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European Affairs Sub-Committee on
The Windsor Framework

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Rt Hon Steve Baker MP
Minister of State
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30 April 2024

Dear Minister,

VETERINARY MEDICINES AND THE WINDSOR FRAMEWORK

1. On 8 January 2024, the House of Lords European Affairs Sub-Committee on the Windsor Framework launched an inquiry into veterinary medicines and the Windsor Framework.

2. As part of its inquiry, the Sub-Committee received written evidence from stakeholders and undertook evidence sessions with a range of expert witnesses on the subject of veterinary medicines in the context of the Windsor Framework. The Committee visited Northern Ireland between 31 January and 1 February 2024 to hear directly from farmers, veterinarians, officials and representatives of the sectors directly affected by the implementation of EU rules with respect to veterinary medicines in Northern Ireland.

3. On 17 January 2024 we heard evidence from Donal Murphy, Head of International and Regulatory Affairs at the National Office of Animal Health (NOAH); Bryan Lovegrove, Secretary General at the Animal Health Distributors Association (AHDA); Edward Ferguson, Director of Regulatory and Quality at Zoetis UK; Dr Esther Skelly-Smith, NI Branch President of the British Veterinary Association (BVA); Dr Mark Little, 2021-22 Branch President and Honorary Secretary, NI Branch of the BVA; and Dr Simon Doherty, Senior Lecturer at Queen's University Belfast.

4. On Thursday 1 February 2024, the Committee held a stakeholder roundtable in Belfast on veterinary medicines and the Windsor Framework with a range of industry representatives.[1] The participants in the seminar were David Brown, President, Ulster Farmers' Union (UFU); Alexander Kinnear, Parliamentary Officer, UFU; Dr Mark Little, 2021-22 Branch President and Honorary Secretary, NI Branch of BVA; Deirdre

[1] Sub-Committee on the Windsor Framework, 'Inquiry into Veterinary Medicines and The Windsor Framework: Roundtable meeting with Northern Ireland based stakeholders, 1 February 2024, Belfast - Note of discussion', committees.parliament.uk/publications/44144/documents/219360/default/

McIvor, Chief Executive, Northern Ireland Pork and Bacon Forum; Daryl McLaughlin, Chief Executive, Northern Ireland Meat Exporters Association (NIMEA); Dr Esther Skelly-Smith, NI Branch President of the British Veterinary Association; Ian Stevenson, CEO, Dairy Council NI; and Denise Walshe, Group Strategic Finance Projects Manager, Lakeland Dairies Co-operative Society Limited.

5. On 13 March, we heard evidence from you, in your capacity as Minister of State with responsibility for the implementation of the Windsor Framework, as well as Gavin Hall, Deputy Chief Executive Officer/Director of Authorisations at the Veterinary Medicines Directorate (VMD); and Brendan Threlfall, Director General of Union and Windsor Framework at the Cabinet Office.

6. We also received five pieces of written evidence from the British Agricultural Bureau (BAB), the Northern Ireland Food and Drink Association (NIFDA), the Ulster Unionist Party (UUP), the Ulster Farmers' Union (UFU) and Rt Hon Steve Baker MP.[2]

7. We are grateful to all our witnesses for their assistance. We are also grateful to you for your oral evidence on 13 March and your follow up letter of 27 March providing further detail on issues raised by the Committee.

8. The cross-party membership of the Sub-Committee, drawn from Northern Ireland and the rest of the UK, has a wide range of expertise in Northern Ireland affairs. Our membership represents a range of views on the Windsor Framework itself and we write this letter without prejudice to the views of individuals.

9. We draw your attention to the list of members' interests published on the Committee's website. As a member of the Veterinary Medicines Working Group, Baroness Ritchie of Downpatrick has recused herself from the deliberations and final agreement of this letter.

10. The following paragraphs reflect the findings of our inquiry, which we draw to your attention in the context of the ongoing implementation of the Windsor Framework. The full list of questions is enclosed at **Annex A.**

Introduction

11. Immediately following the UK's exit from the European Union, the whole of the United Kingdom remained aligned with EU rules on veterinary medicines. However, following the implementation of the EU Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6), new EU rules will apply in Northern Ireland under the Windsor Framework. Commission Notice 2022/C 494/03, published in December 2022, extended the existing grace period for veterinary medicines until 31 December

[2] All oral evidence transcripts and written evidence for this inquiry can be found on the Sub-Committee's website: https://committees.parliament.uk/work/8125/veterinary-medicines-and-the-windsor-framework/publications/

2025, at the end of which EU rules will apply in full unless an alternative solution is reached.

12. The Committee's inquiry has sought to examine the consequences of the application of Regulation (EU) 2019/6 and its potential impact, including the effect on industry if no solution is reached. There was a consensus amongst our witnesses that the full application of EU rules at the end of the grace period may seriously restrict both the range of veterinary medicines available and the availability of products in different pack sizes. Further, there are particular concerns about the ability to import certain medicines, such as the botulism vaccine, which are fundamental to controlling disease in Northern Ireland.

13. Our witnesses have outlined the likely serious economic effects for their respective industries, primarily farming and agrifood, but also for show animals such as horses and companion animals (pets). As a number of our witnesses pointed out, the rural economy is an essential part of the social fabric of Northern Ireland and anything which affects the economic viability of this industry may have serious social as well as economic consequences.

14. Industry experts were also keen to stress the link between animal and human health, particularly for food-producing animals. We heard serious concerns from our witnesses that the loss of veterinary medicines may have consequences for public health in Northern Ireland and on the island of Ireland.

15. We welcome the Government's announcement of a Veterinary Medicines Working Group which was set out in the Command Paper *Safeguarding the Union,* published during the course of our inquiry on 31 January. We have reflected these developments in our letter, including the initial views of our witnesses about the Working Group and the evidence we heard from you and your officials on 13 March.

16. We note also the Government's position, set out in the Command Paper that while an agreed outcome with the EU "remains our clear priority", "we will if necessary deploy all available flexibilities to safeguard and sustain the supply of veterinary medicines in Northern Ireland."

17. We recognise that the Government published its Review of the Veterinary Medicines Regulations 2013 during the course of our inquiry. While this consultation centred on proposed changes to the veterinary medicines regulations applicable in Great Britain, we have raised questions as to the effect that these changes might have in Northern Ireland.

