Shared Free Trade Agreement Principles for a Stronger AUS-UK Trade Relationship

September 2021

Key Principles

AMA and NOAH strongly support the need for science-based regulation of veterinary medicinal products. 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 and promote sustainable industries.

Sound, objective, evidence-based, scientific risk assessment must be the norm when measures are introduced that may affect trade. There are requirements under World Trade Organisation (WTO) rules:

- 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 around the world have access to safe and effective technologies that contribute to better welfare, commercial and environmental outcomes.

AMA and NOAH support 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 (SPS Agreement) and the WTO Agreement on Technical Barriers to Trade (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 sectors.

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

AMA and NOAH support active collaboration between the two countries' animal health industries and regulatory authorities as a means to strengthen trade and investment.

Animal Medicines Australia (AMA) and the National Office of Animal Health (NOAH) are the national industry associations representing manufacturers of animal health products and services in Australia and the United Kingdom, respectively. Their collective members include manufacturers of innovative animal medicines that address public health, animal health and food safety challenges.

Key Opportunities in an AUS-UK Free Trade Agreement

AMA and NOAH wish for negotiators to consider measures that support the following objectives:

1. International regulatory harmonisation through active engagement in VICH and implementation of approved Guidelines.
2. Cooperation through international forums, particularly Codex Alimentarius and the World Organisation for Animal Health (OIE).
3. Support opportunities to improve the efficiency of regulatory assessments by promoting common practices specific to animal health, such as application requirements, joint submissions and evaluations.
4. Commitment to adhere to and comply with the requirements of the Codex Intergovernmental Task Force on Antimicrobial Resistance (AMR) and the ability to draft country-specific One Health National Action plans.
5. Tariff- and quota-free movement of animal medicinal materials, animal vaccines and animal health products.
6. Intellectual Property protection and measures to support innovation and research, such as increased periods of protection of technical documentation relating to marketing authorisations.
7. Enforcement measures to address the unauthorised promotion and supply of veterinary medicines.

Overview of the Animal Health Industry

The animal health industry is an essential sector that provides essential tools to veterinarians and farmers to help them to produce protein from food-producing animals, and to protect and improve the health and welfare of both farm and companion animals. Relative to the human health sector, the animal health industry is small. Nevertheless, animal health is a major industry with a large impact. It provides products and services that are essential for protecting the health and welfare of livestock and companion animals, preventing zoonotic disease, and ensuring the availability of safe, affordable food from animals. Australia and the UK are recognised as important bases for scientific development and innovation in this sector. Within the animal health industry globally, there is a move towards global regulatory convergence with mutual recognition and equivalence agreements to reduce duplication of regulatory burden. This will be critical to ensure a sustainable and innovative animal health market.

Many animal health products that are not defined as veterinary medicines (such as feed additives, devices, diagnostics and biocides), plus future innovative new products currently in development, are important to animal health. It would be appropriate to consider many of the principles outlined in this document and contained in the World Trade Organisation Technical Barriers to Trade Agreement, as they relate to these other non-veterinary medicinal and animal health products which remain important for animal health and welfare.

International Harmonisation of Regulatory Requirements

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is a tri-lateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration. Through the VICH Outreach Forum, VICH also forms the basis for wider international harmonisation of technical requirements, improvement of information exchange and raising awareness of VICH and VICH guidelines in non-VICH countries/regions. Currently, more than 14 countries (including both Australia and the UK), several regional organisations and the OIE participate in VICH.

Implementation and adherence to standards at a broader, global level is required in order to protect the health of animals, those using the medicines, the environment, and consumers of food from treated animals, and to ensure the availability of safe, high quality animal health products. International bodies such as Codex Alimentarius and VICH are at the heart of efforts to globally harmonise regulatory approaches to veterinary medicines. AMA and NOAH wish to see the approaches set out by Codex and VICH as they relate to the regulation of veterinary medicinal products, at the heart of our bilateral trade agreement and we urge our governments to actively participate in these forums and implement the principles of these key organisations.

Cooperation Through International Forums

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 residue established as being safe for human consumption and accepted in a food product obtained from an animal that has received a veterinary medicine. AMA and NOAH would encourage our governments to play an active role in the work of the Codex Alimentarius Commission. The main purpose of Codex is to protect the health of consumers and ensure fair practices in the international food trade. Residues studies are expensive and time-consuming to conduct (as well as being against the principles of reducing animal testing) and systems that lead to different MRLs between countries will hinder trade international trade in food products. AMA, NOAH and our member companies are happy to work with our respective governments to encourage timely development of new Codex MRLs, review authorised lists of MRLs and identify MRL issues/problems that can be raised during trade discussions.

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.

Regulatory Assessments and Submissions

When animal health companies apply to regulatory authorities for a Marketing Authorisation, they are required to submit a detailed dossier to each regulatory authority for independent scientific assessment, with a particular focus on the safety, quality and efficacy of the product. AMA and NOAH wish to see an agreement that reduces regulatory duplication and supports better alignment of regulatory requirements and assessments.

The Australia-UK negotiations provide an opportunity to improve the efficiency of regulatory assessments by adopting common practices specific to animal health, such as data requirements, acceptance of joint submissions and doing joint evaluations. The ability to have a joint assessment at the request of the applicant and involving both Australian and UK regulators would be welcome to help reduce the cost and regulatory burden associated with licensing products. Joint assessments should not be mandatory, as there will be occasions where the benefit/risk balance for a product will vary significantly based on geography, when a mandatory joint assessment would not be appropriate or welcome. However, joint assessments could be of great value with many products, for example, novel innovative products that provide solutions for existing and emerging animal diseases.

Antibiotic Resistance

Antibiotic resistance is a global issue which will require transnational collaborative action. Significant progress has already been made by Australian and UK 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. We support countries' ability 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.

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 would wish to see this prioritised in the agreement. In a more general sense, as veterinary medicinal products often have complex supply chains for the various components, it would be important that rules of origin requirements do not hinder the animal health industry.

Making Australia and the UK Attractive for Animal Health

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

- Measures supporting or developing the manufacturing capabilities in Australia and the UK;
- 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.

Enforcement

We wish to see an agreement for future collaboration between regulatory authorities around 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.

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