EU Exit Policy Statement

Representing 90% of the UK animal medicines industry, NOAH promotes the benefits of safe, effective, quality medicines for the health and welfare of all animals. The UK animal medicines industry is an innovative, high skills-based sector; our members employ around 2,000 people directly in the UK and indirectly support many thousands in related industries. The sector is valued at approximately £625m of B2B sales every year. NOAH membership includes both global multinationals and companies who manufacture, import and market products within the UK.

Executive Summary

As we leave the EU, our priority is a vibrant and innovative animal medicines sector, supporting the health and welfare of the UK's livestock and pets. Our future regulatory model and relationship with both the EU and international partners will be critical to this success. We believe the UK is in a strong position to be a global centre of excellence for animal medicines, supporting both cutting-edge product developments and a regulatory model to benefit our local and international trade – but in order for this to happen, our industry's needs and priorities must be included in how the UK Exit develops.

To ensure farmers and pet owners have access to the medicines they need to support the health and welfare of our animals, the future UK regulatory system must be based on a form of 'mutual recognition' which permits a UK registered veterinary medicine access to the 'EU region' and vice versa. We need a constructive relationship with the EU, in particular the European Medicines Agency (EMA), post-Brexit which supports and encourages trade. Exit from the EU must not risk animal health and welfare due to a lack of access to veterinary medicines.

The regulatory system for veterinary medicines after EU exit must ensure that UK vets, farmers and animal owners have access to new products and technologies. The UK must not become a 'second tier' country where new products are only launched after other regions such as the EU; we must remain a primary market. We have the opportunity to work towards a regulatory and societal climate which leads, encourages and values innovation - allowing companies to develop new and improved medicines for animal health and welfare; ensuring safe, sustainable and productive UK food systems.

Our vision is an environment that delivers a thriving animal medicines sector

- Supporting **trade and innovation**
- Safeguarding **animal health and welfare and public health** and **food safety;** ensuring that UK veterinarians and animal keepers continue to have access to a wide range of appropriate veterinary medicines.
- Businesses have access to **skilled staff** – the right workforce they need
- **Product research and development** is incentivised within a regulatory system which continues to be one of the most stringent in the world – making UK the first choice world-leading regulatory authority
- Companies are encouraged to do business in the UK
- **Transitional arrangements** to support business continuity post EU Exit are built, utilising links with specialist EU infrastructure where necessary

What is needed 1: Regulatory challenges & solutions

Veterinary medicines are, quite rightly, heavily regulated to protect our animals, people and the environment. The UK regulator, the Veterinary Medicines Directorate (VMD) is considered to be a lead regulatory agency across Europe. In 2015 the UK acted as Reference Member State in 43% of EU Mutual Recognition procedures, being the lead regulatory agency for 73 out of 168 applications. The animal medicines industry welcomes this leading role that the VMD plays across Europe and the VMD's expertise is highly respected.

Keeping regulatory efficiencies. For many veterinary medicines work on EU applications for marketing authorisations has been carried out by one or two EU countries, then recognised by the others. This has led to efficiencies and reduced resource needs for UK businesses and regulators alike. Our businesses would benefit by retaining some access to this system so work is not duplicated for the UK. There needs to be a close working relationship with the EU, in particular the European Medicines Agency (EMA), post-Brexit. This would also avoid the need for more regulatory staff to be employed by VMD. Similarly there is an existing EU infrastructure such as electronic submission portals and databases that provides efficiencies and cost savings to both regulators and industry.

Ensuring UK availability of new medicines. A business's decision to develop a new veterinary medicine is often made on a regional basis i.e. a treatment for a disease occurring in a number of countries where the animal population is sufficient to obtain a return on investment. In that context, the EU is often viewed as a single region. Post Brexit, to ensure that access to new medicines is not delayed for British animals and to encourage companies to remain in or even move to the UK, some form of UK/EU 'mutual recognition' which permits a UK registered product access to the 'EU region' animal population could be a solution.

Tackling antibiotic resistance. As resistant bacteria can readily move with the international movement of people, animals and food, consideration needs to be given to how the UK can align with the EU in tackling this important global issue.