18. Notwithstanding the establishment of the Working Group, our witnesses expressed their concern at the current pace of progress and emphasised the urgent need to find a solution well in advance of the end of the grace period, particularly given the upcoming EU and UK elections. Witnesses stressed that commercial decisions are being taken now, which could have ramifications for the supply of veterinary medicines to Northern Ireland for years to come.

19. We set out in this letter some potential overall solutions and solutions to specific issues which were put forward by our witnesses in the course of the inquiry. Our witnesses were united on the importance of political will in resolving this crucial issue

for the people of Northern Ireland, and the urgency in doing so. We echo this and endorse their call for talks leading to a mutually-agreed solution between the UK and the EU.

Consequences of the application of the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6)

20. Our witnesses were in agreement that the application of Regulation (EU) 2019/6 would cause two main problems for the sector. The first is that EU rules require that the registered address of the Marketing Authorisation Holder (MAH) must be within the EU or Northern Ireland and this address must be displayed on the product packaging. The British Agricultural Bureau (BAB) stated that "[a]round 85% of veterinary medicine products authorised in Northern Ireland are registered to a GB address. Therefore, 85% of products would no longer be compliant with EU rules."

21. Although producers could change the registered address to one in the EU, the BAB noted the administrative burden and associated costs this would create for businesses. Donal Murphy, Head of International and Regulatory Affairs at the National Office of Animal Health (NOAH) agreed, arguing that "[i]t may sound like a small thing, and you may ask why we are complaining about changing an address, but the reality is that our sector is highly regulated and to make those changes is not a simple process. It is an administrative burden, time-consuming and costly."

22. Witnesses were concerned that these additional costs could affect producers' assessments of the economic viability of supplying the Northern Ireland market. The BAB noted that the Northern Ireland market is small, and sales volumes are already low so additional costs may negatively affect the business case for the continued supply of some products. Dr Mark Little, 2021-22 Branch President and Honorary Secretary, NI Branch of British Veterinary Association (BVA) agreed, noting that "the pharmaceutical industry has stated that the investment required to implement the changes will not be economically viable for such a small market, leading to discontinuation of vital veterinary medicines."

23. The second problem created by the application of Regulation (EU) 2019/6 is that products moving from Great Britain to Northern Ireland would need to undergo additional batch-testing on entry into Northern Ireland, described by Dr Mark Little as "a further quality check". According to Donal Murphy, for most companies who are members of NOAH a product would be batch-tested, warehoused in GB and then moved into Northern Ireland. Dr Little noted that the new rules would apply "even to veterinary medicines manufactured and batch released previously in the EU and transiting through GB."

24. The BAB argued that batch testing being repeated on entry to Northern Ireland would "[add] cost and burden to manufacturers". They also noted that "[t]here are logistical challenges with direct shipment to NI that cannot be overcome for all veterinary medicines." The Ulster Farmers' Union (UFU) also stated that there is "a lack of availability of suitable warehousing and batch release testing facilities and capacity in NI."

Potential impact if no alternative solution agreed

Reduction in the range of veterinary medicines

25. Our witnesses were clear that the combination of changes to the Marketing Authorisation Holder (MAH) rules and batch-testing has the potential to affect the supply of medicines to Northern Ireland. The British Agricultural Bureau (BAB) said that "access to this range and diversity is threatened after the December 2025 deadline".

26. Witnesses were concerned that the costs associated with adapting to the new rules after the end of the grace period would mean companies choosing not to supply the Northern Ireland market. The Ulster Farmers' Union (UFU) said: "Where products are sold in low volumes, the administrative costs arising from variations, packaging changes, and the consequential extensive work necessary to update internal systems, including those used to co-ordinate the manufacture, logistics, and finance, to ensure a continuation of supply, will simply not justify the expense associated with this additional regulatory burden." They were concerned that applications for authorisations may be limited to GB only as a result. Donal Murphy confirmed this view, explaining "[f]or some of these products, the economic case to spend money on making these changes simply is not there. The animal health industry overall is very small; we are only about 2% to 3% of the size of the human medicines industry, so making these changes is simply not justifiable across the entire portfolio for the companies involved."

27. Edward Ferguson, Director of Regulatory and Quality at Zoetis UK, acknowledged that while some companies may already supply from Northern Ireland or move their goods via the Republic of Ireland, the majority of companies will need to change their supply routes, which comes with associated costs. He argued that as a consequence, "if we proceed as things stand with the December 2025 deadline, Northern Ireland will see a fairly significant reduction in product lines—that is, the number of different presentations—but also in the number of products. That will include some niche products that have specialist transport that cannot be accommodated by the change, and it will potentially mean things coming off the market." Mr Ferguson also suggested this will continue to be an issue because "there will be a permanent lens on the supply of product to Northern Ireland because of economic viability."

28. Following engagement with industry by the UK Veterinary Medicines Directorate (VMD), the number of products estimated to be at risk in Northern Ireland was initially reported as being at 51%. However, in evidence Gavin Hall, the Deputy Chief Executive Officer/Director of Authorisations at the VMD estimated the revised number to be around 34-35% due to the rerouting of supply lines through the Republic of Ireland. He noted that "[a]s we get that number down, there will be a point where you can no longer lower the number, and that is when we need to be having technical discussions with the Commission: 'Here is the difficult nub of the issue. We got rid of the chaff; this is the bit we need to resolve'."

29. **What is the Government's current assessment of the number of products at risk of discontinuation?**

30. **What assessment has the Government made of the capacity of the Veterinary Medicines Directorate to deal with a large number of regulatory changes? Does the VMD have the necessary resources?**

Reduction in range of pack sizes

31. In addition to grave concerns about the different types of products at risk of discontinuation, our witnesses were keen to stress that a reduction in the range of different pack sizes could have a serious impact on industry. Dr Mark Little explained: "If a product is available in pack sizes of 1 litre, 2 litres and 5 litres for treating cattle against worms…we do not know whether pharmaceutical companies will pick a small pack size or a large pack size". He suggested that if companies choose to continue with a small pack size this has the potential be "less economical" but continuation with a large pack size also provides a challenge: "If it is a large pack size, a farmer with 10 cattle may need to buy 5 litres of products, which will last them for 10 years and, in fact, will go out of date before they use it all. The wrong thing to do for antimicrobial resistance is to use the same product again and again, because that drives antimicrobial resistance."

