Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Mr Keith McBride
The Committee Clerk
Room 419,
Parliament Buildings,
Ballymiscaw,
Stormont,
Belfast
BT4 3XX

Edward Murphy
Medicines Legislation Unit
Castle Buildings
Stormont
Belfast
BT4 3SQ

Tel 028 520014

02 February 2026

Dear Mr McBride

The Human Medicines (Amendment) Regulations 2026

I am writing to advise that the Secretary of State in relation to England and Wales and Scotland, and the Department of Health in Northern Ireland, and the Secretary of State acting jointly in relation to Northern Ireland, in exercise of the powers conferred by sections 2(1), 3(1), (2) and 43(2) of the Medicines and Medical Devices Act 2021 (MMDA), and after having considered the matters in section 2(2) to (4) of that Act, propose to make a UK-wide Statutory Instrument entitled "The Human Medicines (Amendment) Regulations 2026", to continue to support the Covid-19 and influenza (flu) vaccine programmes in Northern Ireland (NI). A draft copy of this UK-wide Statutory Instrument with accompanying draft Explanatory Memorandum is enclosed with this letter.

Section 47(6)(c) of the MMDA stipulates that when regulations are made jointly they must be laid before and approved by a resolution of— (i)each House of Parliament, and (ii)the Northern Ireland Assembly. The attached draft regulations will therefore be subject to the draft affirmative procedure.

Background

The Human Medicines Regulations 2012 ("the HMRs") govern the arrangements, across the United Kingdom, for the licensing, manufacture, wholesale dealing and sale or supply of human medicines for human use. As part of the UK's response to the Covid-19 pandemic, the HMRs were amended in 2020 by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 to provide

regulatory flexibility to support the rollout of the Covid-19 vaccination campaign and upscale the flu vaccination programme in the UK, while protecting public safety. The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022 were then introduced in 2022 to extend some of the flexibilities around the supply, distribution and administration of Covid-19 and flu vaccines until 1 April 2024.

On 30 October 2023, following the completion of a UK-wide consultation, the UK Government introduced - The Human Medicines (Amendments Relating to Coronavirus and Influenza) (England and Wales and Scotland) Regulations 2024, which again, extended the flexibilities established by the 2022 regulations, amending three provisions within the HMRs - regulation 3A (R3A); regulation 19 (R19) ; and regulation 247A (R247A), so that they remain in place until 1 April 2026.

Any Statutory Instrument that amends the HMRs on a UK-wide basis is normally made jointly and debated and approved via the draft affirmative procedure in both Houses of Parliament and in the NI Assembly (NIA). As NI had no sitting Assembly at the time, the above was a Great Britain (GB) only Statutory Instrument. Given, the negative impact on NI if certain health service vaccination activities ceased because of the above regulations lapsing, equivalent amending legislation came into operation in NI on the 31 March 2024 - The Human Medicines (Amendments Relating to Coronavirus and Influenza) Regulations (Northern Ireland) 2024. This maintained the three existing provisions with the HMRs, enabling the continued deployment of safe and effective Covid-19 and flu vaccines to the pace and scale required both now and, in the future, while maintaining public safety.

Purpose of Statutory Instrument

The purpose of the attached Statutory Instrument is to further amend the HMRs to continue to safeguard public health and ensure that lessons learned can be used to support the safe supply, distribution and administration of vaccinations both now and in the future. The aim is to maintain important safety measures, while increasing access to vaccines to support uptake, and increasing effectiveness within the system (workforce, supply chain and administrative). The proposed UK-wide amendments will support vaccination across all nations of the UK by regulating:

- the movement, preparation and labelling of vaccinations in defined circumstances (R3A and R19);
- the premises from which community pharmacies can deliver vaccination services to allow them to deliver targeted outreach (regulation 233 (R23) and regulation 3 (R3); and

- the use of a flexible workforce for vaccine administration Schedule 17 (S17) and the proposed new legal provisions replacing R247A).

