Written evidence submitted by British Veterinary Association BVA, relating to the operation of The Windsor Framework
[OWF0002]

Who we are

1) The British Veterinary Association (BVA) is the national representative body for the veterinary profession in the United Kingdom. With over 19,000 members, our mission is to represent, support and champion the whole UK veterinary profession. We are a professional body and our members are individual veterinary surgeons. We take a keen interest in all issues affecting the profession, including animal health and welfare, public health, regulatory issues and employment matters.

2) BVA Northern Ireland Branch exists to represent members in Northern Ireland. It brings together representatives of our specialist divisions, Government, academic institutions, and research organisations in Northern Ireland.

3) We welcome the opportunity to engage with the Northern Ireland Affairs Committee's inquiry on the Windsor Framework. Given the nature of our organisation we will be submitting our views in relation to the issue of access of veterinary medicines in Northern Ireland post December 2025.

Overall view

4) In January 2024, BVA gave oral evidence to the House of Lords' inquiry into Veterinary medicines and the Windsor Framework[1]. During our session, we welcomed the Windsor Framework as a positive step for all communities in Northern Ireland (NI) as it paves the way for trading arrangements between Great Britain (GB) and Northern Ireland through a new UK internal market system (green lane) whilst still requiring full EU process for third country goods moving into the Republic of Ireland (red lane). This was particularly welcomed on agrifood commodities which forms a significant amount of GB to NI trade. The elimination of Export Health Certificates, Phyto Sanitary certificates, and various checks at NI ports or individual agri-food items, as set out within the Windsor Framework, significantly reduces the un-necessary work-load on veterinary professions.

5) However, the Windsor Framework did not provide a solution for the issue of access to veterinary medicines in NI, with this issue still primarily covered by the arrangements set out in the earlier Northern Ireland Protocol.

6) Point 47 of the Windsor Framework is the only mention of veterinary medicines. This point states that the original protocol 'failed to take account of the overwhelming reliance of Northern Ireland on veterinary medicines from Great Britain.' It also states that the UK has 'put in place a grace period arrangement until the end of 2025' and that the 'government is clear that the only practical solution will be a solution, as with human medicines, to guarantee the existing and long-established flow of trade between Great Britain and Northern Ireland.'[2]

Veterinary medicines

[1] https://committees.parliament.uk/work/8125/veterinary-medicines-and-the-windsor-framework/
[2]https://assets.publishing.service.gov.uk/media/63fccf07e90e0740d3cd6ed6/The_Windsor_Framework_a_new_way_forward.pdf

7) Veterinary medicines in NI are regulated by the UK's Veterinary Medicines Regulations 2013, which is legislation that is overseen by the Veterinary Medicines Directorate, an executive agency of Defra for the whole of the United Kingdom. However, as part of the Northern Ireland Protocol, products marketed in NI will be required to comply fully with the European Veterinary Medicinal Products Regulation, which is overseen and regulated by the European Medicines Agency (EMA).

8) Two elements in the European Union's Veterinary Medicinal Products (VMP) Regulation are particularly difficult for GB-based companies to comply with in order to market products in Northern Ireland:

   - **Batch release testing:** When a batch of veterinary medicines is released from a factory, a process known as batch release testing is required to be undertaken before those products can enter the supply chain and be used by vets or others. Under the European veterinary medicinal products regulation, batch testing is required to take place within the EU. Currently, most UK-based companies use the Great Britain supply route, which means medicines enter the Northern Ireland market after being batch released and then warehoused in Great Britain. This supply route and process will not be permitted by the EU after December 2025, since any product entering Northern Ireland from Great Britain will be considered an import into the EU and batch release testing will have to have been carried out, if necessary, a second time within the territory of the EU even if it has already been carried out after manufacture.

   - **Marketing Authorisation Holder (MAH) registered address**: according to European Union's veterinary medicinal products regulation, each veterinary medicine is required to have a "Marketing Authorisation Holder" with registered address within the European Union, and to have that address printed on the product's data sheet and package insert. Those registered addresses are required to be within the European Union. As noted above, the majority of products used in Northern Ireland do not currently comply with this requirement being produced by an MAH registered in Great Britain.

9) Currently, the majority of veterinary medicines are transported from mainland Europe into Great Britain, then into the Republic of Ireland and Northern Ireland. The size of the Northern Ireland market being small (about 2% or 3%[3] the size of the human medicine market) makes it economically and logistically challenging for pharmaceutical companies to invest in submitting a licence variation to change the MAH location and re-batch testing the veterinary medicines when entering Northern Ireland from Great Britain; or to make a change in their supply route.

