HM Government

Protecting Animal Health

The Government's Approach to Veterinary Medicines in Northern Ireland

Summary

1. The Government will always do whatever is necessary to protect public health and food security, ensure the health and welfare of animals, and safeguard the livelihoods of farmers while meeting our obligations under the Windsor Framework. This paper sets out progress in safeguarding the ongoing supply of veterinary medicines in Northern Ireland, and the steps that the Government will take to support this.

2. The Windsor Framework rules governing the distribution of veterinary medicines in Northern Ireland will apply in full from 1 January 2026. From that date, in order to maintain Northern Ireland's full access to the EU's single market, the movement of veterinary medicines into Northern Ireland must comply with relevant EU rules under the Windsor Framework.

3. This access is particularly vital to Northern Ireland's agricultural sector, which relies on privileged access to cross-border supply and processing facilities, as well as the ability to sell Northern Ireland's animals and products of animal origin to both the EU's single market and its own UK internal market. This dual access to markets in both the EU and the rest of the UK supports more than £4 billion of sales from the food and drink processing sector - representing over 70% of that sector's total sales - to either Great Britain or the EU in 2021.

4. These changes will require adaptation by holders of marketing authorisations for veterinary medicines and other Northern Ireland operators. Good progress has been made by industry to date. Indications suggest that for most products, Marketing Authorisation Holders have made the necessary changes, or plan to make these changes, to continue to supply the majority of veterinary medicinal products currently on the market in Northern Ireland. Out of around 3,000 products licensed for supply in Northern Ireland, our current expectation is that there will be very limited disruption, with fewer than 20 products due to face discontinuation that we consider are likely to result in significant adverse impacts if not addressed.

5. The Government will continue to support industry in this endeavour. **It is important that those Marketing Authorisation Holders who have not yet planned to make the necessary changes do so as early as possible.** The Veterinary Medicines Directorate (VMD) is available to engage with any authorisation holders to discuss their particular needs or plans, and has set out technical guidance to support industry to make any changes necessary to continue supply.

6. In the vast majority of cases, we therefore expect vets, farmers and pet owners to continue to have access to the medicines they need. The Government has also confirmed that this will include supply of relevant vaccines in accordance with EU rules. Despite this good progress, the Government also recognises the ongoing concerns that exist in respect of those limited products whose supply may be disrupted. Farmers and pet owners will be understandably worried that even if disruption is limited to a small number of products, that disruption could cause real difficulties in the cases of individual animals, or individual herds or flocks. And veterinary surgeons will know that even a small disruption could impact on their capacity to provide the best treatment for animals under their care.

7. For that reason, even with a relatively small residual problem, the Government is committed to taking the necessary steps to guarantee access to the veterinary medicines that Northern Ireland farmers, pet-owners and veterinary surgeons need in cases where no suitable medicines are authorised or available in Northern Ireland.

8. In line with the commitment in the Safeguarding the Union command paper, the Government will 'deploy all available flexibilities to safeguard and sustain the supply of veterinary medicines in Northern Ireland'. To that end, the Government is setting out steps in relation to the supply routes of veterinary medicines to Northern Ireland, making use of provisions within or consistent with EU law to improve outcomes for farmers, veterinary surgeons and pet owners.

9. All these steps will be delivered within the existing parameters of EU law, and so will be deliverable by the United Kingdom before the end of the year.

Progress to date

10. It is important to acknowledge the vital progress that has been made since the start of 2022, at which point it was estimated that more than half of product lines could be at risk. The Government is immensely grateful for the intensive and constructive engagement of Marketing Authorisation Holders, veterinary representative organisations, farming and agricultural sector representatives, Northern Ireland political stakeholders and the members of the Veterinary Medicines Working Group. Through these channels, the Government has undertaken extensive engagement to fully understand the potential risks prior to the new rule changes from 1 January 2026. In addition, in the context of the action plan set out in the European Commission notice, the UK Government has engaged extensively with the Commission.

11. Through the process of engagement with industry, the Government has identified that, based on our current analysis, only around 10% to 15% of authorised products are expected to be discontinued in Northern Ireland. Further analysis has been undertaken to understand the likely impacts of disruption that could arise from discontinuation of each of those products, having regard to each product's criticality to animal and public health; the availability of identical or similar alternatives which are not at risk of disruption, current supply and known sales levels.

12. While this remains an evolving picture, our analysis suggests that where products have been indicated as being at particular risk of discontinuation, most are either not currently supplied in Northern Ireland, or there is a suitable supply of alternative products authorised in Northern Ireland which meet the same clinical needs of animals.

13. This information was provided by industry on the basis of commercial confidentiality. As such, while the Government is not in a position to specify which products are potential sources of concern, we expect the number of products which are both at risk of discontinuation and likely to have a significant adverse impact if discontinued to be extremely low (current estimates suggest there are fewer than 20 such products).

