BVA British Veterinary Association | Policy statement

BVA policy position on access to veterinary medicines in Northern Ireland

Introduction

Following Brexit, the Northern Ireland Protocol was agreed to avoid a so-called "hard border" between the United Kingdom and the European Union falling between Northern Ireland (NI) and the Republic of Ireland (ROI). This binding protocol required NI to align fully with the EU in certain areas such as customs, goods regulation, VAT, state aid and rules on agri-food, allowing frictionless access to and from the EU single market and preventing the need for physical checks on goods moving between NI and the ROI on the land border. However, a direct consequence, was the introduction of multiple barriers, including the potential for similar checks, to trade between Great Britain (GB) and NI[1]. Although the EU and the UK subsequently negotiated an agreement, the Windsor Framework, to lift or ease a range of the restrictions on GB-NI-GB movement of goods otherwise required under the Protocol, it did not address the issue of veterinary medicines[2].

On human medicines, the EU has adopted legislation allowing for new and innovative human medicines to be accepted for use in NI on the basis of UK authorisations. In practice, this means that the UK's Medicines and Healthcare Regulatory Agency (MHRA) will be able to licence all human medicines for the NI market in accordance with UK law on a UK-wide basis, effectively allowing NI patients to use the same medicines in the same packs as the rest of the UK.

However, veterinary medicines which need to be used in NI will now need to be re-batch tested to meet EU standards, unless they are coming directly from an EU country. By far, the majority of veterinary medicines -even those manufactured in the EU- are warehoused in GB and delivered from there, to the ROI and NI. As the UK is outside the EU, this means that veterinary medicines warehoused in GB need to be re-batch tested to ensure it complies with EU standards.

On 19 December 2022, the European Commission announced a three-year extension to the "grace period" it had previously offered, deferring full implementation of its rules for the supply of veterinary medicines into NI until 31 December 2025. While the future is uncertain beyond this point, it is anticipated, as envisaged by the EU, that full EU rules will apply in perpetuity thereafter.

Ahead of the general election in July 2024, the Labour party made a manifesto commitment to develop a 'Veterinary Agreement' with the EU. Following the election, some trade Ministers, including Douglas Alexander[3] have expressed their commitment to honour this pledge but with no indication of the likely date of commencement of such negotiations. Previously, in January 2024, the EU's ambassador to the UK, Pedro Serrano had said that the EU is 'favourable' to the possibility of an agreement on sanitary and phytosanitary measures in the future[4].

A veterinary agreement could have been the solution to the issue of accessing veterinary medicines in NI beyond December 2025. However, negotiating a veterinary agreement will take longer than the time available before the end of the grace period and therefore a solution to NI veterinary medicines must be sought in the meantime.

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[1] Sargeant, J. (2022, June 14). *Northern Ireland Protocol Bill.* Institute for Government. https://www.instituteforgovernment.org.uk/explainer/northern-ireland-protocol-bill
[2] Whitten, L., & Phinnemore, D. (2023, October 3). *Implementing the Windsor Framework. UK in a Changing Europe*. https://ukandeu.ac.uk/explainers/implementing-the-windsor-framework/
[3] Webb, A. (2025). *Government makes UK EU veterinary agreement pledge*. Ve tTimes. https://www.vettimes.co.uk/news/government-makes-uk-eu-veterinary-agreement-pledge/
[4] Stone, J. (2024, January 23). *EU ambassador: Labour's Brexit plan may mean alignment with bloc's rules*. POLITICO. https://www.politico.eu/article/labours-plans-to-ease-post-brexit-trade-likely-to-require-accepting-eu-rules//

Access to veterinary medicines – what's the issue?

Veterinary medicines in NI are regulated by the UK's Veterinary Medicines Regulations 2013[5], which is legislation that is overseen by the Veterinary Medicines Directorate, an executive agency of Defra for the whole of the UK. However, Veterinary Medicines Regulations (VMRs) 2024 do not apply in NI[6].

Instead, due to the provisions in the Northern Ireland Protocol and the Windsor Framework, products marketed in NI are now required to comply fully with the European Veterinary Medicinal Products Regulation, which is overseen and regulated by the European Medicines Agency (EMA). The 2013 VMRs, in addition to EU laws on veterinary medicines and medicated feeds, do still apply in NI.

