Written evidence submitted by National Office of Animal Health - NOAH, relating to the operation of The Windsor Framework
[OWF0003]

NOAH (National Office of Animal Health)

NOAH represents the UK (Northern Ireland and Great Britain) animal health industry, advocating for the benefits of licensed veterinary medicines and solutions. Our membership covers approximately 97% of the UK animal medicines market. The animal health industry is crucial for ensuring the health and welfare of both farm and companion animals, providing safe food for consumers, and supporting farm sustainability, food security, and resilience.

The Windsor Framework Agreement and Veterinary Medicinal Products

Veterinary medicinal products (VMPs) are essential to animal health and welfare. They significantly contribute to the UK's food security and public health. Ensuring the availability and proper regulation of these products is vital for maintaining the health of both farm and companion animals.

Historically, most animal health companies have operated in both Great Britain (GB) and Northern Ireland (NI), with the NI business managed and supplied from GB. This integrated approach has allowed for efficient management and distribution of veterinary medicinal products across the UK. However, we remain concerned about the implications of the Windsor Framework Agreement (WFA) on our members' ability to fulfil regulatory requirements, maintain product authorisations, and management of supply chains, all leading to a potential disruption to product supply to NI.

The WFA does not adequately address the specific complexities faced by the UK animal health industry. While measures have been enacted for the human medicines sector, similar attention is urgently needed for veterinary medicines to ensure their continued availability in NI. We highlight that 10-15% of veterinary medicinal products could be at risk of discontinuation in NI when the current transition period ends (end of 2025), leading to the full implementation of EU veterinary medicines laws in NI. Such product discontinuations will lead to adverse animal health and welfare outcomes.

Additionally, the application of the EU acquis in NI from the end of 2025 implements an immediate divergence of legislation between GB and NI, increasing the regulatory complexities for both the UK regulatory (Veterinary Medicines Directorate) and industry.

NI is a small market, and the introduction of any NI-specific requirements, whether regulatory or supply chain-related, poses significant challenges. As previously stated, the current form of the WFA risks the discontinuation of many products for the NI market. An 'all island of Ireland' Marketing Authorisation approach remains unviable, as products authorised in the Republic of Ireland are not automatically legally authorised in NI.

We acknowledge the European Commission's extension of the transition period until the end of 2025, ensuring the continuity of veterinary medicinal supplies to NI until this time. However, we remain concerned about the lack of consistent regulatory direction and the potential risk to the availability of veterinary medicines in NI post-2025. This uncertainty surrounding future regulations also poses a significant threat to the stability of the veterinary medicines market in NI.

To address these concerns, we call for regulatory functions to be permitted to remain within the UK (such as the location of the Marketing Authorisation Holder), with recognition and acceptance of batch testing and release conducted in GB or the EU, and no additional manufacturing authorisation or import licenses for medicines supplied from GB to NI. This would allow a product that was batch released in the EU to be warehoused in GB without repeat testing when it is moved from GB to NI, allowing the existing supply chain and logistics network to continue to function. Additionally, we advocate for the use of a single pack and leaflet for both GB and NI markets. These measures would help ensure the continued availability of essential veterinary medicinal products in NI.

The challenges faced by our industry cannot be resolved by additional time alone. The primary issue is the cost of making significant changes specifically for the NI market. We urge the UK Government and the European Commission to continue positive discussions and immediately resume specific talks to address the long-term needs of the veterinary medicines sector in NI. Given the absence of specific talks and the proximity of the EC deadline, industry has had no choice other than to begin implementing changes. Consequently, a swiftly negotiated and mutually agreed regulatory outcome is essential to ensure the long-term supply of veterinary medicines, benefitting animal health and welfare in NI.

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