Brexit and the Animal Health Sector – Two Years on from the UK EU Referendum

The UK's decision to exit from the EU, now two years ago, was not anticipated by the UK animal medicines industry, which for many years has been well integrated in European supply chains. However, since June 2016, NOAH has been working to understand the implications of Brexit for the industry and to ensure continuity of supply of medicines for UK vets and animal keepers.

The UK regulator, the Veterinary Medicines Directorate (VMD), is working with NOAH in an effort to ensure that a full complement of medicines will still be available in the UK on day one of Brexit, to minimise the potential for disease spread and animal suffering. But as this work continues, concern is mounting that time is running out to allow businesses to be able to execute a smooth Brexit process without interruption to the availability of veterinary medicines.

It has also become clear that the impact will not just be on UK medicines supply. The risk to supply will impact many other member states – in particular Ireland and smaller or more vulnerable markets.

We are working hard to raise the profile of the particular issues we face, and to ensure we do not get lost among the needs of much larger sectors. For example, in May 2018, European association AnimalhealthEurope, NOAH and the Irish association APHA, jointly organised an event at the European Parliament highlighting the sector's concerns. Co-hosted by two UK MEPs, Julie Girling (EPP) and James Nicholson (ECR), Vice-President of the European Parliament, Irish MEP Mairead McGuinness also joined the event, where Brexit's wider implications to the medicines supply of the EU-27 as well as the UK were discussed.

Continuity of supply has been identified as a critical concern. The production of veterinary medicines and supply to the UK – and indeed EU-27 – market is totally dependent on complex supply chains that must continue to function effectively after the UK leaves. 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.

NOAH members have been working hard to adjust their businesses to Brexit – both in relation to the UK and the EU-27 – but currently over 70% report that they are only 'somewhat prepared' for a hard Brexit and less than 10% consider their business to be 'prepared' for a hard Brexit. This is neither through lack of effort, nor through unawareness of the need to act, but due to the magnitude of the tasks involved in such a specialist sector.

A transition period – generally called the implementation period – is vital to give time for preparations to take place both in the UK and EU-27, and while this will help, the potential long-term implications to medicines availability also cannot be underestimated.

NOAH has welcomed the UK government's efforts to secure an implementation period, but to make informed business decisions, clarity is urgently needed about the detail of how this will operate. Even then, the proposed transition period until December 2020 might not be enough. What was clear from the May European Parliament event was that until there is clarity in relation to the big political picture, more detailed discussions cannot take place, say, in the European Parliament to try to agree solutions to our sector's concerns. Moreover, there is currently no binding agreement, yet industry must make choices and potentially irreversible decisions now, based on the possibility of working without an implementation period or facing a hard Brexit on 30 March 2019.

NOAH conducted a survey (May 2018) with its members to assess their current 'Brexit preparedness'. Seventy per cent of NOAH members either have UK manufacturing or use UK contract manufacturers. In some cases these are large-scale manufacturing operations supplying not just the EU but a global market, and companies report that it will be very difficult to relocate to the EU-27 by 30 March 2019. Over 60% of those companies supply medicines to the EU market and the future supply of anything from 40 to 80% of their products will be affected.

In addition, over 80% have EU-registered products that are batch-released in the UK. In some cases, up to 100% of their EU products are batch-released in the UK. Batch-release testing, vital to ensure the animal medicines are good quality, is a specialist process requiring licensed facilities and skilled staff which cannot be moved overnight. Many businesses are already planning to invest heavily in new EU facilities for their European market but this is unlikely to be completed by 30 March 2019, and in many cases they will struggle to complete the move by the proposed implementation period end of December 2020.

In addition to where medicines and vaccines themselves are manufactured, there is a very real concern about product packaging. This is an important part of the overall product which carries legally compliant information and is vitally important for veterinary surgeons and animal keepers to ensure medicines are used correctly. The majority of UK companies supplying medicines to the EU market report that they are highly unlikely to be able to make the legally required changes to packaging by 30 March 2019. This means that, unless a solution is found and the implementation period confirmed, perfectly safe medicines will go to waste, supply will be interrupted and animals cannot be treated.

There are implications for which medicines will be available in which market immediately post-Brexit and equally to the innovation and development of new medicines. Decisions to develop a new veterinary medicine are often made on a 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, and 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 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.

Significantly, a large proportion of veterinary medicines are dual-labelled for the UK and other member states such as Ireland, without some form of agreement to continue these products will no longer be economically viable for either the UK or EU markets. For example, of the veterinary medicines available in Ireland, up to 70% share labelling with the UK, accounting for 60% of turnover. This will obviously have a huge potential impact if labelling between UK (post-Brexit) and Ireland can no longer be shared. Every manufacturer would from that moment onwards have to produce dedicated packs for the Irish market, with all the associated costs of smaller-volume runs, separate labelling, and most importantly, separate stockholding.

Some packs would justify the additional complexity and costs to allow supply to continue in the Irish market, but many potentially would not, and lesser-volume products will become permanently unavailable in Ireland. Vaccines are a particular example: many have short shelf-life (some as low as 14 days) and will be some of the most vulnerable products if a pragmatic solution cannot be found to the labelling question.

Overall, Brexit will have a 'moderate' to 'severe' impact on the financial viability of their EU businesses in the short term. The longer-term impact on finance availability for research, innovation and new product development is unknown but will undoubtedly take some time to recover, something which is not good for UK or EU businesses – not the outcome we want for the health and welfare of all our animals.

The UK exit from the EU represents an unprecedented challenge in terms of scale and scope for NOAH member 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. The UK government must deliver a regulatory environment to encourage innovation, investment, productivity and the development of new veterinary medicines.

Animal diseases do not recognise borders. The ultimate goal is to ensure continuity of animal medicines availability for all veterinary surgeons, farmers and pet owners throughout Europe to safeguard animal health and welfare. For that, workable solutions need to be put in place to ensure minimum disruption to product development and approval and to maintain authorisations. It is especially important that veterinary products that are legally released onto the market before 30 March 2019 remain available both in the UK and the EU-27 after the UK departure.

Dawn Howard

Dawn Howard is 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.