R3A, R19 and R247A are time limited and have sunset provisions which will cause them to lapse on 1 April 2026. Without amendments to these regulations, Covid-19 and influenza vaccination services would not be able to continue in their current form and certain NHS vaccination activities would need to cease. R233(8), R3 and S17 do not have the same time limitations, however these proposals suggest ways to further utilise these regulations to ensure the vaccine system is as effective as possible.

Previous Engagement with the Committee

Whilst the Department has not engaged previously with the Committee on these latest proposed amendments, the Committee was briefed by Departmental officials on several former occasions regarding earlier legislative changes to the HMRs introduced to support the rollout of the Covid-19 vaccination campaign and upscale the flu vaccination programme in the UK. This included amendments to extend some of the flexibilities around the supply, distribution and administration of Covid-19 and flu vaccines, and, in 2024, further amendments to maintain three existing provisions with the HMRs, which enabled the continued deployment of safe and effective Covid-19 and flu vaccines to the pace and scale required both now and, in the future, while maintaining public safety.

Financial Implications

None anticipated. The UK Government needs to ensure that the regulatory framework within the HMRs continues to support the Covid-19 and flu vaccination programmes in NI and GB, to ensure that direct impacts of Covid-19 and flu on mortality and morbidity, as well as indirect impacts on health, society and the economy remain minimised as far as possible. The financial impact on the public sector and small businesses of the proposed amendments is expected to be minimal. There may be direct costs to providers such as additional training costs, should they choose to exercise provisions enabled by the proposed changes. However, these costs are likely to be small and could be partially offset by the potential benefits of the proposed changes.

Consultation

Amendments to the HMRs are now made under the powers in the MMDA. Section 45(1) of the MMDA provides that before making changes to HMRs, the “relevant authority” must carry out a public consultation. As the proposal was to make UK-wide changes, the duty to consult is placed jointly on the Department of

Health (NI) and the Secretary of State for Health acting for GB. The regulation of medicines is however a transferred matter in NI.

On 20 January 2026, following the completion of a UK-wide consultation, the UK Government published a response to a joint consultation on proposals to amend the HMRs to support the ongoing supply and deployment of vaccinations across the UK. This consultation and the proposals contained within it, focused on proposed amendments to six provisions within the HMRs summarised above namely: Regulation 3A, R19 (4A) to (4D), Regulations 247A, Regulation 233(8), Regulation 3, and Schedule 7.

DHSC received 217 consultation responses, overall, most of which were supportive of the proposals outlined in the consultation, stating how the existing flexibilities in the regulations had been, and continue to be, useful in supporting access to vaccines and ensuring there is a sufficient vaccination workforce. Across multiple questions, DHSC received comments asking for clarity on how these regulations will be used beyond the influenza and Covid-19 vaccination programmes. Multiple themes were identified during their analysis of the UK-wide responses, these included:

- **Safety** - across all questions, a small proportion of respondents disagreed with the proposals because of their concerns around the risks of vaccine harms. The safety of all vaccinations deployed in the UK remains of the upmost importance. Every vaccine deployed in the UK must first go through rigorous development and testing processes set by the UK's independent medicines regulator, the Medicines and Healthcare products Regulatory Authority (MHRA). Each vaccine candidate is assessed by teams of scientists and clinicians and only authorised once it has met robust standards of safety, quality and efficacy.

- **Wastage** – The UK Health Security Agency (UKHSA) is responsible for the procurement, storage and distribution of Covid-19 vaccines. UKHSA seeks to minimise wastage by ensuring that volumes of Covid-19 vaccine are procured in line with forecasted demand.

- **Governance and assurance** - across all questions, there was comments on the need for strong governance arrangements. There are robust governance processes in place across the vaccination system in the UK to uphold vaccine integrity and ensure patient safety. The Human Medicines Regulations 2012 provides the legal mechanisms for vaccine supply, deployment and administration, including Patient Group Directions (PGDs), Patient Specific Directions (PSDs) and national protocols.