32. The BAB noted that "Northern Ireland's agricultural landscape is typically composed of small, family-run farms, often with smaller livestock numbers compared to those in GB." They argued that if larger pack sizes are the only products available this may result in additional costs and wasted products. Bryan Lovegrove agreed, arguing "[f]arming in Northern Ireland is not quite as intensive as in other parts of the UK, so a lot of farmers have smaller amounts of stock. If the smaller pack sizes were not available, they would be limited in their choices and may end up buying a pack size that would last them two or three years." The UFU was concerned that a reduction in different pack sizes "would encourage continued use of the same product line over several years which ultimately will drive resistance to certain active ingredients." Bryan Lovegrove argued that a reduction in pack sizes "risks the viability of some small farming businesses in Northern Ireland."

33. **What assessment has the Government made of the potential risks associated with a reduction in the range of pack sizes available in Northern Ireland? Does the Government recognise the particular problems faced by small farming businesses?**

Importing specific products such as the botulism vaccine

34. Our witnesses also expressed concerns about being unable to import specific medicines such as the botulism vaccine, which is produced in Australia and South Africa, into Northern Ireland after the end of the grace period. Gavin Hall explained that "there is a list of vaccines that the Commission has, and a list of diseases that the Commission has; if you then want to import a vaccine [from] outside of the EU to treat those diseases, you are not permitted to do so unless it is on that list." The botulism vaccine is not on the EU's list and our witnesses were keen to stress that botulism has no cure.

35. UFU President David Brown gave the following example: "I attended a farm with an outbreak of botulism. The farmer had 140 cows dying in front of me, causing personal

trauma for him and his business. He had not vaccinated for botulism and I can guarantee he will be now. If these vaccines are not available, the impact will be huge." Dr Mark Little highlighted that 25,000 cattle are vaccinated against botulism every year in Northern Ireland, since the disease is "a particular problem due to the farming model in Northern Ireland where we have a high density of the poultry industry, and a lot of family farms have a poultry house and grazing stock." He noted that many farmers in Northern Ireland spread poultry litter on grazing ground which then comes into contact with cattle, whereas in the EU the litter tends to be spread on arable ground. Dr Little said botulism is "more of an issue in Northern Ireland than potentially anywhere else in Europe" and suggested there would be a need for an exemption or easement.

36. **We welcome your view that "having reset the relationship with the European Union, and indeed the Republic of Ireland, we are now in a position where we can say, and be trusted when we say, that it is not in anyone's interests to have no botulism vaccine available in Northern Ireland". Has the UK Government raised the need for access to a botulism vaccine in Northern Ireland in discussions with the European Commission?**

Effect on industry

Agrifood/farming

Economic consequences

37. Our witnesses identified the risk that a lack of veterinary medicines may mean an inability to sell agrifood products to GB, the Republic of Ireland and on the international market. As Daryl McLaughlin noted: "Food chain information and residues are very important from a trade perspective. It is a very thoroughly regulated process and fundamentally underpins the trade aspect."

38. Dr Mark Little, Dr Simon Doherty and Bryan Lovegrove noted that if laying hens do not receive the salmonella vaccine, Northern Ireland producers will not be able to supply the GB market. Dr Simon Doherty, Senior Lecturer at Queen's University Belfast, noted that breeding bulls are often taken to sales in Carlisle and Perth but that if farmers cannot access key medicines such as the leptospirosis vaccines or the IBR vaccine Northern Ireland breeding bulls "will not be welcome".

39. Industry experts also noted that there is a significant reputational risk if there is a perception amongst consumers in GB that the Northern Ireland agrifood sector is unable to access essential veterinary medicines. Bryan Lovegrove noted that "[t]he farming industry across the UK is a very proud one… It is seen by the British consumer as being very professional, and they trust the food that comes from UK farmers. I would hate to see the day when there is negativity or a weakening in the public perception of farmed produce from Northern Ireland because of the lack of availability of veterinary medicines." Ian Stevenson agreed, arguing that "[f]armers take great pride, not just in the perception but in the reality, of operating to the highest standards." Deirdre McIvor, Chief Executive of the Northern Ireland Pork and Bacon Forum, said the pork industry's most valuable market is GB and "perception is everything". She said that if there is "even the merest suggestion" to consumers in

Great Britain that Northern Ireland pork's "quality assurance is not the same as that of pork produced in England" on account of its access to veterinary medicines, then it "would gravely impact our industry." She expressed the concern that this could "be the end of the pork sector here resulting in wide job losses and economic devastation", noting as well as that this could result in food security concerns. Daryl McLaughlin also stressed that "[t]he vast majority of beef produced in NI is for retail in GB" and "[a]round half of lambs in Northern Ireland go to the Republic of Ireland for processing and the rest slaughtered here are destined for the GB market."

40. Denise Walshe, Group Strategic Finance Projects Manager, Lakeland Dairies Co-operative Society Limited, outlined the situation for the milk industry, which is particularly dependent on trade with the Republic of Ireland. She said that of the 2.5bn litres of milk produced in Northern Ireland, 30% goes across the border daily. To enable this process, "DAERA [Department of Agriculture, Environment and Rural Affairs] vets must certify that the milk is produced to an EU standard." She argued that if "DAERA vets can't sign off 30% of the milk that is travelling to the Republic of Ireland, that will lead to culling animals and dumping milk and we don't have the capacity to dump that much milk. We are talking about farmers having to leave their farms because that 30% would destroy the industry. It would affect the farming communities which we rely on."

41. Different witnesses also highlighted the potential consequences for agrifood exports further afield. Dr Simon Doherty said "[t]here is a real market reputation risk here for our agri-tech and our agri-food products that would be associated with the loss of the [veterinary medicines] products." He offered the example of a manufacturer that exports milk powder to China. Deirdre McIvor also noted the importance of the Chinese market which pays a high price for particular cuts such as heads and trotters. She said "[t]he Chinese authorities are exceptionally particular and were there any suggestion that Northern Ireland no longer had access to necessary veterinary medicines, China could very well delist our sites and cease to trade with us, with devastating consequences." She also suggested this would affect the sector's ability to gain access to new world markets. Regarding the dairy sector, Denise Walshe said:

> "If any of our competitors think they can put a stone in our shoe, this is a great way to do it, by questioning what standards are being applied to the food chain in NI, are they UK animal medicines being used or EU animal medicines. As soon as you are defending you are in a weaker position so any risk of damage to the reputation of our food on an international market must be considered."

