

Brexit: How NOAH is Working to Ensure a Thriving UK Animal Health Sector

Following the result of the UK's referendum on membership of the European Union on 23 June 2016, Dawn Howard, Chief Executive of NOAH (National Office of Animal Health) commented that the association was committed to working with the UK regulator, government and other stakeholder organisations on any forthcoming changes to regulations or market access conditions.

Never a truer word: she also said it was clear the process of leaving the EU was not clear and that this will be a lengthy process of negotiations.

Over a year on from the vote, a new UK prime minister and a general election later, and a quarter of the way into the two-year period of negotiation post-trigger of Article 50, the clock is ticking but there is no further clarity on how the Brexit process will evolve.

As the trade association representing the UK animal medicines industry, NOAH has been working hard towards the sector's vision of an environment that delivers a thriving animal medicines sector post-Brexit, informing its members on the latest developments, and helping to steer a course through new legislation in discussions with UK politicians to get the best for animal health.

The UK's future relationship with the EU and access to the single market will be critical. To agree strategy, the NOAH Board of Management established a Brexit Task Force, with representation from companies headquartered in the UK and overseas (in and outside the EU), with UK manufacturing and without, and across the regulatory/commercial spectrum. They set a vision of 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 the UK the first choice world-leading regulatory authority
- Companies are encouraged to do business in the UK as unnecessary regulatory burdens are recognised and removed
- Transitional arrangements to support business continuity post-EU exit are built, utilising links with specialist EU infrastructure where necessary

They developed a paper¹ that examined what was needed in relation to regulatory challenges and future regulatory models.

Veterinary medicines are, quite rightly, heavily regulated to protect 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.

Keeping regulatory efficiencies

Where veterinary medicines work on EU applications for marketing authorisations has been carried out by one or two EU countries, then recognised by the others, there are efficiencies and reduced resource needs for UK businesses and regulators alike. The UK needs continued access to this system to avoid duplication of work and extra resource, as well as to the existing EU infrastructure such as electronic submission portals and databases that provide 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 the question of 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 an 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, the UK will still need to continue to co-operate with its European neighbours to ensure that appropriate measures are in place to prevent and control disease outbreaks.

Future regulation of veterinary medicines in the UK

NOAH members, in particular those operating in a multi-national environment, both in and outside the EU, need to retain access to the UK market. For example, 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. 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.

In parallel, NOAH worked closely with VMD to help identify those issues that need to be addressed to allow the UK regulatory process to continue to function on Day Zero: effectively the first day after the two years following the Article 50 trigger. VMD will be working on these as part of its preparatory activities – without clear signs as to what Brexit will look like these need to be able to assume a 'no deal' scenario.

The UK animal health sector is relatively small (circa £625m ex-factory sales per annum), but it has a big impact on many other sectors and is critical to their success. There is also much commonality on what is needed, for example with the human pharma sector (also currently heavily reliant on the EU regulatory process through the European Medicines Agency (EMA)), with the other associations in the agricultural technology, supply, knowledge transfer and innovation sphere and with the vet profession and farming organisations. Much has been done in collaboration – sharing requirements and ideas through formal alliances such as the Agri-Brexit coalition², through collaboration with the life sciences group and regular discussions with, for example, the British Veterinary Association (BVA) and National Farmers' Union (NFU).

Working together enables NOAH to magnify its voice in the clamour of sectors vying for politicians' attention in developing UK policy, but NOAH is also making sure that the specific needs of and opportunities for the animal medicines sector are recognised. Key to this is communication. To this end, NOAH is developing a series of reports, called the Brexit Barometer.

The uncertainty about Brexit and how negotiations will develop are manifested in NOAH's inaugural Brexit Barometer report³, which was developed following a NOAH Brexit workshop event in London in May 2017 where representatives from 16 NOAH member companies and other key stakeholders came together to discuss and debate the impact of the EU exit on the animal medicines sector. The findings revealed that while there were clear levels of optimism from the majority when it comes to animal health and welfare, 40% of attendees said they felt 'somewhere in the middle' when asked to declare whether they felt optimistic or pessimistic about the overall future of the industry. With 35% feeling optimistic and 25% feeling pessimistic, steering members and stakeholders towards optimism through a collaborative relationship with the Government becomes fundamental to the future success of the industry.

