



Department of
Health

An Roinn Sláinte

Mánnystrie O Poustie

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Consultation on

Amendments to The Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) Regulations (Northern Ireland) 2004

Improving the process to access flu antiviral medicines all year round.

December 2025

Overview

The Department of Health is conducting a six-week targeted consultation on proposals to amend The Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) Regulations (Northern Ireland) 2004, ("the 2004 Regulations") to facilitate out-of-season Health and Social Care (HSC) prescribing and dispensing of two influenza (flu) antivirals - Oseltamivir (Tamiflu®) and Zanamivir (Relenza®) in Primary Care in Northern Ireland (NI).

Influenza (flu) antiviral medicines are recommended for the treatment, prophylaxis, and outbreak control of seasonal or emerging strains of flu among people at risk of significant illness.

In NI, prescribing of flu antivirals in primary care is governed by the 2004 Regulations. These regulations are made under Article 57 of the Health and Personal Social Services (Northern Ireland) Order 1972. They govern what drugs, medicines, and other substances may or may not be prescribed by general practitioners (GPs) working under GMS contracts.

Schedule 2 of the 2004 Regulations lists restricted drugs and substances that GPs can prescribe on an 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 currently listed in Schedule 2 of the 2004 Regulations, meaning they can currently only be prescribed when NI's Chief Medical Officer declares that flu is in circulation. This notification is made to the HSC via annual correspondence from the Chief Medical Officer, which is informed by Public Health Agency flu surveillance data, and enables HSC prescribing in line with these provisions. A further communication is then issued at the end of the flu season when flu levels have returned to baseline levels, which subsequently removes the ability to issue HSC prescriptions.

Outside the flu season, when circulating levels of flu 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.

Policy objective

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

The proposed amendments reflect improvements in respiratory infection testing

since the COVID-19 pandemic alongside the wider availability of the antivirals, meaning that the original rationale for the restrictions no longer apply. They will improve the efficiency of the process to prescribe the antivirals out of flu season, reducing delays and improving health outcomes.

Oseltamivir (Tamiflu®) and Zanamivir (Relenza®) are recommended by the National Institute for Health and Care Excellence (NICE) for the treatment of flu in persons who are 'at risk' and who can commence treatment within 48 hours of symptom onset.

During localised outbreaks of flu-like illness (outside the periods when national surveillance indicates that flu virus is circulating in the community), NICE guidance also recommends that Oseltamivir and Zanamivir may be offered for the treatment of flu in 'at-risk' people who live in long-term residential or nursing homes. However, these treatments should be offered only if there is a high level of certainty that the causative agent in a localised outbreak is flu (usually based on virological evidence of flu infection in the initial case).

While NICE guidance supports the use of antivirals outside the periods where flu virus is circulating in the community, GPs and other authorised prescribers in primary care in Northern Ireland, cannot currently issue HSC prescriptions due to the restrictions set out in Schedule 2 to the 2004 Regulations. This is contrary to other clinical practice when prescribing treatments where GPs and other authorised independent prescribers have the final clinical judgment and discretion.

Although outbreaks of flu outside of season are low compared to within flu season, the potential outcomes for people at risk are no less severe, and so the proposed amendments will benefit anyone who is exposed to flu out of season and will have a positive impact on those most likely to experience severe illness.

England have already introduced legislation to remove the prescribing restrictions on the antivirals in question for NHS Primary Care through ["The National Health Service \(General Medical Services Contracts\) \(Prescription of Drugs etc.\) \(Amendment\) Regulations 2025"](#) (which came into force on the 1 October 2025) following discussions on a UK wide basis between the Chief Medical Officers' and engagement with various health bodies and representatives. The purpose of this targeted consultation is to ensure NI's health representatives are content with the proposals.

Equality and Human Rights considerations

In accordance with guidance produced by the Equality Commission for Northern Ireland and in keeping with section 75 of the Northern Ireland Act 1998, any proposals have been equality screened, and a preliminary decision has been taken that a full EQIA is not required. This preliminary decision is subject to change following analysis of feedback received during this consultation.