42. Ian Stevenson added "[w]e produce 2.5bn litres of milk in Northern Ireland and 75-80% of milk and milk product sales are to destinations outside Northern Ireland…We are an export-focused industry and anything that undermines our very good reputation will harm us."

43. **What is the Government's assessment of the potential economic consequences for the agrifood and farming industries associated with a reduction in the availability of veterinary medicines? Has the Government taken account of the potential for reputational risk if a solution is not found swiftly?**

Implications for human health

44. Our witnesses were also keen to stress the possible consequences for public health. Dr Simon Doherty defined the concept of "one health" as "the interconnectedness between the health of people, animals and the environment". Witnesses highlighted the progress that has been made in Northern Ireland towards using a "prevention being better than cure" approach and Deirdre McIvor described how the UK pig sector has reduced the use of antibiotics by 75% over the last eight years. She argued that "[l]imiting access to veterinary medicines and vaccines flies in the face of the of responsible use of antibiotics and the One Health approach that the sector has successfully adopted". Dr Simon Doherty noted that "we are probably the region of the UK that is absolutely ahead of the game in the control and eradication of bovine viral diarrhoea virus, and we are at risk of jeopardising some of that if we do not look very carefully at it." Ian Stevenson, CEO of the Dairy Council of Northern Ireland, said "[t]he Republic of Ireland is moving forward and is declared free of many diseases and Northern Ireland wants to move towards that. Our ability to do that would be impeded if medicines were not available."

45. Donal Murphy noted that there are several diseases which have the potential to cause both animal health and human health problems, such as salmonella where there is only one vaccine available. Dr Mark Little said they had spoken to the British Medical Association (BMA) regarding the potential discontinuations of the leptospirosis and salmonella vaccines. He stated the BMA "has given us permission to say that the loss of vaccines that prevent diseases will cause a public health emergency in Northern Ireland." Dr Little noted that the World Veterinary Association also produces an essential veterinary medicines list and "[m]any of the veterinary medicines to prevent and control diseases in Northern Ireland that will be discontinued appear on this World Veterinary Association essential veterinary medicines list."

46. The British Agricultural Bureau (BAB) argued that:

> "The absence of adequate access to veterinary medicines risks competitiveness and could lead to increased vulnerability to disease outbreaks, reduced capacity to treat and prevent illnesses, and compromise animal welfare standards. This not only poses a threat to individual animals but has broader implications for public health from zoonotic disease, food safety, and the sustainability of agricultural production systems, ultimately threatening the economic viability of the sector."

47. The Northern Ireland Food and Drink Association (NIFDA) stated that "[i]n the event that no mutually agreed solution is reached, we anticipate a major impact as animal health planning and welfare will be affected." They continued that, "[e]ndemic or epizootic diseases that are currently very well controlled under current available vaccines can take over and spread rapidly meaning significant mortality and

productivity losses impacting on the availability of meat/eggs." They told us that "[p]otential [f]ood borne pathogen control will be at risk if specific vaccines are not available meaning significant impact to public health and supply chains."

48. Some witnesses also argued that there could be knock-on consequences on food supply. The Ulster Farmers' Union (UFU) argued that "[t]he food supply chain on the island of Ireland will be non-existent if a full suite of veterinary medicines is not available. The consequences for NI and [Republic of Ireland] farmers, companion animals, and human health are dire." The NIFDA also stated that a lack of vaccines "may negatively impact farm economics due to disease and put at risk a significant food production base, primarily focused on supplying the UK marketplace." They added that Northern Ireland supplies the UK with "enough meat and dairy products to feed an estimated 10m people" and so any disruption to agrifood production may also affect UK food security.

49. **What assessment has the Government made of the potential consequences for public health if access to veterinary medicines is restricted? What assessment has the Government made of any potential impact on the food supply chain, both in Great Britain and on the island of Ireland?**

Show animals, such as horses, and companion animals (pets)

50. Dr Esther Skelly-Smith, 2023-24 Branch President, BVA in Northern Ireland, noted that the companion animal and equine industries are also affected by the potential reduction in veterinary medicines. The equine industry contributes about £200 million to the Northern Ireland economy and there is particular concern about the loss of vaccines against equine influenza, tetanus and equine herpes as well as pain management products. A loss of these products has the potential to cause animal welfare concerns but could also prevent horses being able to travel to competitions, including the Olympics.

51. Dr Skelly-Smith argued "[e]quine influenza, like human flu, can affect the weak and the vulnerable… If we lose access for example to two out of three or maybe all those flu products, that will affect the herd immunity within the industry." She noted that it is mandatory for horses to have the equine influenza vaccine every six months to compete in shows and that if the necessary vaccines are not available "it will affect the ability of the industry to continue" and "will have very wide-ranging implications for our way of life".

52. Dr Skelly-Smith also raised the importance of the equine herpes virus vaccine which is particularly important for the breeding industry to prevent abortion storms.[3] She argued that alongside animal welfare concerns, an abortion storm "also has a huge economic impact. We must not forget the human side of this as well—the trauma. If you have ever seen an abortion storm, it is pretty horrific. That is difficult for the vets and the owners." She noted that failing to vaccinate against the disease would "fail to comply with the HBLB international code of practice on equine herpes virus. We

[3] An outbreak of disease which causes multiple abortions in herds.

would not be managing ourselves at a high standard, so it would put us in a place of weakness."

53. Pets or companion animals may also be affected by the full implementation of EU regulations. Gavin Hall noted that the rise in pet ownership during the pandemic has also contributed to vaccine shortages.

