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30 April 2022

Australia-UAE CEPA Coordinator
Middle East FTAs Branch
Regional Trade Agreements Division
Department of Foreign Affairs and Trade
Canberra, ACT

By email only: UAECEPA@dfat.gov.au

Dear Australia-UAE CEPA Coordinator,

Re: Submission on a Comprehensive Economic Partnership Agreement between the United Arab Emirates and Australia.

Thank you for the opportunity to provide a submission on the development of an Australia-United Arab Emirates (UAE) Comprehensive Economic Partnership Agreement (CEPA). The following comments may also be considered if negotiations for a free trade agreement with the Gulf Cooperation Council (GCC) resume.

Animal Medicines Australia (AMA) is the peak industry body representing the leaders of the animal medicines industry in Australia. Our members companies are the innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products to protect and treat animal illness, disease and injury, and support animal welfare across the livestock, equine and companion animal sectors. AMA members range from local businesses to the local divisions of global companies and includes companies who manufacture in Australia for global export markets. AMA members represent more than 90% of Australian sales of registered veterinary products.

Veterinary medicinal products are essential tools for veterinarians and farmers to promote and protect the health and welfare of livestock and companion animals. Animal health is the foundation of animal welfare, and veterinary medicines are essential to keep animals healthy, prevent zoonotic disease, support agricultural production, productivity and sustainability and ensure the availability of safe, affordable food and fibre derived from animals.

This submission outlines key considerations to support a stronger Australia-UAE trade relationship. These measures promote trade, facilitate market access, increase investment and innovation, support animal welfare, address antimicrobial resistance, encourage good regulatory practice, reduce technical barriers to trade, promote adoption of international science-based regulatory standards and requirements, and protect globally integrated manufacture and supply chains.

In the consideration of veterinary medicinal products in the CEPA, AMA notes that its comments should be considered to apply to a range of products of importance to animal health and welfare, including:

- Finished medicinal products for veterinary use, including biological and immunobiological products;
- Active pharmaceutical ingredients, additives, intermediates, excipients and other components used in the manufacture and administration of veterinary medicinal products;
- Investigational and diagnostic veterinary medicinal products, including sensors and identification tools;
- Animal health products that may not be defined as veterinary medicines, such as feed additives, devices, diagnostics and biocides; and
- Innovative new products currently in development.

As a sector, we are strong proponents of the importance of good animal health and welfare. Veterinary medicines and animal health products are essential to maintain animal health and welfare, facilitate trade, protect public health and promote sustainable industries.

AMA is pleased to provide this submission for your consideration during the CEPA negotiations.

If we can provide any further information, please feel free to contact me.

Yours sincerely,

Ben Stapley

Executive Director

(unsigned for electronic submission)

SUBMISSION TO THE

Comprehensive Economic Partnership Agreement between the United Arab Emirates and Australia

30 April 2022

Animal Medicines Australia

Introduction

Animal Medicines Australia (AMA) is the peak body representing the leading animal health companies in Australia. AMA member companies are the innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products that prevent, control and cure disease across the companion animal, livestock and equine sectors.

Key Principles

AMA strongly supports the need for science-based regulation of veterinary medicinal products. International bodies such as Codex Alimentarius and VICH are at the heart of efforts to globally harmonise regulatory approaches to veterinary medicines. AMA wishes to see the approaches and principles of these key organisations (as they relate to the regulation of veterinary medicines) at the core of trade agreements.

AMA supports the multilateral, rules-based system established under the World Trade Organisation (WTO), including international trade agreements such as the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) and the WTO Agreement on Technical Barriers to Trade (the TBT Agreement), that establish rules for regulatory decision-making and provide a framework for regulatory cooperation. We support an agreement that incorporates and strengthens those rules by enhancing scientific risk-based policy making, laying strong foundations for cooperation across ministries and departments, promoting regulatory consistency, transparency and predictability, and strengthening engagement in international organisations identified as priorities for our sector.

AMA encourages active collaboration between the Australian and United Arab Emirates (UAE) animal health industries and regulatory authorities to strengthen trade and investment. Sound, objective, evidence-based, scientific risk assessment must be the norm when measures are introduced that may affect trade. Risk-based regulation is a requirement under WTO rules, which state that:

- Risk-based regulation is the surest way to protect human and animal health without unduly restricting trade.
- Risk-based regulation promotes innovation and ensures that agricultural producers have access to safe and effective technologies that contribute to better animal welfare, commercial and environmental outcomes.