The Department has also considered the policy from a Human Rights perspective and has provisionally concluded that this policy will not engage any of the rights.

Rural Impact

The Rural Needs Act (Northern Ireland) 2016 places a duty on public authorities, including government departments, to have due regard to rural needs when developing, adopting, implementing or revising policies, strategies and plans and when designing and delivering public services. The proposed changes have been

subject to an initial screening and it is not expected that implementation of this policy will present any specific or differential rural impacts. This preliminary decision is subject to change following analysis of feedback received during this consultation.

Regulatory Impact

The Department has conducted an initial screening and considers that a regulatory impact assessment is not appropriate. The proposed amendments impose no costs on charities, social economy enterprises or the voluntary sector.

Responding to the Consultation

You can respond to the consultation document by e-mail. If this document is not in a format that suits your needs, please contact us and we can discuss alternative arrangements. Before you submit your response, please read below the effect of the Freedom of Information Act 2000, the Environmental Regulations 2004, the Data Protection Act 2018 (DPA) and the General Data Protection Regulation (EU) 2016/679 on the confidentiality of responses to public consultation exercises.

For further information about how the Department will process the information you provide in response to this consultation, please see the following Privacy Notice – <https://www.health-ni.gov.uk/sites/default/files/publications/health/DoH-Privacy-Notice.pdf>

This consultation has been launched today and will run for six weeks, **closing at 5.00pm on Tuesday 20th January 2026.**

Responses should be sent to:

Email: pharmacyconsultations@health-ni.gov.uk

The consultation response form included at **Annex A** provides the consultee with an opportunity to answer questions relating to the specific proposals and provides further opportunity for respondents to give additional feedback relating to any equality, human rights or rural access implications.

RESPONSE FORM**CONSULTATION ON PROPOSED AMENDMENTS TO THE HEALTH AND PERSONAL SOCIAL SERVICES (GENERAL MEDICAL SERVICES CONTRACTS) (PRESCRIPTION OF DRUGS ETC) REGULATIONS (NORTHERN IRELAND) 2004**

Please indicate your answer to the questions by placing an X by your selection. You can also provide further comments in the free text field.

Responses to be sent by e-mail to:

pharmacyconsultations@health-ni.gov.uk

The deadline for consultation responses is 5.00pm Tuesday 20th January 2026.

Respondent details

I am responding: as an individual ☐

on behalf of an organisation ☒

Name (optional):

Ryan Duffy

Organisation and job title (if applicable):

Pharmaceutical Society NI- Interim
Senior Policy Officer

E-mail (optional):

Ryan.duffy@psni.org.uk

If replying as an individual, please indicate if you do not wish for your identity to be made public

Yes ☐

No ☐

PART A

Views are invited on the following questions.

Proposal – to amend the Health & Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) Regulations (Northern Ireland) 2004 (“the 2004 Regulations”) to facilitate out-of-season Health and Social Care (HSC) prescribing in Primary Care of two influenza (flu) antivirals - Oseltamivir (Tamiflu®) and Zanamivir (Relenza®) in Northern Ireland.

The overarching policy objective is to remove the flu antiviral restrictions set out in Schedule 2 of the 2004 Regulations, to enable Oseltamivir (Tamiflu®) and Zanamivir (Relenza®) to be prescribed and dispensed via standard Primary Care prescription processes outside of flu season in Northern Ireland.

Q1. Do you agree with this proposed reform?

Yes ☒

No

☐

Don't know/no views

☐

Q2. Do you have any comments on this proposed reform?

The Pharmaceutical Society of Northern Ireland (the Society) welcomes the opportunity to respond to this consultation and supports the proposed amendment to remove the seasonal prescribing restrictions on Oseltamivir (Tamiflu®) and Zanamivir (Relenza®). Enabling HSC prescribing outside the traditional flu season reflects current clinical evidence, NICE guidance, and advances in diagnostic testing, and aligns Northern Ireland with legislative changes already implemented in England.

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. 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.

Any other comments

Q3. Please use this space to provide any further comments.

The Society notes that pharmacists play a key role in the safe dispensing, counselling, and optimisation of antiviral medicines. Clear prescribing criteria and accurate documentation will support pharmacists in verifying appropriate use and advising patients effectively.

