NOAH - Written evidence (NIP0013)

18th of June 2020

Summary of key concerns for Animal Health Industry re the Northern Ireland (NI) Protocol

About NOAH

The animal health industry is dedicated to providing safe, effective, quality products and services for the treatment and welfare of all animals, large or small. The National Office of Animal Health (NOAH) has been representing the companies that research, develop, manufacture and market licensed animal medicines in the UK since 1986.

The association's membership represents over 95% of the UK animal medicines market worth in excess of £725 million per annum (2019) and directly supporting over 4000 highly skilled jobs, as well as indirectly supporting 22000 vets, around 7000 qualified animal health advisors (SQPs), over 13500 veterinary nurses and thousands of livestock farmers and people involved in pet and equine care, sports and leisure. As well as animal medicines our members also produce additional important animal health products such as feed additives, which are currently regulated by the European Food Safety Authority (EFSA).

Overview

- The veterinary medicines sector is rightly a heavily regulated sector. This is important for society as it ensures that authorised veterinary medicines maintain animal health and welfare for both companion animals and farm animals. This regulatory system also helps to ensure that food from treated farm animals will not lead to any harmful (for human health and the environment) residues of veterinary medicines.
- The NI protocol is a major concern for the animal health industry. There is a real danger that companies may withdraw products from the NI market as they simply do not have the resources to manage the increased regulatory burden that will be required to maintain products on the NI market. This is a major concern for animal health and welfare because a lack of access to products could cause animal health problems.
- For many decades up to the present day, European Regulations for veterinary medicines have been applicable in the UK after first being transposed into UK national law. The UK regulator, the Veterinary Medicines Directorate (VMD), has played a central and highly active role in the European regulatory network, carrying out between 30-40% of the shared regulatory work prior to Brexit.
- The veterinary medicines market is small, circa 4.5% of the human health market (in value of sales in £) and it therefore does not have the economies of scale that the human health market has. As a result, additional administrative and regulatory burden can severely weaken the case for

products remaining available on the market or indeed being viable for development in the first place.

- The priority for the UK animal health sector is to ensure that Northern Ireland vets, farmers and animal owners retain access to the existing range of veterinary medicines to ensure animal health and welfare is maintained.
- The NI market on its own is a very small market, for some companies only 2-3% of their UK business. Any measures that lead to additional regulatory or administrative burden run the risk of reducing the availability of products. Any increased costs will make an already marginal market even less attractive and there is a real risk of some companies withdrawing completely from the NI market.
- The NI protocol will mean that NI will follow EU regulations for veterinary medicines as part of the single all island regulatory zone on the island of Ireland.
- Any introduction of specific NI only requirements for products to be maintained on the market runs the risk of products not remaining available in the NI market.

<u>Questions Committee asked to be addressed, with NOAH responses in *italics*</u>

1. What is the worst-case scenario here for the Northern Ireland agrifood sector, and what is the best case? Which issues are you most worried about?

   The NI market on its own is a very small market from the perspective of the veterinary medicines industry- measures that lead to additional regulatory or administrative burden, such as complex and time consuming customs checks and procedures, run the risk of companies not marketing veterinary medicinal products in this small marketplace.

   In the worst-case scenario, a lack of access to veterinary medicinal products could have a negative effect on animal health and welfare and on the economic viability of farms. In NI there are over 25000 farming businesses, with beef, sheep and dairy being the largest sectors, as well as major pig and poultry businesses[1].

   In the best-case scenario, an appropriate and collaborative UK/EU Free Trade agreement that included animal health and veterinary medicines including feed additives in its scope, would lead to a smooth flow of Veterinary Medicinal Products from GB into NI, leading to no supply problems for VMPs.

2. What challenges do you anticipate for Northern Ireland agrifood products going into Great Britain?
   a. What do you hope to see from the UK Common Frameworks in the relevant areas?

   Our understanding is that in the short term there will be minimal problems or challenges for agrifood products moving from NI to GB.

However, in the mid to long term, if the UK and EU were to adopt significantly different regulatory approaches, for example if the EU were to permit the use of a product in food producing animals and the UK did not, this could hinder trade in agrifood products moving from NI to GB.

3. What do you expect the impact to be on the agrifood sector of any additional formalities in the following areas after the transition period, for goods moving from Great Britain to Northern Ireland?
    a. Sanitary and phytosanitary (SPS) formalities
    b. Customs (including tariffs), VAT and excise, and product-related regulatory controls.

    SPS formalities, customs checks and product related regulatory controls all have the potential to adversely affect the movement of goods from GB to NI in the absence of a free trade agreement between the UK and EU that addresses such issues.