International Harmonisation of Regulatory Requirements

Within the animal health industry globally, there is a move towards regulatory convergence with mutual recognition and equivalence agreements to reduce duplication of regulatory burden.

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is a tri-lateral (EU-Japan-US) programme that develops internationally recognised guidelines on technical requirements for veterinary product registration. The VICH guidelines are science-based standards that, when implemented, support regulatory convergence for veterinary medicines around the world.

AMA encourages the use of VICH guidelines by both parties to support regulatory convergence and harmonisation. Implementation and adherence to standards at a broader, global level is required to

protect the health and welfare of animals, those using the medicines, the environment and the consumers of food from treated animals, and to ensure the availability of safe, high quality animal health products.

Cooperation through International Forums

The animal health industry supports the mission of the World Organisation for Animal Health (OIE) – the animal equivalent of the World Health Organisation. The OIE is the appropriate forum to engage on global issues affecting animal health. Strong cooperation between member countries is needed to meet the goals of the OIE, which include improving animal health outcomes, reporting on animal diseases occurring in member countries, collecting and disseminating information on animal disease control, supporting members countries in controlling and eradicating animal diseases, publishing health standards for international trade of animals and animal health products, and coordinating with Codex Alimentarius to set food safety standards for commodities derived from animals.

AMA supports the development of science-based international standards to create predictable market conditions for our businesses and customers, and that are within the mandate of key international standard setting bodies including OIE, Codex Alimentarius and VICH. We encourage countries to adopt globally consistent standards and support our governments' engagement in these bodies. We further support the development of a forum for discussion and cooperation on SPS measures with regard to animal-derived commodities to aid the free flow of trade.

An important matter in the regulation of veterinary medicines for food-producing animals is the maximum residue limit, or MRL, which is the maximum concentration of residues established as being safe for human consumption and accepted in a food product derived from an animal that has received a veterinary medicine. Different MRLs between countries will hinder international trade in food products and commodities.

The key purpose of Codex Alimentarius is to protect the health of consumers and ensure fair practices in the international food trade. AMA encourages the adoption of Codex MRLs as the standard for trade in animal-derived commodities.

Tariff and Quota-Free Movement of Animal Medicinal Materials, Vaccines and Veterinary Medicines

Tariff and quota-free movement of finished veterinary medicinal products, additives, active ingredients, intermediates and other excipients and components used in the manufacture and administration of veterinary medicinal products, diagnostics, sensors and identification tools is an important consideration for the animal health industry. We wish to see this prioritised in trade agreements. Further, as veterinary medicinal products often have complex supply chains for the various components, it is important that rules of origin requirements do not hinder the animal health industry.

Enforcement

We wish to see an agreement for future collaboration between regulatory authorities on proportionate enforcement measures to address the unauthorised promotion and supply of veterinary medicines, such as counterfeit products. It is important to ensure that safe and effective

veterinary medicines continue to be accessible and that companies are allowed to innovate in how they legally promote and distribute medicines. These measures are valuable in ensuring access to animal medicines to support better animal health and welfare.

Antibiotic Resistance

Antibiotic resistance is a global issue which will require trans-national, multi-sectoral, collaborative action. Significant progress has already been made by Australian veterinarians and farmers in recent years to ensure antibiotics are prescribed and used responsibly. A commitment to adhere to and comply with the requirements of the Codex Intergovernmental Task Force on Antimicrobial Resistance (TFAMR) would be a solid basis on which to develop bilateral trade with the UAE. We further support the ability of each country to draft country- and industry-specific One Health action plans that implement AMR commitments in the local market and where progress can be meaningfully assessed.

Further Considerations

We wish for negotiators to consider the following additional points during negotiations:

- Measures supporting or developing the manufacturing capabilities in Australia and the UAE;
- Measures that enhance innovation, including those to support the conduct of veterinary clinical trials in both countries;
- Measures to ensure that innovative research-and-development-focused companies are supported and that the regulatory system enables them to obtain a return on their innovation-based investments; and
- Measures to provide attractive Intellectual Property protections and periods of protection of technical documentation relating to marketing authorisations.

End of submission.