The report will be repeated to track shifting sentiment as the Brexit process unfolds.

Attendees at the workshop examined the exit from the EU and its impact on the industry through six different lenses: animal health and welfare, public health and food production, trade and investment, R&D and innovation, bringing new products to market and post-licensing controls for the overall market.

Brexit event attendees were also asked to share their levels of optimism on each of the six areas. In order of positivity, the top three topics were as follows:

1. Animal health and welfare
2. Public health and food production
3. Post-licensing controls for the overall market

Alongside tracking sentiment, the report sets out a series of specific opportunities for each of the six topic areas, outlining what the industry and its stakeholders require from government to realise each of these. NOAH will be working closely with its members and stakeholders to communicate and address this feedback in the coming months.

It is good to see a degree of optimism among our diverse audiences. NOAH is very conscious of the need to translate the largest proportion (40%) of undecided respondents into positive sentiment to enable us to capitalise on Brexit despite the uncertain political climate. People are prepared to embrace Brexit, but providing the sector's needs are recognised.

What the UK Government needs to do has been recognised, for example by Neil Parish MP, Chair of the Environment, Food and Rural Affairs (EFRA) Select Committee.⁴ He said that Brexit will affect us all and the process will not be simple. The animal medicines industry plays a vital role in supporting the health and welfare of the animals that produce food from UK farms and the pets that share our homes. Government will need to work closely with the sector to address issues ranging from building on the UK's existing high standards of animal welfare and protecting against a post-Brexit labour shortage, to ensuring that innovative medicines and vaccines can continue to be brought to the UK market through appropriate regulation and trading agreements between the UK and the EU. The results of this initial report very clearly illustrate that the future of the industry lies very much in the balance, and steering it towards optimism and success needs to be a priority in view of the challenges that lie ahead.

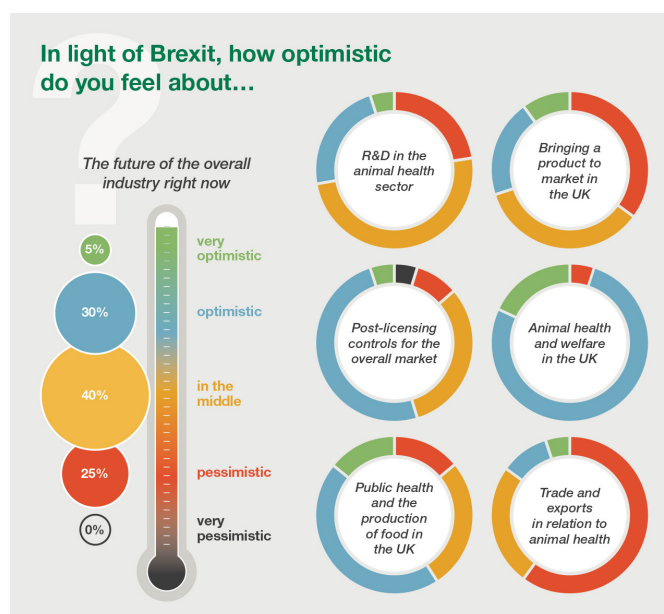


Figure 1: NOAH Brexit Barometer 1 – optimism on different aspects of Brexit in relation to the animal health sector

The report says that after it leaves the UK, the UK can be a well-funded global centre for research and development and innovation supported by talent from around the world (Figure 1).

But the Barometer identified certain things that the UK Government needed to do to help enable this to happen:

- Provide guidance on securing continued collaboration and funding for the future through EU framework programmes
- Provide clarity over future funding for scientific research to avoid erosion of the UK veterinary science base
- Explore opportunities to access new collaboration and funding, both nationally and globally
- Explore opportunities to collaborate with other partners beyond the EU
- Consider funding availability for UK-based scientists to ensure the UK retains its world-leading status in veterinary science research
- Set out a clear single system for attracting talent from around the world
- Define the role of the animal health and welfare industry and promote cross-industry collaboration
- Reduce administrative burdens and improve the protection of companies' intellectual property and technical documentation.

