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NOAH
Supporting the future of animal health

Representing the UK Animal Health Industry

NOAH priorities for international UK trade agreement negotiations

Summary

- The UK has a global reputation for high standards in animal health and welfare. This reputation must be maintained and NOAH is ready to assist in ongoing and future trade agreement negotiations to ensure optimal benefit for UK citizens, farmers and the UK economy.
- Trade in veterinary medicines and their components should be free of tariffs and quotas to ensure the sector stays competitive.
- Where there are preferential or free trade agreements, rules of origin should not restrict the supply and manufacturing processes of veterinary medicines.
- Science-based regulation will help to promote innovation in the sector, as well as making the livestock products sector more competitive on global markets.
- Where possible, UK should adhere to, and encourage uptake and use of the international harmonisation of regulatory requirements, through bodies such as the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and Codex Alimentarius.
- The World Trade Organisation's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) sets out the basic rules for food safety and animal and plant health standards. Sanitary and Phytosanitary (SPS) chapters of future trade agreements should include cooperation on Maximum Residue Level (MRL) setting and regionalisation, as well as mutual recognition or equivalence agreements on Good Manufacturing Practice (GMP), pharmacovigilance and regulatory assessments and submissions.
- NOAH would also encourage the use of Veterinary Equivalence Agreements with countries with which there are no ongoing trade discussions, to ease the flow of livestock products.
- Where possible and desirable for animal health companies, primary packaging requirements should be harmonised between UK and its trade partners.
- The UK should ensure its progress in reducing antibiotic usage in the veterinary sector and tackling antibiotic resistance is recognised by trade partners with a commitment from future trade partners to comply with the CODEX Taskforce on Antimicrobial Resistance (AMR).
- Trade agreements should also ensure strict Intellectual Property controls on veterinary medicines to support innovation as well as a commitment to tackle the illegal supply and trade of both authorised and unauthorised veterinary medicines.
- NOAH would encourage the UK to join the Multiparty Interim Appeal Arbitration Agreement (MPIA), and work with WTO member countries towards restoring the WTO's Appeal process**.**

Key principles

- NOAH strongly supports the need for science-based regulation of veterinary pharmaceutical products.
- As a sector, we are strong proponents of the importance of good animal health and welfare. The products that animal health companies market play an essential role in maintaining animal health and welfare with the associated benefits that has for animals and for society.
- Sound, robust evidence-based science and risk assessment should be the norm when measures are introduced that may affect trade. These are requirements under WTO rules:
    - Risk-based regulation is the surest way to protect human and animal health without unduly restricting trade.
    - Risk-based regulation also promotes innovation and ensures that agricultural producers around the world have access to safe and effective technologies.
- NOAH supports initiatives, including international trade agreements such as the World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement), that establish rules for regulatory decision-making and provide a framework for regulatory cooperation.
- NOAH also supports the development of science-based international standards that create predictable market conditions for business and that are within the mandate of those standard setting bodies. NOAH encourages countries to adopt those standards, and can support the UK engagement in these bodies.

Overview of the animal health industry

1. The animal health industry is an essential sector for the production of protein from food producing animals and for the maintenance of both farm and companion animal health and welfare. Relative to the human health sector, the animal health industry may be comparatively small by value – for example, UK sales of veterinary medicines are circa 3% of the human health sector [1,2,3]. Nevertheless, animal health is a vitally important industry with a large impact and essential to achieve 'One Health'. It provides products and services that are essential for protecting the health and welfare of farmed and companion animals, prevention of zoonotic disease and plays an important role in ensuring the availability of safe, affordable food from animals. The UK is recognised as an important centre for scientific development and innovation in this sector. Within the animal health industry globally, there is a wish for a move towards global regulatory convergence with mutual recognition and equivalence agreements and avoidance of duplicated regulatory burden. This will be critical to ensure a sustainable UK animal health market.

International harmonisation of regulatory requirements

2. The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is a trilateral (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 harmonization of technical requirements, improvement of information exchange and raising awareness of VICH and VICH guidelines with non-VICH countries/regions. Currently approximately 14 countries and 4 regional organisations are participating.

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 VICH and the Codex Alimentarius Commission are at the heart of efforts to globally harmonise regulatory approaches to veterinary medicines. NOAH wishes to see the approaches set out by VICH and Codex, as they relate to regulation of veterinary medicinal products, at the heart of any trade agreements between the UK and other countries or regions.

Maximum Residue Levels

3. 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 accepted in a food product obtained from an animal that has received a veterinary medicine established as being safe for human consumption. NOAH would encourage the UK Government to play an active role in the work of the Codex Alimentarius Commission. The CODEX Commission's main goals are to protect the health of consumers and ensure fair practices in the international food trade. Residue studies are expensive and time consuming to conduct (as well as being against principles of reduction in animal testing) and systems that lead to differing MRLs between countries hinder international trade in food products so any efforts that can be made to collaborate with other countries are welcome. NOAH is happy to work with the UK government to review any potential trade partner's authorised lists and MRLs and identifying particular MRL issues/problems that can be raised during trade discussions.