10) From the 1st of January 2026, as soon as the "grace period" expires, all veterinary medicines entering Northern Ireland from Great Britain, will have to be re-batch tested and have a MAH address in the EU to comply with EU regulations. This effectively means that from January 2026, veterinary medicines in Northern Ireland will have to comply with EU legislation, while still being regulated by the UK's competent authority, the VMD.

Impact of the lack of supply of veterinary medicines

11) It is unclear what the percentage of Northern Ireland's veterinary medicines could be at risk. Earlier estimates indicated that up to 50% of medicines could be at risk[4]. The

[3] https://committees.parliament.uk/oralevidence/14122/pdf/
[4] https://www.noah.co.uk/topics/business-and-trade/northern-ireland-

figure was then thought to be closer to 30%, and recent insights give a figure closer to 10%. However, it is not only the percentage of medicines that may be lost but the type and nature of these medicines, the volumes used and the health and welfare impact that their unavailability may cause on both animals and human health.

12) There is also a risk that new VMPs may not be able to be used in Northern Ireland. This could not only be an animal welfare problem (eg a new canine drug) but also a public health problem (eg novel livestock vaccines that might need to be used in an emergency). This would also pose a risk for trade between Great Britain and Northern Ireland as if a disease could not be controlled in NI, then the UK would not have a freedom from status.

13) Some of the medicines that are thought to be at risk include everyday essential preventative medicines such as vaccines, including the only salmonella vaccine and one or more of the licensed leptospirosis vaccines for cattle that are currently licensed, as well as vaccines and treatments for companion animals and horses.

14) The loss of the salmonella vaccine for cattle would increase the risk of disease which could cause severe consequences for animal welfare and health, production and public health. The loss of this vaccine could have the potential for herds to have abortions, illness, death and premature culling. There are also public health risks from the inability to control such potential zoonoses, and a negative economic impact as a result of decreased production[5]. This is causing significant stress for both farmers and veterinary professionals who want to maintain animal health and welfare and who play a key part in public health too. Data from the Public Health Agency reported an increase in the cases of Salmonella infections reported from 125 in 2015 to 144 in 2016, a 15% increase[6].

15) Every year Salmonella causes approximately 200 million to over 1 billion infections globally. This includes 93 million cases of gastroenteritis and 155,000 deaths. Shockingly, 85% of these illnesses are exclusively related to contaminated food[7]. Salmonella species are also increasingly antibiotic resistant with evidence of adverse human health consequences due to the occurrence of resistant microorganisms. This highlights a secondary importance of vaccination as a measure to reducing spread and infection (and consequent antimicrobial use) as a long-term method of control.

16) There are also issues with the import of the botulism vaccine. Botulism in cattle is a significant animal health issue in Northern Ireland given the high density of poultry flocks and the small percentage of arable land for poultry litter and manure to be spread on. The botulism vaccine is manufactured in South Africa or Australia and currently imported into NI under a Special Import Certificate (SIC) issued by the VMD. As this is manufactured outside the EU, it will not be allowed to be used inside the EEA, including in Northern Ireland after the “grace period”. Loss of access to an effective botulism vaccine is a significant risk to animal welfare following cessation of the current arrangements for supply of veterinary medicines to NI.

Conclusions

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protocol/#:~:text=Industry%20estimates%20that%20up%20to,and%20animal%20health%20and%20welfare

[5] https://www.sciencedirect.com/science/article/abs/pii/S0167587712003285

[6] https://www.publichealth.hscni.net/sites/default/files/directorates/files/N%20Ireland%20Gastrointestinal%20Surveillance%20Report%202016.pdf

[7] https://www.sciencedirect.com/science/article/pii/S2772416624000081

17) Overall, BVA believes that the Windsor Framework positively addresses some concerns of veterinary professionals, farmers, agrifood businesses, and pet owners alike. Throughout the UK, the veterinary profession continues to manage the challenges with workforce shortages, and it is therefore encouraging that the proposals simplify the flow of goods and minimise the need for unnecessary but time-consuming veterinary intervention as animals and goods move between Great Britain and Northern Ireland.

18) We acknowledge that point 47 of the Windsor Framework emphasizes the importance of maintaining an uninterrupted flow of veterinary medicines to Northern Ireland. However, the Windsor Framework does not propose a solution on how to achieve this. Although we welcomed the extension to the grace period at the end of 2025, we remain extremely concerned about this issue and we continue to work with the UK Government, EU Commission, and other stakeholders to find a permanent solution.

January 2025