In relation to bringing new products to market, the Barometer showed the sector at its least optimistic (Figure 1). The UK can provide the most streamlined and simplified route to market for product manufacturers – introducing an innovative licensing system, removing unnecessary administrative burden and working with industry to develop a regulatory model which encourages innovation. But to realise this opportunity there is a lot that needs to be done:

- Promote the UK as a place to do business
- Update UK regulations to reflect the benefits offered by the new European regulation of veterinary medicines, enabling us to achieve continued innovation and positioning within the market
- Avoid regulatory divergence in technical data requirements for product registrations
- Secure a seat for the UK at the VICH
- Provide stability, certainty, openness and transparency throughout the exit process
- Secure the status of EU nationals to retain expertise in the UK
- Ensure that access to new medicines is not delayed for British animals
- Ensure an environment that encourages companies to remain in or move to the UK
- Develop a form of 'mutual recognition' which permits a UK-registered product access to the 'EU region' animal population
- Safeguard regulatory efficiencies and retain access to current EU marketing authorisation systems as well as electronic submission portals and databases
- Recognise that the VMD has the expertise and flexibility to manage the evaluation of innovation medicines.

The UK will be able to control its imports and supply chain – drawing on the VMD as a resource for pharmaceutical inspection, providing improved education (for example about improvements to pain management, vaccination or better ways to manage antibiotic use) and managing the potential for counterfeit products (Figure 1). To realise this opportunity, we need government to:

- Recognise the important role of the animal health industry during the exit process
- Provide continuity with existing and future EU legislation
- Provide assurance that the UK does not lose its position as a market of first choice
- During the UK's exit timeline, maintain its level of influence

around policy within the EU

- Minimise costs and admin burden for post-licensing controls
- Support multi-national members in retaining access to the UK market through a possible regulatory model which 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
- Develop a new process for the small number of animal health products currently regulated by the European Food Safety Authority (EFSA)
- Ensure the continued ability to import actives and medicines and ensure that additional tariffs on these do not affect prices.

One thing is clear: the UK animal medicines industry does not want to miss the opportunity presented by new veterinary medicines legislation, as proposed by the European Commission, with the benefits of reduced administrative burden and stimulating investment and innovation in our sector. The current EU Veterinary Medicines Directive is translated into UK law by the Veterinary Medicines Regulation 2013 – but this is of course under review and will not be finalised in time for it to be swept into the European Union (Withdrawal) Bill (or 'Repeal Bill').

Yet the UK will need to mirror the new EU regulations where possible – such as licensing procedures and product packaging – to avoid barriers to trade or additional cost of complying with a dual UK:EU regulatory system. The animal medicines sector is not alone in this: it is a strong argument from the human pharma sector, citing fears of what a no-deal scenario could bring⁶.

A letter from UK Health Secretary Jeremy Hunt and Business Secretary Greg Clark indicated this message has got through – they are fully committed to continuing a close working relationship with the EMA post-Brexit⁷. The statement was made in the context of human medicine, but NOAH has responded with a letter also published in the *Financial Times*⁸ saying the association agrees access to medicines for human patients is vitally important, but explains that we must also ensure that our pets and farm animals have continued access to the best veterinary medicines to protect their health and welfare.

It says animal medicines are equally subject to the stringent regulatory controls of their human counterparts, based on EU legislation, using the EMA.

Animal medicines are integral to the health and welfare of animals on our farms and the pets sharing 12 million UK households, as well as nearly 10,000 assistance animals and 1500 working dogs. The Barometer report sets out a clear opportunity for the UK to be the benchmark for animal health and welfare on a global stage – through, for example, setting progressive, flexible and innovative legislation. This could include recent government suggestions for incentivising good health and welfare, with George Eustice, MP, Minister of State, Department for Environment, Food and Rural Affairs, stating that he wishes to place 'animal welfare at the heart of the design of future agricultural policy'⁹. Prevention of disease is of course an important part of that.

The Brexit Barometer's publication coincided with warnings from the House of Lords (in its EU Select Committee's Brexit: Farm Animal Welfare report¹⁰) that potential trade deals post-Brexit could threaten health

and welfare standards for farm animals, showing that government needs to take decisive action to safeguard the competitiveness of those farming to the UK's high health and welfare standards as well as ensuring continued access to medicines for our vets, farmers and pet owners.