54. **While much of our evidence has focused on agrifood and farming we draw to your attention the potential impacts for show animals and companion animals. How will the Government ensure that key medicines remain available in order to avoid disruption to these industries?**

Social risk – threatening way of life

55. A number of our witnesses were keen to stress the potential impact on the way of life in Northern Ireland. The Northern Ireland Food and Drink Association (NIFDA) noted that "[t]he Northern Ireland rural economy is heavily dependent on the income generated from farming, both directly in family spend in our rural towns and villages and also indirectly, for example, in purchases made by rural manufacturers, supplying products such as sheds, concrete, fence posts etc.". The British Agricultural Bureaua (BAB) described the farming sector as "integral to the social and economic fabric of the country."

56. **What assessment has the Government made of the impact on the rural economy and the potential social impact on farming families and communities?**

Concern at the pace of progress

57. Our witnesses emphasised the urgent need to find a solution and expressed concern at the pace of progress in resolving the issues in relation to veterinary medicines.

58. Donal Murphy emphasised that "in the world of regulatory affairs of medicines and veterinary medicines there are very long lead-in times for changes to supply chains and product licences, all of which must go through the regulatory authorities." He said that: "Companies are making decisions—last month, this month and next month—about what products they will continue to market in NI and what will be discontinued…We need these issues to be resolved as soon as possible, because decisions are being made now."

59. Asked if there was any way to shorten the lead-in times necessary to adapt to new requirements, Edward Ferguson said:

> "If you have, say, 100 products that you commit to supply to Northern Ireland, you need to make the necessary changes...All animal medicine companies will be making the same change and there is only limited resource at the Veterinary Medicines Directorate, our regulators. You then have to batch generally around 10 variations per licence holder per month. That is 100 in 10 months. For most companies, it is more than 100. I have already planned what we need to do for products that we need to change for supply

to Northern Ireland. I am up to June 2025, and that is if I started last month [December 2023]."

60. In this context, witnesses were unaware of any current negotiations between the UK and the EU. Donal Murphy, the Ulster Farmers' Union (UFU) and Dr Mark Little all told us that they were not aware of any formal discussions between both sides on this issue. The issue of the current state of discussions between the UK and the EU is explored further below.

61. Witnesses also expressed that there appears to be a difference of opinion between the UK and the EU about the very purpose of the grace period. As the UFU told us: "It would appear to UFU that the grace period extension from the EU's perspective is about transitioning to full EU compliance by the beginning of 2026, whilst the UK government seems to take the view that the grace period is time to further negotiate and seek an alternate solution. Both views cannot be correct at the same time."

62. Donal Murphy agreed. He added that the issue with the EU's view is not just the timescales but that "some of these changes are simply uneconomic for companies to make for small-volume products, so more time will not be the answer for some products. Even if it was 10 years, time is not the answer; it is the regulatory system."

63. In this context, we note the EU's Commission Notice of 19 December 2022, which states that an extension of the grace period "can only be justified if measures are put in place to ensure that supplies of veterinary medicinal products to Cyprus, Ireland, Malta and Northern Ireland conform to the Union *acquis* on veterinary medicinal products and the provisions of the IE/NI Protocol in full no later than 31 December 2025."[4]

64. We further note your statement that the EU "wish us to comply, and the grace period is about how we will comply. The truth is that we have looked at it, and just complying has the problem that it is economically infeasible for some of the firms involved to reorientate the supply routes, to have a market authorisation holder in Northern Ireland or to do retesting."

Safeguarding the Union

65. Since we launched our inquiry, the Government published its Command Paper *Safeguarding the Union* on 31 January 2024. It states that the "Government is continuing to work at pace on practical, long-term solutions" and that "engagement with key stakeholders, including the agrifood sector, industry and political representatives" has led to the identification of a "number of key issues to resolve" through discussions with the EU.

66. To inform these discussions, the Government states that it "will put in place a Veterinary Medicines Working Group to advise the Government on the flexibilities that are needed by farmers, industry and animal owners." It also states that the "group will be composed of elected representatives, farming and industry

[4] https://commission.europa.eu/document/download/a11e0daf-91b4-4f38-8654-3ec0ff69cecc_en?filename=C_2022_9653_F1_OTHER_AUTONOMOUS_ACT_EN_V3_P1_2447309.pdf

representatives as well as legal and trade experts" and that the Government "will appoint the Working Group rapidly and ask it to report its findings urgently."

67. In this context, we note the statement by Brendan Threlfall, Director General of Union and Windsor Framework at the Cabinet Office, that the Government wants to do "some intensive work with the working group first" to build a "unanimous position" around a set of solutions, before engaging with the EU.

68. Our witnesses broadly welcomed the establishment of the Working Group, the membership and terms of reference of which have been deposited in the House libraries.[5] The British Agricultural Bureau (BAB) urged the Government to establish it rapidly "and set targets, timescales, and clear objectives." It also called on "the group to regularly report its findings to ensure full transparency with the sector and allow farmers, vets and industry professionals to adapt."

69. We note your statement in evidence to us on 13 March 2024 that you are "seized of the imperative to make rapid progress" and that the Working Group first met on 25 March. We further note your assurance that the "overall composition of the committee…is wide-ranging" and includes a "broad and representative group of experts in the field" including "politicians, veterinary scientists and Members of Parliament."

70. We note your view that the Government "should certainly be talking to the European Union by the autumn…" In this context, we draw attention to the political calendar in the EU and the UK, with European elections in June, the appointment of a new Commission after 31 October and uncertainty surrounding the date of the UK General Election.

71. **We welcome your recognition of the need to make "rapid progress" on this issue. While we recognise the merits in building a consensus around solutions, we once again underscore the urgency of the issue and the tight timescale to find a resolution in the context of upcoming elections in both the EU and the UK. How will the Government ensure consistency in approach in light of this year's political calendar?**

72. **We welcome your assurance that the Working Group is composed of a "broad and representative group of experts in the field". How will you ensure that the Working Group reports its findings regularly to ensure transparency, as urged by our witnesses?**

73. **Does the Government agree with our witness's assessment that there is a difference of opinion between the UK and the EU about the purpose of the grace period? If so, how will the Government bridge this gap?**

Potential overall solutions

74. Witnesses outlined a number of possible solutions to the potential disruption to the supply of veterinary medicines to Northern Ireland.