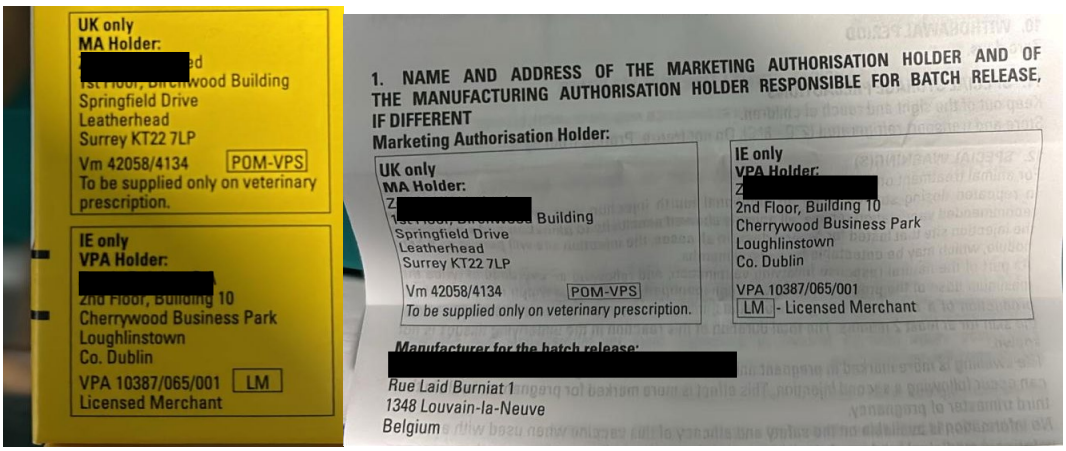
Batch release testing and Marketing Authorisation Holder (MAH)

Two elements in the EU Veterinary Medicinal Products Regulation will be particularly difficult for GB-based companies to comply with in order to market products in NI. They are as follows.

- **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 **EU V**eterinary **M**edicinal **P**roducts **R**egulation, that batch testing is required to take place within the EU. Currently, most UK-based companies use the GB supply route, which means medicines enter the NI market after being batch released and then warehoused in GB.

  This supply route and process will not be permitted by the EU after December 2025, since any product entering NI from GB will be considered an import into the EU. This means that batch release testing will have to have been carried out 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 EU's veterinary medicinal products regulation, each veterinary medicine is required to have a "Marketing Authorisation Holder" with a registered address within the EU, and to have that address printed on the product's data sheet and package insert. As noted above, the majority of products used in NI do not currently comply with this requirement being produced by an MAH registered in GB.



From the 1st of January 2026, therefore (ie as soon as the "grace period" expires), all veterinary medicines entering NI from GB, will have to be re-batch tested and have an MAH in the EU in order to comply with EU regulation. This effectively means that from January 2026, veterinary medicines in NI will have to comply with EU legislation, while still being regulated by the UK's competent authority, the VMD.

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[5] *Veterinary medicines legislation*. (2014, April 14). GOV.UK. https://www.gov.uk/guidance/veterinary-medicines-regulations

[6] *RCVS publishes guide to help professions navigate the 2024 Veterinary Medicines Regulations*. (2024, October 2). RCVS. https://www.rcvs.org.uk/news-and-views/news/rcvs-publishes-guide-to-help-professions-navigate-the-2024/

In preparation for Brexit, and to ensure the UK continued to have access to necessary veterinary medicinal products, the VMD had already made provisions to accept batch testing of veterinary medicinal products undertaken in the EU, EEA and the countries the EU has made appropriate arrangements with, in the same manner as today[7]. Similarly, they also allow these products with a Marketing Authorisation Holder in the EU to be used in the UK[8]. This effectively means, that products with an MAH or batch tested in Europe can be used in the whole of the UK. However, the converse does not apply; products that have left the EU -e.g. by being transported and warehouse in the UK cannot be used in the EU unless they are re-batch tested and have a MAH location within the EU.

Currently, the majority of veterinary medicinal products are transported from mainland Europe into GB, then into the ROI and NI. The size of the NI market being small (about 2% or 3%[9] 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 NI from GB; or to make a change in their supply route.

Access to Union Product Database (UPD)

The UPD serves as a single source of information on all authorised veterinary medicines and their availability in the EU and the EEA Member States[10]. This database was set up by the EMA which maintains the information about veterinary medicines in collaboration with member states and the European Commission.

The VMD, as the relevant regulator for veterinary medicines in Northern Ireland is required to list the veterinary medicines used in this database, however, as the UK has left the EU, the VMD does not have access to this database and therefore cannot list the veterinary medicines as required.

Recommendation 1: The European Commission should work with the UK government to ensure that the VMD has access to the relevant public database in order to list the veterinary medicines being used in Northern Ireland.

Impact of the discontinuation of veterinary medicinal products

It is unclear what percentage of NI veterinary medicinal products could be at risk. Earlier estimates indicated that up to 50% of medicines could be at risk. The 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 products that may be lost but the type and nature of these, the volumes used and the health and welfare impact that this may have on both animal and human health.