Good Manufacturing Practice, testing and batch release

4. Good Manufacturing Practice (GMP) describes the required standard that a medicines manufacturer must meet in their production processes. Regulatory authorities carry out inspections to verify compliance with these standards. NOAH calls for future trade agreements to include mutual recognition of GMP inspections, in order to prevent duplication of effort on the part of both the regulatory authority inspectors and the animal health industry. NOAH believes that the Pharmaceutical Inspection Co-operation Scheme (PIC/S), a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use, should be referred to and used as part of trade agreements. PIC/S aims at harmonising inspection procedures worldwide by developing common standards in the field of GMP and by providing training opportunities to Inspectors. It also aims at facilitating co-operation and networking between competent authorities, regional and international organisations, thus increasing mutual confidence.

   Testing, certification, and release of batches of medicines by Qualified Persons is a regulatory process that exists to assure the quality of the medicine and to give assurances that the product has been manufactured in accordance with good manufacturing practice. NOAH calls for future trade agreements to include mutual recognition or equivalence agreements on batch testing, certification, and release procedures, to prevent duplication of work and to reduce demands on laboratory services.

Pharmacovigilance

5. All authorised veterinary medicines have undergone a rigorous process of assessment that includes scrutiny of safety for animals, the public and the environment, quality, and efficacy by the independent regulatory authorities. Safe medicines are approved for market when the benefits to animals outweigh any known potential risks. There is also a process of on-going monitoring and assessment, termed pharmacovigilance, to further define and scientifically evaluate the safety and efficacy of the product. These pharmacovigilance activities allow for the detection of any suspected adverse reactions that may occur, when medicines are used in a larger and more diverse population of animals i.e. under 'field conditions'.

   Veterinary pharmacovigilance broadly describes the science and activities relating to the monitoring and evaluation of adverse events and improving the safety of veterinary medicines. Pharmacovigilance duties involve an exchange of significant volumes of data between the Marketing Authorisation Holder (animal health company licensed to sell the product) and the regulatory authorities. NOAH members wish to see future agreements between the UK and other countries include agreements on pharmacovigilance activities and information sharing to avoid unnecessary duplication and administrative costs. For example, an agreement that the report is only assessed in the country where the event occurred, with no subsequent assessment in the other country would be appropriate for inclusion in trade agreements relating to animal health products. Agreements for both parties to follow the relevant VICH PV guidelines would also be welcome.

Regulatory assessments and submissions

6. When animal health companies apply to the regulatory authorities for a Marketing Authorisation, they are required to submit a detailed dossier to the regulatory authorities for independent scientific assessment with a particular focus on the safety, quality and efficacy of the product. NOAH members wish to see future agreements with other countries that lead to a common format for data submission and a common timeline for regulatory assessments.

   The ability to have a joint assessment at the request of the applicant involving UK regulators and the regulators in another country would also be welcome to help reduce the cost and regulatory burden associated with licensing products. However, such a joint assessment should not be mandatory as there will be occasions where the benefit/risk balance for a product will vary significantly based on geography, so a mandatory joint assessment would not be appropriate or welcome. Such non-mandatory joint assessments could be of value with many products, for example, for novel innovative products to provide solutions for existing and new and emerging animal diseases.

Packaging requirements

7. Packaging for veterinary medicinal products is heavily regulated and regulatory authorities must approve product packaging before veterinary medicines can be placed on the market. A system that allowed for the primary pack in both countries that only required minimal info (and nothing country specific) and agreed on the use of the same pictograms would be welcome. This would allow the primary pack to be used for multiple markets even if the secondary packs and leaflets have to be different to include relevant information in the required language. Such a measure could reduce the administrative burden for animal health companies and help to maintain products on the market.

Antibiotic Resistance

8. Antibiotic resistance is a global issue which will require transnational collaborative action. In the UK in recent years, significant progress has been made by UK vets and farmers 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 (AMR) is a solid basis on which to develop trade. The UK has a One Health National Action plan where it can be demonstrated in the animal sector that good progress has been made. Another country which is to be the subject of a trade agreement will also have to show it has a One Health Antimicrobial Resistance (AMR) National action plan (or equivalent) and be able to demonstrate in the animal sector that suitable progress has been made.

Tariffs and Quotas

9. Tariff and quota free movement of finished veterinary medicinal products, active ingredients, other excipients and components used in the manufacture of veterinary medicinal products is an important consideration for NOAH members; we wish to see this prioritised in any free trade agreements. 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 did not hinder the animal health industry.

Education and professional requirements

10. Mutual recognition of educational and professional requirements, for example of Qualified Persons for certification and release, may be required to facilitate some of the measures described in the previous points and should be considered within the scope of future trade agreements.

Making the UK attractive for animal health businesses

11. NOAH also wishes for UK negotiators to consider the following additional points during the course of any negotiations;

    - Measures supporting or developing manufacturing capabilities in the UK
    - Measures that enhance innovation, including measures that could enhance use of the UK for veterinary clinical trials
    - Measures supportive of Intellectual Property protection, such as increased periods of protection of technical documentation relating to marketing authorisations.

Enforcement

12. NOAH would wish to see agreement for future collaboration between regulatory authorities around enforcement measures to stop the illegal promotion and supply of veterinary medicines.

Non Veterinary Medicinal products of relevance to animal health

13. Many animal health products that are not veterinary medicines such as feed additives, devices, diagnostics and biocides, plus a range of new products in development, are important to animal

health. It would be appropriate to consider many of the principles outlined in points 1-13 as they relate to these other non-veterinary medicinal product animal health products which remain important for animal health and welfare.

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References

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2. https://www.noah.co.uk/about/industry-facts-and-figures/
3. https://www.abpi.org.uk/facts-and-figures/uk-pharmaceutical-market/gross-value-added-in-the-uk/