[5] Deposited paper DEP2024-0446 - Deposited papers - UK Parliament

The importance of political will

75. With the exception of unilateral action on the part of the UK, all of the proposed solutions discussed below would require some level of consensus between the UK and the EU, involving agreed legal changes or mutual recognition of standards. Reaching such an agreement would require urgent political effort, on both sides, to find a lasting solution. As Bryan Lovegrove told us: "It is about making sure that people are willing to listen and finding that political will at the highest possible level."

Human medicines-type solution

76. Witnesses had a range of views on whether a solution could be found to veterinary medicines which is comparable to that reached between the UK and the EU on human medicines in the Windsor Framework in February/March 2023.

77. Donal Murphy told us that, on the part of the EU, there has been a "seeming unwillingness to change the Northern Ireland protocol for veterinary medicines, as opposed to human medicines, because veterinary medicines used in food-producing animals impact on the food chain." This was due to the fact that there is a single market for food from treated animals, to which Northern Ireland has access. The risk, as the EU sees it, is that "the UK has left the European Union and is no longer applying the European veterinary medicines regulations" and therefore there was a future risk of "veterinary medicines that no longer align with the EU veterinary medicines regulations entering Northern Ireland and being used in food-producing animals and that food can then move around the single market."

78. In this context, British Agricultural Bureau (BAB) said that a "similar solution to that implemented for human medicines could be considered i.e. medicines with a valid marketing authorisation in GB can be supplied to Northern Ireland." It added that: "Any solution must also respect Northern Ireland's place in the UK single market."

79. Donal Murphy told us that he recognised the EU's legitimate concerns about the potential for divergence in relation to veterinary medicine products. Nevertheless, he did not think the issue was "unsolvable." He noted that around 3,000 products are authorised in the UK, adding that:

> "We are not talking about hundreds of products diverging year on year; you will have small numbers that would diverge significantly from the EU's requirements. Their concerns are legitimate, and any solution needs to listen to those concerns, but there are ways in which the regulators in the UK and the EU could come up with solutions to these matters in such a regulated and controlled industry where products are not just flying off shelves. Things are controlled very strictly throughout the supply chain."

80. Dr Mark Little agreed, stating that "divergence is not an issue in terms of veterinary medicines and UK and EU regulations." While he understood that "the EU is trying to protect its food product," he said that "the [Veterinary Medicines Directorate] assesses veterinary medicines to the same standard as the EU, so there is no divergence at present."

81. Dr Mark Little said that he would like to ask the EU:

> "whether losing 51% of the veterinary medicines in its aim to protect the EU standards for food quality is the bigger risk, or whether the bigger risk is simply losing half the veterinary medicines in Northern Ireland with the resulting impact of having a disease outbreak, and that disease outbreak then threatening because of food products such as milk and meat going across to the Republic of Ireland. I think the biggest risk to the EU would be restricting veterinary medicine supply to Northern Ireland and the potential disease outbreaks associated with that."

82. **Does the Government intend to seek a wider deal with the EU on veterinary medicines, similar to that reached previously on human medicines? If so, what does it believe the outlines of such a deal would look like? If not, why not? Does the Government recognise EU concerns about future divergence in relation to veterinary medicines? Does the Government agree with our witnesses' characterisations of the wider risks, including to human and animal health, if Northern Ireland loses access to a significant percentage of its veterinary medicines?**

Veterinary medicines agreement, possibly as part of a Sanitary and Phytosanitary (SPS) agreement

83. Witnesses discussed the possibility of a veterinary agreement between the UK and the EU, potentially as part of a wider Sanitary and Phytosanitary (SPS) agreement. The Ulster Farmers' Union (UFU) told us that they would like to see the UK Government "seek on behalf of the entire UK an SPS/Vet agreement with the EU. This could but only help resolve this issue, amongst many other outstanding Brexit issues." The Northern Ireland Food and Drink Association (NIFDA) suggested that this could be on the basis that the UK and the EU mutually recognise "each other's standard as being of equivalency."

84. Support for a veterinary agreement was echoed by other Northern Ireland agri-food producers, including the Lakeland Dairies Co-Operative Society Ltd and the Northern Ireland Pork and Bacon Forum, who supported greater alignment of issues relating to the food supply. Denise Walshe told us that her company favours a veterinary or SPS agreement because it would "take away the possibility for divergence because once divergence happens you lose access to one market." She pointed to increased costs to consumers, resulting from a requirement for veterinary certifications, adding that "the food sector sees more value in alignment than not. With this alignment in general the public pays less for food."

85. Other witnesses questioned, however, whether the current level of dialogue was likely to translate into an SPS or veterinary agreement in time to resolve the specific issue of veterinary medicines.

86. We note your assumption "that the EU would offer us only an [SPS] agreement that involved automatic alignment to its rules and standards" and that "the act of aligning would be a major political problem for any Government" in the context of Brexit.

87. While we recognise that veterinary medicines are not an SPS good, some of our witnesses felt that some of the solutions reached for SPS products could be relevant in a veterinary medicines context. In particular, we highlight what Dr Mark Little told us. He said that:

> "A solution similar to the SPS agreement where there is a bonded warehouse where veterinary medicines destined for Northern Ireland could be stored without having to go through these additional and unnecessary batch release issues would solve some of the problem. This has already been agreed with SPS products. The book does not have to be rewritten, because this is a solution that the EU has already agreed to. It could be extended to veterinary medicines. In fact, I would urge the EU to see this as a very sensible, practical, cost-effective solution that it has already agreed to, just for another product."

88. This solution was also suggested by the UFU.

89. **What is the Government's response to the suggestion that a solution analogous to that of a Sanitary and Phytosanitary (SPS) agreement, involving a bonded warehouse for veterinary medicines destined for Northern Ireland, could avoid the problem of unnecessary batch testing?**

Sourcing products from the EU

90. Our witnesses were asked why, under the EU's 2019 regulations, could Northern Ireland not simply source its veterinary medicines from the EU.

91. Dr Simon Doherty replied that the issue comes down to the fact that veterinary medicines in Northern Ireland are regulated by the Veterinary Medicines Directorate (VMD). He said that if European products were becoming available for use in Northern Ireland "they would all need to be regulated by the VMD, which currently they are not being. The VMD currently is managing the portfolio of products that are currently available" and if Northern Ireland lost access to a substantial amount of those and "European vaccine manufacturers in Spain, Portugal or Italy that wanted to flood the Northern Ireland market for some reason, those products would need to be regulated under the current Veterinary Medicines Regulations through the VMD." He added that: "There would be a time element to having those products available. It is because we are in this Catch-22 situation: the EU wants us to have EU tick-the-boxes product available in Northern Ireland, but the VMD also needs to have that oversight of products that are available in Northern Ireland."