14. Notwithstanding these low numbers, the Government understands that the potential impacts from lack of availability of these products will nonetheless be concerning to all those with an interest in protecting animal and public health. The Government is not complacent, and recognises the need for solutions to be put in place to address the potential gap left by these products.

15. The Government will continue to monitor the situation up to 1 January 2026 and beyond. It is vital that the Government is operating with the most up-to-date data on availability of products and so we urge industry to continue to work closely with us. The Government will also continue to engage with other operators, such as wholesalers and retailers, to assess the evolving picture.

16. In addition to this monitoring and engagement, however, the Government recognises that solutions cannot just apply rigidly to those products identified as being of specific concern. While those products will be the priority for solutions, consistent with its legal obligations under the Windsor Framework, the Government will build resilience into the market through new schemes to address these risks. These schemes - set out in the following section - are designed to provide a responsive, adaptable and flexible means of addressing any issues that arise with supply of veterinary medicines, including unforeseen issues.

Protecting the supply of veterinary medicines in Northern Ireland

Continued availability of authorised products from 1 January 2026

17. The Government's first priority is ensuring that there is no harm to animal health and welfare or food security, or indeed a cliff-edge in the supply of veterinary medicines from 1 January 2026. Industry can be reassured that products can continue to be placed on the market in Northern Ireland under the current arrangements up to 31 December 2025. In addition, any products on the Northern Ireland market before the end of 2025, including those that have been batch released by a Qualified Person and with a contract of sale in place, even if the product is not yet physically in Northern Ireland, can remain on the market up until their expiry date without any further steps.

18. This will help ensure there is a smooth transition through 2026 and will guarantee that veterinary surgeons, farmers, wholesalers and retailers can continue to sell and use products already placed on the market before the end of the year. Industry should consider supplies of medicines in Northern Ireland, in order to provide continuation of sufficient stocks of medicines during the early period of 2026 covering the transition to new arrangements.

Authorisation holder guidance and government support

19. For most products, Marketing Authorisations Holders have already taken steps to make the necessary adaptations to continue supplying their veterinary medicinal products in Northern Ireland. The Government will continue to support this adaptation, and is committed to supporting industry to take the steps necessary to safeguard the supply of veterinary medicines to Northern Ireland.

20. The UK's VMD continues to engage extensively with Marketing Authorisation Holders and stands ready to support them in ensuring that the necessary variations to their authorisations are submitted and approved before 1 January 2026. Plans are in place for the majority of products that need to undergo variations and we encourage Marketing Authorisation Holders to contact the VMD immediately to discuss their arrangements, if they have not already done so.

21. The VMD will process these variations as swiftly as possible. Approval will be contingent on Marketing Authorisation Holders providing the requisite information, and adapting information and labelling in line with guidance issued by VMD.

22. Additionally, the Government has set out detailed guidance for veterinary surgeons, Marketing Authorisation Holders, farmers, pet owners, wholesalers and retailers covering the changes that will be needed for the end of the year. The Government's intensive engagement with industry and stakeholders will continue to ensure there is full clarity on the new arrangements and that any emerging issues can be fully understood and rapidly addressed. We will make further updates to the guidance where necessary or helpful to support industry.

The Veterinary Medicines Health Situation Scheme

23. The Government will closely monitor the expected supply of products to Northern Ireland and will engage with industry through to the end of 2025. Our current assessment is that we expect vets, farmers and pet owners to continue to have access to the medicines they need in the vast majority of cases, but that there remains a risk of disruption, including for a small number of critical products. From 1 January, the Government will therefore apply a new Veterinary Medicines Health Situation Scheme, which will permit the use of suitable alternative products from outside Northern Ireland, by exception to the normal rules, if the situation of animal or public health so requires. If such a situation does materialise, the VMD will allow the use on an expedited basis of suitable alternative products where these are available, in accordance with the Windsor Framework. These arrangements will last for as long as the animal or public health justification for it persists.

24. The specific products to be covered by this scheme will be set out by VMD should the situation arise, and will be kept under review to ensure that this adapts to meet the needs of Northern Ireland. VMD will act based on emerging evidence where needed to avoid gaps emerging in the supply of critical medicinal products.

25. For products authorised through this new scheme, veterinary surgeons and wholesalers will be able to supply and use those products, without any additional process or administrative burdens, on a temporary basis, as long as there is a need for such products for public or animal health reasons.

26. This will provide us with the resilience to cope with unexpected issues and ensure that if such an animal or public health situation arises, the use of alternative products in Northern Ireland will be speedily approved. This will allow those products to move from outside Northern Ireland, in accordance with the Windsor Framework, to plug any emerging critical gaps.