The Society encourages the Department to ensure that any supporting guidance accompanying the regulatory amendment reinforces antimicrobial stewardship principles, clear diagnostic justification, and appropriate patient counselling. Continued communication between prescribers, pharmacists, and public health bodies will remain essential to ensure safe, proportionate, and effective use of antivirals throughout the year.

PART B – EQUALITY AND HUMAN RIGHTS

Section 75 of the Northern Ireland Act 1998 requires departments in carrying out their functions relating to Northern Ireland to have due regard to the need to promote equality of opportunity:

- between persons of different religious beliefs, political opinion, racial group, age, marital status or sexual orientation;
- between men and women generally;
- between person with a disability and persons without; and
- between persons with dependents and persons without.

In addition, without prejudice to the above obligation, Departments should also, in carrying out their functions relating to Northern Ireland, have due regard to the desirability of promoting good relations between persons of different religious belief, political opinion or racial group.

In accordance with guidance produced by the Equality Commission for Northern Ireland and in keeping with Section 75 of the Northern Ireland Act 1998, the Framework has been equality screened, and a preliminary decision has been taken that a full Equality Impact Assessment (EQIA) is not required. Departments also have a statutory duty to ensure that their decisions and actions are compatible with the Human Rights Act 1998 and to act in accordance with these rights.

Q4. Do you consider that the proposal contained in this consultation document would have an adverse impact on any of the nine equality groups identified under Section 75 of the NI Act 1998? If yes, please state the group(s) and provide comment on how these adverse impacts could be reduced or alleviated in the proposals.

Yes ☐ No ☒ Don't know/no views ☐

Comments:

Q5. Are you aware of any indication or evidence – qualitative or quantitative – that the proposal sets out in the consultation document may have an adverse impact on equality of opportunity or on good relations? If yes, please give details and comment on what you think should be added or removed to alleviate the adverse impact.

Yes ☐

No ☒

Don't know/no views ☐

Comments:

Q6. Is there an opportunity to better promote equality of opportunity or good relations among any of the nine equality groups identified under Section 75 of the NI Act 1998? If yes, please give details and comment on how the Department could better promote equality of opportunity or good relations among the group or groups you have identified.

Yes ☐

No ☒

Don't know/no views ☐

Comments:

Q7. Are there any aspects of the proposals where potential human rights violations may occur?

Yes ☐

No ☒

Don't know/no views ☐

Comments:

PART C – RURAL IMPACT

The Rural Needs Act (NI) 2016 places a duty on public authorities, including government departments, to have due regard to rural needs when developing, adopting, implementing or revising policies, strategies and plans and when designing and delivering public services.

Q8. Are the actions/proposals set out in this consultation document likely to have an adverse impact on rural areas? If yes, please provide comment on how these adverse impacts could be reduced or alleviated.

Yes ☐

No ☒

Don't know/no views ☐

Comments:

Confidentiality and Access to Information Legislation

The Department may publish a summary of responses following completion of the consultation process. Your response, and all other responses to the consultation, may be published or disclosed on request in accordance with information legislation; these chiefly being the Freedom of Information Act 2000 (FOIA), the Environmental Information Regulations 2004 (EIR), the Data Protection Act 2018 (DPA) and the General Data Protection Regulation (GDPR) (EU) 2016/679. The Department can only refuse to disclose information in exceptional circumstances.

Before you submit your response, please read the paragraphs below on the confidentiality of consultations and they will give you guidance on the legal position about any information given by you in response to this consultation.

The FOIA gives the public a right of access to any information held by a public authority, namely, the Department in this case. This right of access to information includes information provided in response to a consultation. The Department cannot automatically consider as confidential; information supplied to it in response to a consultation. However, it does have the responsibility to decide whether any information provided by you in response to this consultation, including information about your identity should be made public or be treated as confidential.

If you do not wish information about your identity to be made public, please include an explanation in your response.

For further information about confidentiality of responses please contact the Information Commissioner's Office on **0303 123 1113** or via <https://ico.org.uk/global/contact-us/>).