92. **What solutions are the Government considering in relation to VMD regulation and licensing of veterinary medicines in Northern Ireland? Has any thought been given to the possibility of establishing a separate regulatory body in NI?**

Unilateral action

93. In its Command Paper, the Government states that its priority remains "pursuing an agreed outcome with the European Union on sustainable solutions." The Government also states that it is "clear that in all scenarios it will of course be imperative to safeguard the supply of veterinary medicines in Northern Ireland, which is in itself critical to maintaining animal health protections on the island of Ireland." It adds that: "While fully respecting our international obligations and the Belfast (Good Friday) Agreement we will if necessary deploy all available flexibilities to safeguard and sustain the supply of veterinary medicines in Northern Ireland."

94. Some witnesses interpreted the Government's statement as a suggestion that the Government might be prepared to take unilateral action and expressed concern at the consequences of such an outcome. Dr Mark Little said that: "I would worry about unilateral action, which has implications for trade and the veterinary sector. I would emphasise that there are two sides and we would like dialogue between the EU Commission and the UK Government for a long-lasting and sustainable solution for Northern Ireland." Daryl McLaughlin, Chief Executive, Northern Ireland Meat Exporters Association (NIMEA) stated that "If there is a supply issue, it is absolutely vital for a joint solution going forward." The BAB and UFU agreed.

95. In this context, we note your statement that the Government "would look at all flexibilities and comply with international law" and that you did not want to elaborate further because "there are too many people who would want to take anything I said and blow it up into some threat to be unilateral."

96. We further note your comment in this context clarifying, in the context of unilateral action, "That is not where we are." We welcome your emphasis on the UK and the EU's "common interest in animal health and well-being—and indeed human health and well-being—on the whole of the island of Ireland. If we can just converge on common interests, I believe we will solve it."

97. **What progress has been made to date in reaching a solution with the EU? How will the Government keep stakeholders, including the veterinary and agri-food sectors, updated on progress towards solving the issues in relation to the supply of veterinary medicines to Northern Ireland?**

Solutions to specific issues

98. Short of an overarching veterinary agreement based on the mutual recognition of equivalent standards or regulatory alignment, or an arrangement similar to that found on human medicines, our witnesses explored and put forward a number of potential solutions to specific issues which would mitigate the impact on the supply of veterinary medicines to Northern Ireland at the end of the grace period.

'Grandfather rule'

99. Some witnesses called for a 'grandfather rule.' Dr Mark Little said that as the VMD licensed veterinary medicines to the same EU standards before Brexit, a "grandfather rule would allow for the continued supply of veterinary medicines that were supplied

to Northern Ireland pre-Brexit. It would make sense to continue supplying those veterinary medicines, so that only newly licensed products would be required to go through EU checks." This was echoed by the UFU and the Ulster Unionist Party (UUP).

100. **Does the Government agree with this suggestion? If so, how will it convince the EU of the merits of such an approach?**

Acceptance of a Marketing Authorisation Holder (MAH) located in Great Britain

101. Some witnesses told us that the requirement for a Northern Ireland MAH to have an EU address should not be allowed to disrupt the supply of veterinary medicines to Northern Ireland. Dr Mark Little told us that it "makes sense not to get caught up with an address on the inside of a label inside a packet of veterinary medicines, because an address is not the problem here."

102. Several witnesses, including the UFU and Bryan Lovegrove, called for the EU Commission and UK Government to agree "that the [marketing authorisation] holder for UK national authorisations with NI in their scope be permitted to remain located in Great Britain (GB)."

The Veterinary Medicines (Amendment etc.) Regulations 2024

103. Since we heard this evidence, we note that the Government has published its response to its Review of the Veterinary Medicines Regulations 2013. In the consultation, it proposed:

> "To adjust the information that we require to be provided with an application for an MA. The information would be similar to the requirements for an MA application submitted to the European Medicines Agency. The data requirements would be harmonised to the extent possible with those in Annex II to the Regulation (EU) 2019/6, which would remove divergence between the requirements for GB and Northern Ireland (NI) facilitating the process for UK-wide coverage."

104. In response to the consultation, this proposal was amended "to ensure that the technical data that need to be submitted with the application for an MA, including the SPC [Summary of Product Characteristics], will be consistent with the EU rules."

105. We note that the Government's amended proposal has now been reflected in The Veterinary Medicines (Amendment etc.) Regulations 2024, which have been laid before Parliament for approval by resolution of each House of Parliament. The Draft Explanatory Memorandum states that "amending the Summary of Product Characteristics, packaging and labelling requirements on medicines [will] increase

alignment between requirements for Great Britain and Northern Ireland where beneficial, making it easier for companies to use UK-wide packaging."[6]

106. **We endorse the proposals from our witnesses that part of a solution could involve both the UK and EU agreeing to recognise a Market Holder Authorisation based in Great Britain. Does the Government share this view? If so, how does it plan to engage and convince the EU to seek agreement on this basis, and on what timescale? Are the provisions in the Government's 2024 Regulations consistent with this approach? If so, how and to what extent?**

Recognition of GB batch-testing

107. Several witnesses also told us that EU recognition of Great Britain's batch-testing would remove the requirement for re-testing upon entry to NI and therefore solve a large part of the problem. As the Northern Ireland Food and Drink Association (NIFDA) said:

> "Recognising Northern Ireland is too small a market to have an independent supply chain established shipping direct from Europe, (too many products with too small a demand to warrant the investment in a dedicated Northern Ireland), a solution needs to be found to allow for the continuation of this UK based redistribution of EU product."

108. The BAB said that for the issue of batch-testing, "an option could be recognition of GB batch-testing and warehousing by the EU." The Ulster Farmers' Union (UFU), Dr Mark Little and Bryan Lovegrove agreed. Donal Murphy added that if batch release and the marketing authorisation holder address and packaging issue discussed above were resolved, "it would go a long way. It would basically resolve the majority of the problem."

