and Dangerous Goods storage
- Chemical diversion illicit drugs and chemicals of security concern
- Retail storage
- Work Health & Safety
- Trade Measurement
- Waste management

Users of veterinary medicine products can be confident that extensive, effective and rigorous regulatory systems are in place to guarantee that registered veterinary medicines, when used in accordance with label instructions, or under veterinary supervision, are safe and effective.

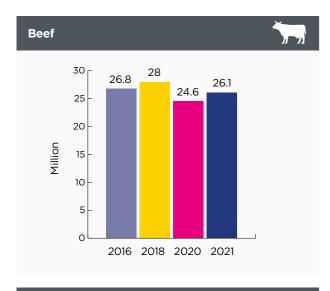
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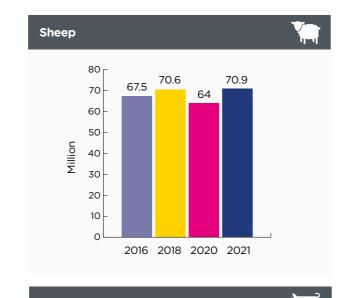


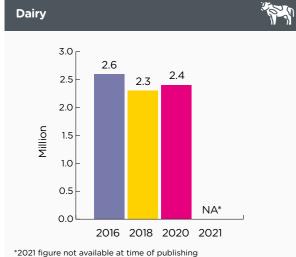
Australian animal populations over time

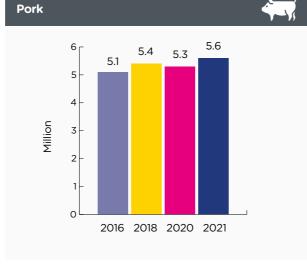
Australia's livestock populations are influenced by multiple factors including climate, commodity prices, market conditions and regulatory controls. Veterinary medicines and animal health are critical inputs supporting these industries.

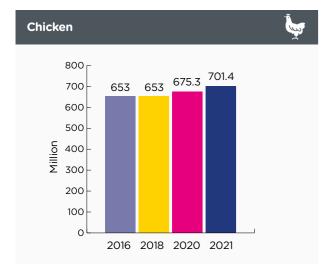
Livestock (2016 to 2021)5









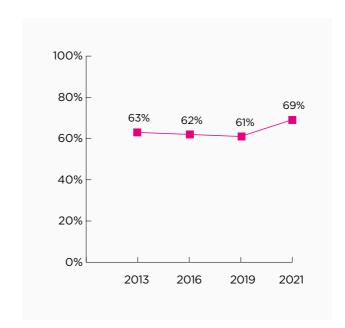


⁵MLA Industry projections 2022 Australian cattle: mla.com.au/ globalassets/mla-corporate/docs/mla_australian-cattle-industryprojections-february-2022v2.pdf MLA Industry projections 2022 Australian sheep: mla.com.au/

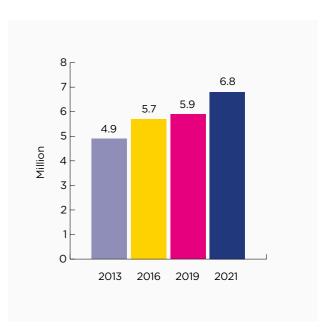
MLA Industry projections 2022 Australian sheep: mla.com.au/globalassets/mla-corporate/prices--markets/documents/trends-analysis/sheep-projections/mla_australian-sheep-industry-projections-2022_140222_r1.pdf

ABS Statistics Livestock: abs.gov.au/statistics/industry/agriculture/agricultural-commodities-australia/latest-release#livestock
ACMF Australian Industry Facts & Figures - Chicken Production:
chicken.org.au/facts-and-figures

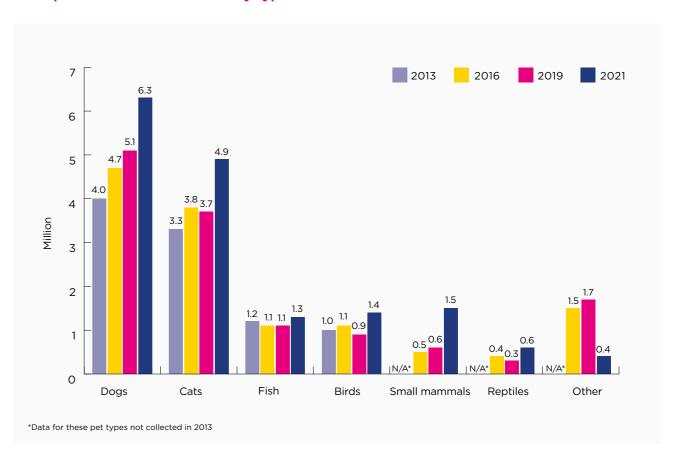
Household % with a pet



Total households with a pet*



Total pet numbers in Australia by type



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Benefits of animal health

Food safety

Some veterinary medicines and animal heath products are used to ensure animal products are safe to be consumed by humans. This is particularly important for protecting against potentially harmful zoonotic diseases. For example, each year in Australia more than 10,000 people are infected by salmonella bacteria that cause gastroenteritis. Controlling salmonella in poultry production significantly reduces these infections and benefits human health.