Some of the veterinary medicinal products that are thought to be at risk include everyday essential preventative products such as vaccines for production animals, as well as treatments for companion animals and horses. Effective disease control in production animals is important because it is directly linked to food safety, supports zoonotic disease control and also promotes efficient production. This is

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[7] *Registration of veterinary medicines if there's a no-deal Brexit*. (2018, September 24). GOV.UK. https://www.gov.uk/government/publications/registration-of-veterinary-medicines-if-theres-no-brexit-deal/registration-of-veterinary-medicines-if-theres-no-brexit-deal

[8] *Marketing authorisations for veterinary medicines*. (2015, June 15). GOV.UK. https://www.gov.uk/guidance/marketing-authorisations-for-veterinary-medicines

[9] European Affairs Committee: The Windsor Framework Sub-Committee *Corrected oral evidence: Veterinary medicines and the Windsor Framework*. (2024, January 17). Https://Committees.parliament.uk/Oralevidence/14122/Pdf/

[10] *Union Product Database.* (2022, January 12). European Medicines Agency (EMA). https://www.ema.europa.eu/en/veterinary-regulatory-overview/veterinary-medicinal-products-regulation/union-product-database

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 and One Health.

There are also issues with the import of the botulism vaccine. Botulism in cattle is a significant animal health issue in NI 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 NI 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 medicinal products to NI.

The discontinuation of veterinary medicinal products will also put cross-border trade at risk. A third of Northern Ireland's annual 2.5 billion litres of milk is shipped to the ROI, but Stormont's Department of Agriculture, Environment and Rural Affairs (DAERA) must certify that it meets EU standards, which it will not be able to do unless a medicines deal is agreed[11]. Recently, a milk processor in the ROI, said that up to 30% of their milk pool could be impacted by the changes to veterinary medicines regulations[12]. This is a significant concern for NI as dairying remains the largest contributor to the total value of Gross Output for agriculture in NI at £892 million in 2023[13].

Recommendation 2: The UK government should raise awareness of the situation and the potential risks for animal health and welfare, public health and One Health implications, working with veterinary professionals, and farmers in Northern Ireland.

Potential Solutions

There are several solutions that could be put in place from long-term to medium or short term.

Long-term solutions

The best possible long-term solutions are:

- **A Veterinary Agreement with the EU which includes Veterinary medicinal products (VMPs):** As stated in our policy position on an EU-UK Veterinary Agreement, negotiating a Swiss-style agreement with the EU which includes VMPs will be the best long-term solution as it will solve not only access to veterinary medicinal products for NI but also ensure SPS measures are harmonized and mitigate the risk to NI exports described above.
- **Mutual Recognition Agreement (MRA):** an MRA would be a simpler solution to the issue of access to veterinary medicinal products in Northern Ireland. MRAs are trade agreements that aim to facilitate market access and encourage greater international harmonisation of compliance standards while protecting consumer safety. These agreements differ from Veterinary Agreements in that they only include regulated products – such as medicines or other supplements, such as vitamins - rather than a more global or holistic approach including research, qualification recognition or animal or livestock trade, therefore easier to negotiate. However, negotiating an MRA with the EU could still take substantially longer than 12 months and therefore it will not be a suitable solution to the issue of access to veterinary medicinal products.

Medium-term solutions

[11] ibid
[12] Donnelly, M. (2024, October 8). *Up to 30pc of Lakeland Dairies' milk could be impacted by vet meds regulation*. Independent.ie; Irish Independent. https://www.independent.ie/farming/agri-business/up-to-30pc-of-lakeland-dairies-milk-could-be-impacted-by-vet-meds-regulation/a1862388986.html
[13] *Northern Ireland agricultural incomes in 2023*. (2024, July 9). DAERA. https://www.daera-ni.gov.uk/news/northern-ireland-agricultural-incomes-2023.

There are some medium-term solutions that could take considerably less time to negotiate and that would secure access to veterinary medicinal products for Northern Ireland almost immediately:

- **Re-routing through the ROI:** the majority of veterinary medicinal products in present day usage are already dual licensed to be used in both the UK and the EU (usually the ROI due to the use of English language labels in both countries). If pharmaceutical companies were prepared to re-route products destined for Northern Ireland through ROI direct from their place of manufacture in the EU instead of via GB, they would not need to be relabeled with a new MAH or re-batch tested as they would already have a EU address.

  This would satisfy EU law; and the Veterinary Medicines Directorate as they already permit medicines which are licensed to be used in the EU to be used in NI and the entire UK.

