COM/2023/192 Proposal for a Directive on the Union code relating to medicinal products for human use

COM/2023/193 Proposal for a Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency

Response from Department of Health – 9 June 2025

As shared previously with Members of the Northern Ireland (NI) Assembly's Windsor Framework Democratic Scrutiny Committee, the Department is working closely with the Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency (MHRA) to understand the implications of the proposed EU pharma reforms on the whole of the UK, including NI. The MHRA has been analysing the technical details of the EU proposals, which included seeking clarification on the proposed reclassification of antimicrobial medicines as prescription only medicines.

On 4 June 2025, the Council of the European Union agreed a mandate to negotiate the EU pharma proposals with the European Parliament, which contains updates to the initial EU pharma proposals published on 26 April 2023, COM/2023/192 and COM/2023/193. The updated text within the mandate now appears to exclude antimicrobials intended for topical use to be reclassified as prescription only medicines.

Given the current uncertainty in respect of the final text of this legislation, as demonstrated in the changes to the Council's agreed mandate, and if or how it will apply to medicines authorised in NI, the Department cannot be more specific on potential implications at this time.

Should the proposals be agreed and finalised and there is clarification from the MHRA's analysis of the technical details, the Department will consider all implications and potential actions to take. This will include considering the implications for GPs, pharmacies and the general public and considerations on the provisions for making supplies.

As indicated to the Committee during the oral briefing, should further information and detail become available, the Department will endeavour to update Members as soon as practicable.

In the meantime, the Department's guidance advising GPs not to prescribe medicines that can be purchased over-the-counter (OTC) by patients when they are being used to treat minor conditions or self-limiting illness continues to apply - https://niformulary.hscni.net/deprescribing/over-the-counter-medicines/. Patients are encouraged to continue to self-care and seek advice from their local community pharmacist to help manage these minor and self-limiting conditions.

Northern Ireland Assembly

[redacted], Senior Assistant Clerk
Windsor Framework Democratic Scrutiny Committee (DSC)

Ref: DSC 163/25

29 May 2025

[redacted] Principal Pharmaceutical Officer, Department of Health

[redacted] Senior Principal Pharmaceutical Officer and Head of the Medicine Regulatory Group, Department of Health

Issued via email to: [redacted]

Dear [redacted]

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At its meeting on 29 May 2025, the Windsor Framework Democratic Scrutiny Committee (DSC) considered written answers provided by the Department of Health on the above proposed EU acts.

The Department states, "*If antimicrobials medicines are to be classified as prescription only medicines, this would mean products currently licensed as General Sale List or Pharmacy only medicines could no longer be supplied or sold under their current provisions, and they would need to be supplied or sold under provisions as prescription only medicines*".

The DSC agreed to request more specific information on the implications for GPs, pharmacies, and the general public, if antimicrobial medicines have to be supplied or sold as prescription only medicines.

I would appreciate a response by 19 June 2025.

Yours sincerely,

[redacted]

[redacted], **Senior Assistant Clerk**
Windsor Framework Democratic Scrutiny Committee

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