- **Training -** multiple comments on the need for training for those staff who will be utilising these provisions, All healthcare staff with a role in delivering vaccination programmes must meet the National Minimum Standards and Core Curriculum for Vaccination Training guidance published by the UK Health Security Agency in June 2025. This updated guidance merged existing training guidance which were separate for registered and non-registered healthcare staff. The update reflects the increasingly complex and varied landscape where healthcare staff from a wide range of occupations now give vaccinations in many different settings and service areas. This includes a range of less traditional venues adapted to facilitate rapid delivery in response to pandemics and outbreaks, often at huge scale.

NI response to the consultation

DHSC received **6** consultation responses from NI – **2%** of which were from individuals sharing their personal or professional views (3 individuals) and **4%** (3 organisations) were from organisations who stated that they operate or provide services in NI only.

There was an overall broad level of support expressed in the NI responses to the consultation from the NI organisations that participated in it, whilst the responses from individuals sharing their professional and personal views and experiences were mixed. Those comments falling into the personal views and experiences, were of a more negative nature, and unsupportive of vaccines in general.

Key findings include:

- **83%** of NI responders **agreed** with the proposal to let the provisions under R3A (1) and (2) lapse from 1 April 2026, as it was generally felt that they were introduced as a time-limited emergency measure during an unprecedented public health event. With vaccination programmes having stabilised, usual manufacturing and assembly standards should be reinstated to maintain the highest level of assurance around quality, safety, and accountability. In the event of another pandemic, emergency amendments would be an option to have them reinstated.

- **50%** of NI responders **both agreed and disagreed** with the proposal to retain the provisions under R3A (3) and (4) as permanent legislation.

- **50%** of NI responders **both agreed and disagreed** with the proposal to expand the provisions under R3A (3) and (4) to all vaccine preventable diseases.

- **50%** of NI responders **both agreed and disagreed** with the proposal to retain the provisions under R19 (4A) to (4C) as permanent legislation to support distribution when necessary.

- **50%** of NI responders **both agreed and disagreed** with the proposal to expand the provisions under R19 (4A) to (4C) to all vaccine preventable diseases.

- **33%** of NI responders agreed, and **67%** neither agreed nor disagreed, with the proposal that the legislation should set out preconditions and safeguards to regulate the use of R19 (4A) to (4C).

- **83%** of NI responders agreed, and **17%** disagreed with the proposal to let R247A lapse from 1 April 2026.

- **50%** of NI responders agreed and **50%** disagreed, with the proposal to introduce a new permanent provision from 1 April 2026 to support the use of an extended workforce to supply and administer Covid-19 and influenza vaccines, with the option for this provision to be used on other vaccination programmes commissioned by the NHS.

- **50%** of NI responders agreed and **50%**, neither agreed nor disagreed that an age condition should be included in the proposed provision which specifies that a VGD cannot be used to vaccinate those below a certain age (principally infants eligible to receive a vaccination as part of the routine childhood immunisation schedule.

- **50%** of NI responders agreed and **50%** disagreed with the proposal to extend the provisions under R233 (8) to all other vaccine preventable diseases.

- **50%** of NI responders agreed and **50%** disagreed with the proposed amendment to regulation 3 to make provision for pharmacists and pharmacy technicians to prepare or assemble medicines for patients without a manufacturer’s licence.

- **50%** of NI responders agreed and **50%** disagreed with the proposal to expand the category of occupational health vaccinators in S17 to include a wider cohort of healthcare professionals in alignment with part 4 of schedule 16.

- **34%** of NI responders agreed, **33%** disagreed and **33%** neither agreed nor disagreed, with the proposal to extend the relevant provisions under S17 to include private healthcare provider.

- **50%** of NI responders agreed, **33%** disagreed and **17%** neither agreed nor disagreed, with the proposal to extend the provisions related to the category of occupational health vaccinators in S17 to cover all vaccinations or immunisations offered as part of an OHS.

Key themes identified during the Department's analysis of the NI responses to the consultation included:

- **Safety** – across all questions, a small proportion of respondents in the individual response category, disagreed with the proposals because of their concerns around the risks of vaccine harms.