  This should not be an issue for those products currently in use in NI which are already licensed in the UK – just supplied to the NI market from GB. This could also be the easiest solution as it would not require negotiating with the EU but rather pharmaceutical companies to change their supply routes. It is our understanding that some pharmaceutical companies have already started doing this

  However, this will not solve the problem of those products which are manufactured in the UK and do not have an address in the territory of the EU and / or have not been batch tested in the EU. This group is thought to be a minority of products currently supplied to NI, and no significant products.

  Similarly, this solution would still not solve the issue of those products which are not manufactured in the UK or EU, but are available within the UK to the UK's livestock and companion animal industry under Special Import License issuing Special Import Certificates (SICs) such as the botulism vaccine.

- **Developing a Special Import Certificate (SIC) scheme for NI:** In order to solve the issue of those veterinary medicinal products that are imported from outside the EEA under Special Import Licensing, the VMD and the European Commission should work together to enable DAERA to have the relevant powers to manage a scheme for Special Import Certificates. This will not only ensure that NI could import those products from outside the EEA but also any products from GB that it may need.

- **Applying exceptions to allow veterinary medicinal products** that were aligned with regulation before Brexit to continue to be supplied to NI without having to have the MAH location changed or re-batch tested to enter the market, with newly licensed veterinary medicinal products then adhering to EU rules (ie a de facto further extension of the "grace period" in perpetuity for these products). However, this solution will not account for novel products which may need to be used in NI.

Mitigations

While UK Government negotiates any of the above solutions and with the prospect of not being able to establish any of the solutions described in the previous section before the end of the grace period, BVA strongly recommends that the following mitigations are considered:

- **List of impacted products**: The Government could publish a list of the impacted veterinary medicinal products as currently, veterinary professionals, farmers and pet owners do not know with certainty which products will be discontinued which makes it challenging to plan for such scenario. The most urgent mitigation is for the Government to fully disclose a list of impacted medicines. Access to the list of discontinued products will help veterinary professionals and other stakeholders to inform and educate farmers and other animal owners and seek alternative products or treatment options, or advise on alternative husbandry practices to reduce disease incidence. It may also allow valuable time to find and source alternative supplies of veterinary medicinal products from other countries.

- **Applying exceptions to certain medications**: It is likely that universally applying exceptions to all impacted products will not be possible due to industry concerns and/or political concerns. An alternative approach would be to apply exceptions to certain medications currently licensed in both the UK and the EU which are the most crucial to safeguard animal and human health. Our proposal is that a ranking system is applied starting with high volume products which are likely to prevent and treat unnecessary suffering. Examples of such drugs are vaccines used in farm species.

- **Animal health fand welfare pathway**: DAERA could begin work on developing an animal health and welfare pathway in NI, similar to the Animal Health and Welfare Pathway[14] currently deployed in England. The Pathway approach supports protecting and enhancing farm animal health and welfare, supporting farmers to transition to higher welfare practices and systems and, improving biosecurity, which will help manage endemic disease risk. If disease is prevented, there will be less reliance on veterinary medicines such as antibiotics, however, there will still be a need for vaccines– some of which would require one or other of the solutions separately proposed above.

Recommendation 3: The UK should prioritise negotiating an EU Veterinary Agreement or an MRA agreement (including mutual recognition of approvals of veterinary medicines) as soon as possible. Any agreement needs to allow for new VMPs to be registered and that process needs to be efficient enough that it will not delay access to VMPs in the event of an emerging disease incursion.

Recommendation 4: The Veterinary Medicines Directorate (VMD) should work with pharmaceutical companies to facilitate and encourage them to change their supply route so that they can deliver veterinary medicinal products from the EU straight into the ROI and/or NI without going through GB.

Recommendation 5: DAERA should be given the powers necessary to manage Special Import certificates (SIC) for NI, specifically from GB.

Recommendation 6: The Government must urgently publish a full list of impacted products so that veterinary professionals can prepare. If a full list cannot be disclosed, a list of the most used products which are most likely to prevent and treat unnecessary suffering should be published.

Recommendation 7: The EU should consider applying an exemption to allow veterinary medicinal products that were aligned with regulation before Brexit to continue to be supplied to NI without having to change the MAH location or be re-batch tested.

Recommendation 8: DAERA could consider establishing an Animal Health and Welfare Pathway similar to the one established in England to reduce the reliance on veterinary medicines generally.

[14] *Animal Health and Welfare Pathway*. (2025, January 21). GOV.UK. https://www.gov.uk/government/publications/animal-health-and-welfare-pathway/animal-health-and-welfare-pathway