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NOAH 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 £645m of B2B sales every year. NOAH membership includes both global multinationals and companies who manufacture, import and market products within the UK.

Executive Summary

Brexit is an unprecedented challenge to the animal medicines industry. As we leave the EU, our priority is a regulatory system and relationship with both the EU and international partners, which can deliver a vibrant and innovative animal medicines sector, supporting the health and welfare of the UK's livestock and pets. Industry and the regulatory network both in the UK and in the EU must be able to collaborate and co-operate to ensure access to veterinary medicinal products (VMPs) both in the UK and across EU member states. 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. The proposed 21 month Implementation Period is an essential, and minimum, requirement for UK businesses, given the scale of work and resource required. Clarity and guidance is needed on the operational conditions of the Implementation Period, to allow industry to plan, to safeguard jobs and continuity of business in the UK.

High standards of animal health are integral to good animal welfare; veterinary medicines are vital for good health, preventing and treating disease in our farm animals and pets. To ensure vets, farmers and pet owners have access to the medicines our animals need and to avoid the UK becoming a 'second tier' country for medicines supply, UK government must negotiate a constructive post-Brexit relationship with the EU, in particular the European Medicines Agency. 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.

- **Trade and innovation** flourish

- **Animal health and welfare and public health** and **food safety are safeguarded:** UK vets and animal keepers have access to the range of veterinary medicines our animals need

• Access to **skilled staff** – the right workforce businesses 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 a first choice world-leading regulatory authority

• Companies are encouraged to do **business in the UK**

• **Transitional arrangements** with an Implementation Period, which supports businesses and links with specialist EU infrastructure are maintained

What is needed 1: Functioning Supply Chains

The production of veterinary medicines and their onward supply onto the UK market cannot occur without supply chains that function effectively. These supply chains will span the new UK:EU border post Brexit. Raw materials will need to arrive at manufacturing sites and veterinary medicines will need to be transported across this border to meet market requirements. Any border delays, complex processes or increased costs will risk medicines availability in the UK.

What is needed 2: 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 an internationally recognised leading regulatory agency, a role welcomed and supported by industry.

Implementation Period. The animal medicines industry welcomes Government efforts to secure the proposed 21 month Implementation Period. However, currently, there is no binding agreement but industry must make choices now, based on the possibility of working within an Implementation Period or facing a hard Brexit. To make informed business decisions, clarity is urgently needed about how the Implementation Period will operate.

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. During the implementation period access will continue to be needed to existing EU infrastructure such as electronic submission portals and databases to provide efficiencies and cost savings for both regulators and industry.

Ensuring UK availability of current and new medicines. Decisions to develop a new veterinary medicine is often made on a regional/geographical 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 or lost for UK 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 and vice versa is needed. Similarly, a large proportion of veterinary medicines are dual labelled for the UK and other member states such as Ireland, without some form of mutual recognition these products will no longer be economically viable.

Tackling antibiotic resistance. As resistant bacteria can readily move with the international movement of people, animals and food, the UK must continue to collaborate and co-ordinate with the EU in tackling this important 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). Following Brexit, the UK will need to avoid costly and unnecessary duplication of work and establish a system to recognise the sound, science-based decisions made by other international authorities, such as the EMA, to adopt the same MRLs for substances and withdrawal period for products on the UK market.

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 need to continue to co-operate on European disease surveillance to ensure that measures are in place to prevent and control disease outbreaks in the UK.

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 offers benefits to both parties given the prominent role the UK regulator has held in the EU regulatory network for veterinary medicines. Improvements to the regulation of veterinary medicines in Europe will take effect across Europe in the next 3 to 4 years and it will be important for business that the UK regulatory system is able to take advantage of the opportunity to embody similar improvements to the regulatory system in the UK.

Certain animal health products are currently regulated by the European Food Safety Authority (EFSA). Clarity on a suitable UK process to replace EFSA is urgently required.

What is needed 3: Research, Development and Innovation

Helping innovation. Development of new veterinary medicines will continue to be needed to address disease challenges. Incentives to stimulate innovation, for example to provide alternatives to antibiotics, or vaccines for new emerging diseases, must be brought forward and it is important companies can focus their R&D spend on innovation. Any reduction in costly administrative burden will improve the case for R&D. 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 opportunities for scientific research is needed to avoid an erosion of the UK veterinary science base. UK government should consider funding availability for scientists to work in the UK and collaborate internationally ensuring 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, providing efficiencies and flexibility whilst being recognised with the

EU. This would 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 VMPs 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. Retaining our ability to inform professional animal keepers, for example about improvements to pain management, vaccination or how to responsibly use prescribed antibiotics will all help to ensure our high animal welfare standards.

What action are we taking?

We are working together to identify the challenges of the EU Exit for our members. We are collaborating with partners across the sector: veterinary, human health, agricultural, pets and others and engaging with government departments to ensure that veterinary medicines are included in future industrial and agricultural strategies.

Conclusion

The UK exit from the EU represents an unprecedented challenge in terms of scale and scope for NOAH members businesses. The continued health of UK businesses depends on clarity from government, clarity on the Implementation Period and future trading conditions and the development of a 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 is more supportive of innovation than the current regulatory environment. It will be important to ensure vets and animal keepers continue to have access to the medicines they need to maintain the animal health and welfare expected by the British public. UK government must deliver a regulatory environment to encourage innovation, investment, productivity 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/