  Some of the NI organisation responses highlighted the need for clear safeguards to ensure consistent implementation and to maintain public confidence. Several preconditions were listed such as documented temperature-control transport procedures, clear ownership and accountability at each stage of transfer, audit trails and alignment with MHRA and professional regulatory standards.

  There was consensus that public safety must be paramount when considering the implementation of these proposals.

- **Regulation of pharmacy technicians in NI and workforce shortages** – the fact that NI does not have registered pharmacy technicians was raised on several occasions by one NI organisation throughout their consultation response, as were, references to 'ongoing workforce shortages' and the need for a VGD mechanism for community pharmacies in NI.

- **Training -** multiple comments on the need for training for those staff who will be utilising these provisions. Any permanent models must include clear, minimum training, competency and supervision standards.

- **Governance and assurance** - across all questions, there was comments on the need for strong governance arrangements.

- **Private providers** – Whilst one NI organisation did not oppose the principle behind the proposal to allow the use of private providers, they highlighted that further thought may be required as to the potential impacts of broadening the scope to include this.

Compliance with Section 24 of the Northern Ireland Act 1998

The provisions in this SI do not breach section 24 of the Northern Ireland Act 1998, as they are not incompatible with any of the Convention rights or community law, and they do not discriminate against a person on the grounds or religious belief or political opinion. Article 2 Windsor Framework screening was carried out by the Department on this proposal. It was not believed that the UK-wide consultation engaged a right (or equality of opportunity protection) included in the relevant part of the Belfast/Good Friday 1998 Agreement.

Consideration by the Executive

N/A

Equality Impact

The Department carried out an Equality Impact screening against the proposals to identify if the policy might have an impact on any of the nine Section 75 groups listed in the Northern Ireland Act 1998. No adverse or significant impacts on any of the Section 75 groups has been identified so the Department has concluded that a full Equality Impact Assessment is not required.

Regulatory Impact

The UK Government did not carry out a full Impact Assessment for this instrument because the regulatory changes are expected to have low levels of impact on business and therefore a De Minimis Assessment (DMA) was performed by the Department of Health and Social Care. They will publish this alongside the Explanatory Memorandum (EM) on the legislation.gov.uk website in due course.

Rural Needs Impact

The Department has given due regard to rural needs by its carrying out of a Rural Needs Impact screening against these Regulations to identify if the policy might have a negative impact on rural communities. The proposed legislative changes will not affect people in rural areas any differently than those in urban areas, so the Department has concluded that a full Rural Impact Assessment is not required.

Data Protection Impact

These Regulations will not involve or impact on the collection, processing or sharing of personal data in the UK therefore a Data Impact Assessment is not necessary.

Child Rights Impact

These Regulations will not have any direct impact on children's rights therefore a Child Rights Impact Assessment is not necessary.

Position in Great Britain

This Statutory Instrument will apply on a UK wide basis, and a Department of Health senior official is co-signatory for any amendments along with the Secretary of State for Health.

Any other information

N/A

Proposed timing of consideration of the SL1

The SL1 has been submitted to the Committee in accordance with the minimum four-week timeframe. The proposed date for consideration of the SL1 by the Committee is **05 March 2026**.

Proposed Operational Date

As the regulations will be subject to the draft affirmative procedure an Assembly debate on the Regulations is required before the regulations can be made. We plan to lay them in the NI Assembly as soon as reasonably possible following Health Committee clearance. These Regulations are being progressed at pace, given that the necessary provisions for the continued support of the Covid-19 and flu vaccinations programmes in NI need to be in place by **1 April 2026.**

Subject to the Assembly's agreement during the debate they will then be signed by a senior official in the Department of Health and will come into operation on 31 March 2026. The date of the debate is yet to be confirmed.

I would be grateful if you would bring this matter to the attention of the Health Committee at your earliest convenience.

Yours sincerely

E. Murphy

Edward Murphy
Medicines Legislation Unit

cc: NI Human Rights Commission
Equality Commission