Animal health, welfare and social licence

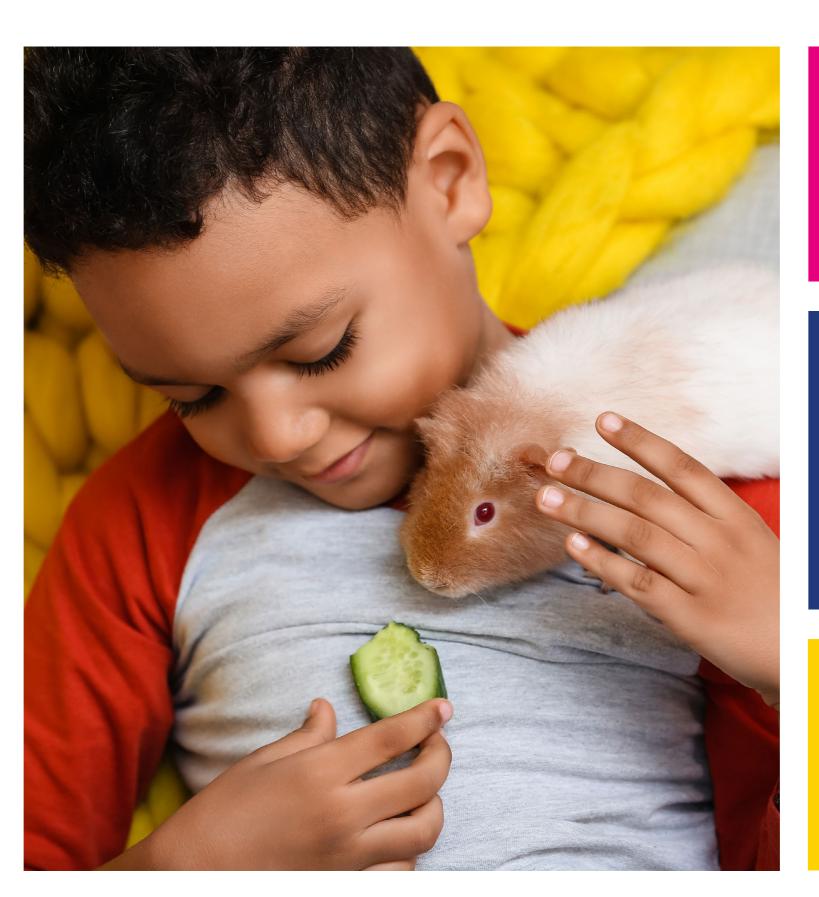
Veterinary medicines are essential to protecting the health and welfare of our pets and livestock. Indeed, good animal health is a precondition to good animal welfare. Animal illness, injury and disease can cause pain, distress and discomfort. By maintaining animal health, we can improve animal welfare of our animals.

Animal health products also help meet community expectations around necessary animal husbandry practices. New innovations in animal health and pain relief can mean that necessary husbandry procedures can be done in a way that minimises or avoids pain and distress.

Productivity and sustainability

Healthier animals need fewer land, feed and water resources, increasing productivity for producers while minimising environmental impacts.

Globally, despite doubling production, industrialised nations have reduced land requirements by 20%.⁶ Increasing the adoption of existing animal health, husbandry, feed and management technologies could further lower livestock emissions by 30%.⁶



Human health

Around 70% of new and emerging diseases are zoonotic, meaning that they can spread between humans and animals. Protecting the health of our animals through vaccination, preventative treatments and improved biosecurity measures can prevent zoonotic diseases being transferred to humans.

Animal health industries are constantly innovating to provide new products and services that treat new and emerging diseases.

Benefits for pet owners

Our pets play multiple, varied and important roles in our lives. They are companions for relaxation, for exercise and for teaching children responsibility. They provide humour, fun and a sense of purpose. Overall, pet ownership helps build happier, healthier and more connected communities across Australia.

Animal health products and veterinary medicines are a core component of responsible pet ownership. Responsible and judicious use of these products ensure owners meet the needs of their pets, and can enjoy long, rewarding and beneficial ownership experiences.

Trade

Responsible use of veterinary medicines and animal health products can ensure that animal sourced food and fibre meets standards required by export markets, facilitating and supporting productivity and sustainability of agricultural industries which are critical to Australia's economy.

 6 AMA Pets and the Pandemic 2021: animalmedicinesaustralia.org.au/wp-content/uploads/2021/08/AMAU005-PATP-Report21_v1.41_WEB.pdf

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Innovation

A new medicine or product can take anywhere from five to 15 years⁷ and tens of millions of dollars in research and development from first discovery until it is available to treat an animal. This requires significant investment by companies to identify, research and develop new products. This includes conducting tests and trials required to generate data to demonstrate to a regulator that a product is safe and efficacious.

Animal health companies continue to innovate in different ways to provide new products and services for animal owners. Innovation can mean using existing products in new ways, developing new application and use tools to enhance safety, addressing sustainability and waste issues through improved packaging and recycling or by using genetics, data monitoring and surveillance systems to address animal health issues before clinical indications of illness are present.

Whatever the form a new innovation takes, it will be supported by extensive research, development and testing. Animal health companies support extensive Australian research activities that ensure quality data supporting Australian use patterns can be assessed by regulators.

Future innovations, such as the digital revolution in predictive, monitoring and veterinarian diagnostics technology, will reduce health threats and continue to provide safer, more effective and more sustainable products to meet an ever-widening range of animal health challenges.



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