While optimism remains high (Figure 1), the animal medicines industry needs a continuation of its high standards of health and welfare to help tackle antibiotic resistance and to put the UK in a strong influencing position with our ability to trade. Six key measures in relation to health and welfare that government needs to take to realise the opportunities were outlined in the report. These are:

- Maintaining the current Animal Welfare Acts and evolving them to secure the UK's position from 'Day 0'
- Ensuring the industry is not disadvantaged by lack of veterinary medicines availability during the transition period and beyond, as new products come on the market
- Ensuring that veterinary services are available in inner city and rural areas throughout the UK
- Ensuring that a cross-border programme is in place to maintain cooperation between the UK and Europe
- Recognising that animal diseases do not respect borders and co-operating with our European neighbours to ensure that appropriate measures are in place to prevent and control disease outbreaks
- Balancing first-class welfare standards with creating a level playing-field for UK farmers and ensuring that British product does not become uncompetitive.

This shows the sector sees a very clear opportunity for the UK to show leadership when it comes to animal health and welfare; industry is united in supporting high standards of animal welfare post-Brexit¹⁰. Good animal health is integral to good welfare, and we support the report's acknowledgement that the veterinary profession is integral to the welfare role. Our sector provides tools such as vaccines to help the veterinary profession prevent disease and suffering, and medicines to treat where needed.

In summary, NOAH is confident about the future of animal health after exit from the EU, but delivering on the sector's priorities is a complex challenge. It requires all parts of industry to come together to help address the challenges and to collectively harness the opportunities, while speaking up to government about exactly what support is needed to ensure business continuity.

REFERENCES

1. NOAH Brexit position paper <https://www.noah.co.uk/medicine-topics/brexit/>
2. Agri-Brexit Coalition <http://www.agri-brexitcoalition.org.uk/>
3. NOAH 1st Brexit Barometer Report <https://www.noah.co.uk/wp-content/uploads/2017/07/NOAH-Brexit-Barometer-Summer-17-6pp-A4-vf.pdf>
4. Neil Parish MP, Chair of the Environment, Food and Rural Affairs (EFRA) Select Committee, personal communication (NOAH Members' Day, 14 June 2017)
5. The European Union (Withdrawal) Bill <http://bit.ly/2sTov55>
6. Drug firms fear bitter pill of a 'no deal' Brexit: Daily Telegraph, 17 June 2017 <http://www.telegraph.co.uk/business/2017/06/17/drug-firms-fear-bitter-pill-no-deal-brexit/>
7. The UK wants to continue to work with the EU on medicines: letters (Jeremy Hunt and Greg Clark), Financial Times,



4 July 2017 <https://www.ft.com/content/a94326ac-5dbd-11e7-9bc8-8055f264aa8b?mhq5j=e3>

8. The health of our livestock and pets is important too: letters (Dawn Howard), Financial Times, 6 July 2017 <https://www.ft.com/content/0b700eac-60e4-11e7-91a7-502f7ee26895?mhq5j=e3>
9. Leaving the EU: Animal Welfare Standards in Farming, Hansard, column 93WH (George Eustice) 17 January 2017 <https://hansard.parliament.uk/Commons/2017-01-24/debates/7E2FCDD9-C80D-4488-92C5-1783E703AC45/LeavingTheEUAnimalWelfareStandardsInFarming>
10. House of Lords European Union Committee Report Brexit: Farm Animal Welfare, 5th report of session 2017-19, published 25 July 2017 – HL Paper 15 <https://publications.parliament.uk/pa/ld201719/ldselect/lducom/15/1502.htm>



Dawn Howard

Chief Executive of NOAH. Prior to joining NOAH in 2014 Dawn was based in Brussels and spent a number of years representing UK agriculture in the office of the UK National Farmers Union where her responsibilities included animal health and welfare. She later headed up the European body for farm animal breeders, EFFAB.

Dawn previously worked in Defra's Animal Health and Welfare policy unit in Westminster and prior to that both Plant Health and pesticides policy in York, originally joining as a field-based inspector.

Whilst originally qualified as a botanist, Dawn has a passion for raising animal health and welfare standards.

Email: d.howard@noah.co.uk