Ensuring food safety and continued trade. To ensure food is free from any harmful residues, maximum residue levels (MRLs) are set for withdrawal periods (i.e. the time between and animal receiving the last dose of a veterinary medicine and the first collection of foodstuffs e.g. milk). The EU participates in Codex, a body responsible for setting international MRLs, which helps facilitate trade in food. The UK will need to review and increase its participation in Codex meetings in the future.

Animal diseases do not respect borders. Disease can be transferred both where there is trade in animals and animal products and in the absence of such trade. In the future, we will still need to continue to co-operate with our European neighbours to ensure that appropriate measures are in place to prevent and control disease outbreaks.

Future regulation of veterinary medicines in the UK. Our members, in particular those operating in a multi-national environment, both in and outside the EU, need to retain access to the UK market. A possible regulatory model may be a new UK/EU bilateral treaty with the UK recognising the EU veterinary medicines legislation and continuing technical input from the UK offering expertise and capacity to the EU. This would offer benefits to both parties given the prominent role that the UK regulator has played in the EU regulatory network for veterinary medicines. It is expected that improvements will be made to the regulation of veterinary medicines in Europe in the new revised European Veterinary Medicines Regulations anticipated to take effect across Europe in 2021. It is important for business that the UK regulatory system evolves to include similar improvements to the regulatory system in the UK.

A small number of animal health products are currently regulated by the European Food Safety Authority (EFSA). Post-Brexit, a UK process will need to be developed for them.

What is needed 2: Research, Development and Innovation

Helping innovation. New veterinary medicines will continue to be needed to address disease challenges. To maximise innovation, for example to provide alternatives to antibiotics, or vaccines for new emerging diseases, it is important companies can focus their R&D spend on innovation. Any reduction in administrative burden will assist. Improvements

in the protection of company's intellectual property and technical documentation are also recognised as a way to encourage new product development.

Protecting UK science. Clarity over future funding for scientific research will avoid an erosion of the UK veterinary science base. UK government may wish to consider funding availability for UK-based scientists to ensure the UK retains its world leading status in veterinary science research.

Opportunities

Within future trading relationships, EU Exit may represent an opportunity to develop a new, innovative regulatory system, able to incentivise companies to gain product approval and launch onto the UK market in advance of the EU. In certain circumstances, carrying out our own scientific risk assessments on the authorisation of veterinary medicinal products could allow UK vets, farmers and pet owners access to a greater range of medicines, in some case before the EU. For example,

(i) Special routes to authorisation in the UK where the disease is different from the EU e.g. emerging disease, or a species not popular in EU, such as sheep

(ii) Special opportunity to authorise a product when a positive benefit:risk assessment is appropriate for the UK but negative in the EU.

This is also an opportunity to ensure the retention of the UK's POM-VPS and NFA-VPS categories of veterinary medicines: a system with a long track record of ensuring appropriate access to certain medicines for UK farmers and pet owners which NOAH members support. Our ability to communicate to farmers is also under threat from the EU. Retaining our ability to inform animal keepers, for example about improvements to pain management, vaccination or better ways to manage antibiotic use will all help to ensure our high animal welfare standards.

What action are we taking?

NOAH Board of Management, leaders of UK veterinary medicines businesses, are working together to identify the risks and opportunities offered by the UK post EU Exit for our members. We are collaborating with partners across the sector, veterinary, human health, agricultural, pets and others. We are also engaging with relevant government departments to ensure that veterinary medicines are included in future industrial and agricultural strategies.

Conclusion

EU Exit may represent an opportunity for NOAH members businesses. This will depend on clarity from government and the development of an appropriate UK regulatory system firmly based on internationally recognised science and technical expertise. It should be aligned, where necessary, with the new EU legislation for veterinary medicines, as this will be more supportive of innovation than currently. It will be important to ensure vets and animal owners continue to have access to the medicines they need to maintain the animal health and welfare expected by the British public. Such a regulatory environment would act to encourage innovation, investment and the development of new veterinary medicines.

NOAH and our members are open to engage fully to assist UK government in identifying solutions to issues arising from our exit from the EU.

For more information about the animal medicines industry https://www.noah.co.uk/