



Department of  
**Health**

An Roinn Sláinte

Mánnystrie O Poustie

[www.health-ni.gov.uk](http://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

23rd February 2026

Dear Mr McBride

**The Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) (Amendment) Regulations (Northern Ireland) 2026**

I am writing to advise that the Department of Health in Northern Ireland (NI), in exercise of the powers conferred by Articles 57D and 106(b) of the Health and Personal Social Services (Northern Ireland) Order 1972, proposes to make The Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) (Amendment) Regulations (Northern Ireland) 2026, to allow out-of-season Health and Social Care (HSC) prescribing and dispensing of two influenza (flu) antiviral medicines in Primary Care in NI. A copy of this NI Statutory Rule (SR) with accompanying Explanatory Memorandum (EM) is enclosed with this letter.

**Background**

The Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) Regulations (Northern Ireland) 2004 (“the 2004 Regulations”) set out rules governing what drugs, medicines, and other substances may be prescribed under General Medical Services (GMS) contracts in Northern NI.

Schedule 2 to the 2004 Regulations lists restricted drugs and substances that GPs can prescribe on a Health and Social Care (HSC) prescription, but only under specific conditions. The regulations define the circumstances, which often relate to specific clinical indication; public health alerts (e.g. flu outbreaks) and

patient risk categories (e.g. immunocompromised, elderly, those with diabetes or heart disease, and individuals who are pregnant). This ensures that certain high-cost or specialist medications are only used when clinically justified.

Oseltamivir (Tamiflu®) and Zanamivir (Relenza®) are two antiviral medicines listed in Schedule 2 to these Regulations. These provisions prohibit HSC prescribing of antivirals for influenza unless the Department has notified GPs that influenza is circulating in the community. This notification is made to the HSC via annual correspondence from the Chief Medical Officer, which is informed by PHA influenza surveillance data, and enables HSC prescribing in line with these provisions. A further communication is issued at the end of the flu season when influenza levels have returned to baseline levels, which removes the ability to issue HSC prescriptions.

Outside the flu season, when circulating levels of influenza are at baseline, GPs in NI currently cannot issue HSC prescriptions for Oseltamivir (Tamiflu®) and Zanamivir (Relenza®). While outbreaks of flu outside of the flu season are relatively infrequent, the consequences can still be serious for vulnerable people and the current restrictions can lead to delays in accessing necessary treatment, with negative impact on patient outcomes.

### **Purpose of Statutory Rule**

The purpose of the SR is to remove the flu antiviral restrictions in Schedule 2 to the 2004 Regulations, to enable Oseltamivir (Tamiflu®) and Zanamivir (Relenza®) to be prescribed and dispensed via HSC standard prescription processes outside of flu season in Primary Care in NI.

The proposed amendment reflects improvements in respiratory infection testing and availability of the antivirals, meaning the original rationales for the restrictions no longer apply, as well as lessons learnt from the Covid-19 pandemic. It will improve the efficiency of the process to prescribe the antivirals out of flu season, reducing delays and improving health outcomes.

### **Previous Engagement with the Committee**

On the 9 December 2025 a letter was issued to you, informing you of the Department's launch of a short, targeted consultation on the proposed amendments to the 2004 Regulations, to allow out-of-season HSC prescribing and dispensing of Oseltamivir (Tamiflu®) and Zanamivir (Relenza®). A copy of the consultation document was also attached with this letter. It was requested that this was brought to the attention of the Health Committee.

## **Financial Implications**

None anticipated. The financial impact on the public sector and small businesses of the proposed amendments is expected to be minimal, as this is a minor change to dispensing arrangements for these medicines. The clinical reasons for prescribing flu antivirals will not change and so prescribing levels are expected to remain broadly consistent with current levels.

## **Consultation**

A targeted Departmental consultation on the proposed changes to the 2004 Regulations ran from 9 December 2025 to 20 January 2026. It was circulated to several key internal and external stakeholders including representatives from GP, Pharmacy and Regulatory bodies, and officials from the Department's vaccination and screening policy, and pharmaceutical advice and services branches.

The Department received one response to the consultation, which was from the Pharmaceutical Society of Northern Ireland (PSNI). It is likely that the low response rate was due, not only to the targeted nature of the consultation, but the uncontroversial and positive aim of the proposed amendments, which reflects not only current clinical evidence but NICE guidance and advice in diagnostic testing.

PSNI's response to the consultation was positive, and they supported the proposed amendment to remove the seasonal prescribing restrictions on Oseltamivir (Tamiflu®) and Zanamivir (Relenza®). Enabling HSC prescribing outside the traditional flu season reflects all the above, and aligns NI with legislative changes already implemented in England. They indicated that from a medicines' safety perspective, the ability to prescribe antivirals based on clinical need rather than seasonal triggers supports timely intervention for patients at higher risk of severe outcomes, particularly in residential and nursing home settings where outbreaks may occur outside the typical flu season, while reducing administrative barriers will also help avoid delays in access to treatment and improve patient outcomes.

The Society considers that "the proposed change appropriately restores clinical discretion to authorised prescribers, while maintaining existing safeguards through NICE guidance, professional standards, and medicines governance arrangements", highlighting that continued communication between prescribers, pharmacists, and public health bodies will remain essential to ensure safe, proportionate, and effective use of antivirals throughout the year.

## **Compliance with Section 24 of the Northern Ireland Act 1998**

The provisions in this SR 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 of 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 NI 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 Department 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, charities or voluntary organisations because clinical reasons to prescribe flu antivirals will not change. Prescribing levels are expected to remain broadly consistent with current levels, but patients will receive treatment much faster.

## **Rural Needs Impact**

The Department has given due regard to rural needs by 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**

On 1 September 2025, NHS England made [The National Health Service \(General Medicines Services Contracts\) \(Prescription of Drugs etc.\)\(Amendment\) Regulations 2025.](#) This instrument amends Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 also known as the Selected List Scheme (SLS), enabling Oseltamivir (Tamiflu®) and Zanamivir (Relenza®) to be prescribed and dispensed via standard NHS prescription processes by GPs and pharmacists outside of the flu season, based on a positive flu diagnostic test. This came into force on the 1 October 2025.

## **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 **26 March 2026**.

## **Proposed Operational Date**

Both the Committee and the Examiner of Statutory Rules will review the rule for legality, clarity and compliance with the legislative powers. As the regulations will be subject to the negative resolution procedure, a Northern Ireland Assembly debate is not required, and it will automatically become law unless annulled by the NIA within 21 days from the date it is laid.

We are proposing to lay the SR in early April 2026, so it can come into force by 1 May 2026, meaning there would be no break in NI's ability for HSC Primary Care prescribing of flu antivirals all year round.

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