Veterinary Medicines Internal Market Scheme

27. In the vast majority of cases, vets, pet owners, and farmers will be able to use medicines authorised in Northern Ireland. But for all veterinary products, it is important that veterinary surgeons and wholesalers have the flexibility to meet the needs of their patients and clients. While the Veterinary Medicines Health Situation Scheme will address any public or animal health situation that may arise from the discontinuation of products in Northern Ireland, the Veterinary Medicines Internal Market Scheme will allow vets to use specific individual medicines not authorised or available in Northern Ireland when needed. This will provide important resilience to the supply of veterinary medicines that cannot be provided through the Veterinary Medicines Health Situation Scheme on its own to deal with cases where insufficient authorised medicines are available. Some limited exceptions to this scheme will apply, such as the sourcing of vaccines. The scheme will, however, be available for use in respect of the vast majority of therapeutic medicines. The scheme will be reviewed after 12 months to assess whether there is an ongoing need and whether it is working as intended.

28. The scheme builds on existing processes under the ‘cascade’, whereby vets are able to prescribe and use medicines not authorised in Northern Ireland, by exception to the rules, when no suitable authorised medicines for an indication are available, consistent with the relevant legal provisions governing the cascade under the Windsor Framework. It will, however, improve the way vets can access medicines when specific needs arise. Following the existing process, veterinary surgeons treating animals should first make a clinical judgment as to whether any appropriate medicines authorised in Northern Ireland are available. If no products authorised in Northern Ireland for a specific animal or condition are suitable or available, vets should consider if there is an appropriate authorised veterinary medicines available in the EU, a suitable medicine authorised for human use in Northern Ireland or the EU, or available as an extemporaneous preparation. Where this is not the case, vets can obtain products from Great Britain.

29. The Veterinary Medicines Internal Market Scheme will provide a smoother way of accessing specific unavailable veterinary medicines where there is a critical need. It also reflects the importance of the UK’s internal market in veterinary medicines, recognising that sometimes, products from Great Britain may be the only reasonable alternative to Northern Ireland-authorised products to prevent unacceptable suffering in animals in their care.

30. Currently, to obtain products from Great Britain, veterinary surgeons are required to obtain a Special Import Certificate per animal which can be time-consuming and burdensome. Reflecting the importance of the UK's internal market, we will remove the requirements that would otherwise arise for Great Britain products to move into Northern Ireland following the Special Import Process and the issuing of a Special Import Certificate per animal. Those requirements exist to provide assurance in respect of products moving from outside the UK into the UK. They are inappropriate in the context of movements within the UK's internal market. Furthermore, they would be burdensome for veterinary surgeons and act as an unnecessary barrier to vets using the most appropriate veterinary medicinal products, where the other requirements of the scheme are met.

31. As such, where veterinary surgeons need to procure and use a product from Great Britain, and can do so under this scheme, they will be able to do so with no further administrative process, certification or approvals required. Special Import Certificates are a requirement of UK law rather than EU law, and so this change is fully compatible with the Windsor Framework.

32. In addition, we will make the process of vets bringing in products from the EU as swift and painless as possible. VMD will pre-assess potential alternatives in the EU market, where potential disruption in the Northern Ireland market is known or has been reported to us, and ensure that Special Import Certificates can be quickly made available to vets in these cases.

33. The scheme will be grounded in the practical reality for veterinary surgeons and trust in their professional judgment. Vets will determine whether an appropriate product is available in Northern Ireland, the EU, or among human medicines or extemporaneous preparations. Under their direct personal responsibility and consistent with the relevant legal provisions, vets will be allowed to use the scheme to determine whether products are available in their clinical judgment, bearing in mind the imperative to avoid unacceptable animal suffering.

34. We will also be clear that veterinary surgeons do not need to wait until a situation requiring the use of the scheme arises before procuring the relevant products. Instead, in order to prepare for unforeseen or urgent treatment needs, they will be able to procure a limited amount of products under the scheme pre-emptively where, in their professional judgment, such products may become necessary in the course of their treatment of specific animals, and where there are clinical benefits to having the product available to them immediately when the need arises. The amount held should be justified by the immediate clinical need under the cascade rules. These medicines should not be used as a first-choice treatment and their use is subject to the case-by-case assessment in accordance with the cascade provisions. Veterinarians should keep up to date with new authorisations. If the clinical need does arise to use these medicines, vets can access them without any potentially harmful delays.

Next steps

35. The measures set out here will be implemented before the end of 2025. Guidance has now been published to ensure that all stakeholders with an interest in the supply of veterinary medicines in Northern Ireland and the health and welfare of animals are fully equipped and prepared for new arrangements. We will make further updates to the guidance where necessary or helpful to support industry.

36. The combination of progress to date on the adaptation by industry and the measures set out in this paper means that the Government is confident that Northern Ireland will continue to enjoy access to the veterinary medicines necessary to protect the health and welfare of animals, and the livelihoods of farmers and veterinary surgeons.

37. Intensive engagement will continue through to the end of 2025 and beyond to ensure that any gaps or emerging issues are identified and addressed as early as possible. The Government invites the pharmaceutical industry to inform us of their supply intention, if they have not already, and reach out to discuss any questions or concerns.

38. To that end, the Government will invite the Veterinary Medicines Working Group to continue to meet to provide a forum for discussion of both the implementation of the measures set out, and for the identification and escalation of issues to be addressed.