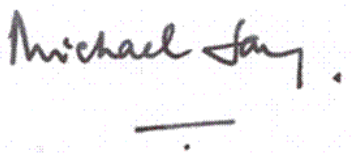
109. **We endorse the suggestions of our witnesses in relation to batch-testing and note the Government's statement in its Command Paper, which lists "the costs and burdens of repeat testing and release of EU products transiting through GB" as one of the issues to resolve. How does the Government plan to resolve the issue of batch testing, and on what timescale?**

The Committee would be grateful if you could respond to this letter before the end of June 2024.

[6] https://www.legislation.gov.uk/ukdsi/2024/9780348258523/pdfs/ukdsiem_9780348258523_en_001.pdf

I am copying this letter to Rt Hon Chris Heaton-Harris MP, Secretary of State for Northern Ireland; Sir William Cash MP, Chair of the Commons European Scrutiny Committee; Sir Robert Buckland MP, Chair of the Commons Northern Ireland Affairs Committee; Philip McGuigan MLA, Chair of the Northern Ireland Assembly Windsor Framework Democratic Scrutiny Committee; Andrew Muir MLA, Minister of Agriculture, Environment, and Rural Affairs of Northern Ireland; Tom Elliott MLA, Chair of the Northern Ireland Assembly Committee for Agriculture, Environment and Rural Affairs; Maroš Šefčovič, Executive Vice-President, European Commission, and Pedro Serrano, European Union Ambassador to the United Kingdom

Yours sincerely,



Lord Jay of Ewelme
Chair of the Sub-Committee on the Windsor Framework

Annex A: Summary of questions

1. *What is the Government's current assessment of the number of products at risk of discontinuation?* (Paragraph 29)

2. *What assessment has the Government made of the capacity of the Veterinary Medicines Directorate to deal with a large number of regulatory changes? Does the VMD have the necessary resources?* (Paragraph 30)

3. *What assessment has the Government made of the potential risks associated with a reduction in the range of pack sizes available in Northern Ireland? Does the Government recognise the particular problems faced by small farming businesses?* (Paragraph 33)

4. *We welcome your view that "having reset the relationship with the European Union, and indeed the Republic of Ireland, we are now in a position where we can say, and be trusted when we say, that it is not in anyone's interests to have no botulism vaccine available in Northern Ireland". Has the UK Government raised the need for access to a botulism vaccine in Northern Ireland in discussions with the European Commission?* (Paragraph 36)

5. *What is the Government's assessment of the potential economic consequences for the agrifood and farming industries associated with a reduction in the availability of veterinary medicines? Has the Government taken account of the potential for reputational risk if a solution is not found swiftly?* (Paragraph 43)

6. *What assessment has the Government made of the potential consequences for public health if access to veterinary medicines is restricted? What assessment has the Government made of any potential impact on the food supply chain, both in Great Britain and on the island of Ireland?* (Paragraph 49)

7. *What assessment has the Government made of the impact on the rural economy and the potential social impact on farming families and communities?* (Paragraph 56)

8. *We welcome your recognition of the need to make "rapid progress" on this issue. While we recognise the merits in building a consensus around solutions, we once again underscore the urgency of the issue and the tight timescale to find a resolution in the context of upcoming elections in both the EU and the UK. How will the Government ensure consistency in approach in light of this year's political calendar?* (Paragraph 71)

9. *We welcome your assurance that the Working Group is composed of a "broad and representative group of experts in the field". How will you ensure that the Working Group reports its findings regularly to ensure transparency, as urged by our witnesses?* (Paragraph 72)

10. *Does the Government agree with our witness's assessment that there is a difference of opinion between the UK and the EU about the purpose of the grace period? If so, how will the Government bridge this gap?* (Paragraph 73)

11. *Does the Government intend to seek a wider deal with the EU on veterinary medicines, similar to that reached previously on human medicines? If so, what does it believe the outlines*

of such a deal would look like? If not, why not? Does the Government recognise EU concerns about future divergence in relation to veterinary medicines? Does the Government agree with our witnesses' characterisations of the wider risks, including to human and animal health, if Northern Ireland loses access to a significant percentage of its veterinary medicines? (Paragraph 82)

12. *What is the Government's response to the suggestion that a solution analogous to that of a Sanitary and Phytosanitary (SPS) agreement, involving a bonded warehouse for veterinary medicines destined for Northern Ireland, could avoid the problem of unnecessary batch testing?* (Paragraph 89)

13. *What solutions are the Government considering in relation to VMD regulation and licensing of veterinary medicines in Northern Ireland? Has any thought been given to the possibility of establishing a separate regulatory body in NI?* (Paragraph 92)

14. *What progress has been made to date in reaching a solution with the EU? How will the Government keep stakeholders, including the veterinary and agri-food sectors, updated on progress towards solving the issues in relation to the supply of veterinary medicines to Northern Ireland?* (Paragraph 97)

15. Some witnesses called for a 'grandfather rule.' *Does the Government agree with this suggestion? If so, how will it convince the EU of the merits of such an approach?* (Paragraph 100)

16. *We endorse the proposals from our witnesses that part of a solution could involve both the UK and EU agreeing to recognise a Market Holder Authorisation based in Great Britain. Does the Government share this view? If so, how does it plan to engage and convince the EU to seek agreement on this basis, and on what timescale? Are the provisions in the Government's 2024 Regulations consistent with this approach? If so, how and to what extent?* (Paragraph 106)

17. *We endorse the suggestions of our witnesses in relation to batch-testing and note the Government's statement in its Command Paper, which lists "the costs and burdens of repeat testing and release of EU products transiting through GB" as one of the issues to resolve. How does the Government plan to resolve the issue of batch testing, and on what timescale?* (Paragraph 109)

Annex B: List of acronyms

AHDA	Animal Health Distributors Association
BAB	British Agricultural Bureau
BMA	British Medical Association
BVA	British Veterinary Association
DAERA	Department of Agriculture, Environment and Rural Affairs
MAH	Marketing Authorisation Holder
NOAH	National Office of Animal Health
NIFDA	Northern Ireland Food and Drink Association
NIMEA	Northern Ireland Meat Exporters Association
UFU	Ulster Farmers' Union
UUP	Ulster Unionist Party
VMD	Veterinary Medicines Directorate