    Furthermore a NI system for regulation of Veterinary Medicinal Products (VMPs) that required a different approach in NI to that taken in Great Britain, for example with specific labelling requirements for products aimed at the NI market, has the potential to adversely affect animal health and welfare with a potential follow on impact on animal health and welfare and on the viability of agriculture in NI.

    Put simply, even the cost of additional or different information on the packaging components for a UK product destined for NI could make it uneconomic to supply to NI. Even modest additional tariff or excise costs would have the same effect. Any limitations on availability of products in this manner could adversely affect animal health and welfare in NI.

    A further concern is whether there are sufficient numbers of trained personnel e.g. veterinary surgeons and customs staff, to complete the required SPS checks.

    Regarding VAT and tariffs, there are concerns about whether there will be sufficient time to set up the correct IT systems and to provide information and guidance for the companies and staff that will be required to use these systems.

4. How can the UK-EU future relationship reduce any possible negative impacts of the Protocol on the agrifood sector?

    An appropriate and collaborative UK/EU Free Trade agreement that included animal health, animal disease control, food regulations and standards in its scope with the UK adopting a corresponding and similar approach to regulation of VMPs and feed additives could lead to a smoother flow of products from GB into NI, thus reducing the risk of supply problems. For veterinary medicinal products, a free trade agreement that included mutual recognition agreements for various aspects of veterinary medicinal products

such as compliance with inspections and batch release recognition could also help to reduce the negative impacts.

Furthermore, customs systems and checks that were simplified and not time consuming as a result of the systems being corresponding and similar could also help ensure continued supply of VMPs and feed additives to the NI market.

5. How can the Government better engage with and provide support to your members and the wider Northern Ireland agrifood sector?

Animal health companies need urgent clarity on customs and regulatory checks that will be required for the movement of VMPs and feed additives from Great Britain into Northern Ireland. The requirements for such checks and what measures companies will be required to follow to move products from GB to the island of Ireland remains unclear. This is a key question that needs to be answered as soon as possible so that companies can make required logistical and administrative changes. To date, the information provided by government has been inadequate and does not provide animal health companies with what they need to plan. While NOAH's members will do everything in their power to continue supply, the dearth of information on the NI situation makes such preparation and arrangements all the more difficult, potentially leading to supply delays or failures.

Our understanding is that VMPs in NI will be required to follow the EU regulations for veterinary medicines. Clarity is needed on the way in which animal health companies will be required to register and maintain authorisations for VMPs. For example, will the UK regulator (the VMD) operate separate GB and NI (following EU rules) regulatory systems and, if so, what analysis, including financial costs for industry, has been conducted on the potential impact on industry and the attractiveness of the UK as a whole to animal health companies? To date, the limited information available from government does not give animal health companies sufficient information or clarity on what they are required to do.

The EU has identified a lack of port facilities to carry out SPS checks as a concern that the UK government could act to correct. [2]

6. What are the most pressing actions needed from the Joint Committee and its supporting bodies?

From the perspective of the animal health industry, the response to question 5 above addresses the most pertinent points. This includes maintaining product labels in conformance with EU regulations and recognizing the EU batch release without the need for duplication of tests and certificates, via a mutual recognition agreement.

7. Do you expect the Protocol arrangements to be ready for 1 January 2021?

We do not expect either government or the animal health industry to be ready for 1st of January 2021 based on the lack of information and instruction provided by government to date. The animal health industry has not received sufficient information to allow them to plan to supply NI with veterinary medicinal products and feed additives after 01/01/2021. Some scenarios, for example a requirement to re-route product to meet EU requirements or to update packaging to meet EU requirements, could take over a year to implement and can only commence once the UK Government has provided sufficiently clear guidance, which to date has not been provided.

8. How is COVID-19 affecting the agrifood sector's preparation for the Protocol?

   To date, during the COVID 19 crisis, in general supplies of VMPs have been maintained. There is a concern that in the event of there not being a free trade agreement with the EU at the end of the transition period, supply chain problems could lead to problems with the availability of VMPs and feed additives. This concern would apply to both GB and NI. In this context, it is important to note that the majority of VMPs and feed additives are imported, many of them from the EU, so supply of VMPs is very sensitive to supply chain disruption, whether that disruption is driven by COVID 19 or by trade related issues.

9. Will the Protocol solve the issues it is intended to?

   No comment from the animal health industry.

References:

1. Ulster Farmers' Union website- https://www.ufuni.org/farming
2. Technical note on the implementation of the Protocol on Ireland /Northern Ireland, published April 2020 https://ec.europa.eu/info/sites/info/files/brexit_files/info_site/20200430_note_protocol_ie_ni.pdf