



Medicines & Healthcare products
Regulatory Agency

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United Kingdom
[gov.uk/mhra](https://www.gov.uk/mhra)

[REDACTED]
Assistant Assembly Clerk
Windsor Framework Democratic Scrutiny Committee (DSC)
Room 371, Parliament Buildings
Ballymiscaw
Stormont
Belfast
BT4 3XX

By email: [REDACTED]

Ref: DSC 140/25; CEO 20381

17 June 2025

Dear [REDACTED],

Thank you for your letter requesting the Medicines and Healthcare products Regulatory Agency (MHRA) to provide its views on the EU proposals, COM/2023/192 and COM/2023/193 to the Northern Ireland Assembly's Democratic Scrutiny Committee.

The MHRA continues to analyse the technical details of the EU proposals, including recent developments in the legal text, working closely with the Department for Health and Social Care and the Cabinet Office, as well as the Northern Ireland Department of Health. The UK Government is committed to engaging the European Commission on these issues, through the appropriate channels.

The UK Government will set out its assessment in an Explanatory Memorandum in accordance with the usual processes for regulations under Article 13(3a) of the Windsor Framework.

Yours sincerely

[REDACTED]

[REDACTED]
Chief Executive, MHRA
[REDACTED]



██████████, Assistant Assembly Clerk
Windsor Framework Democratic Scrutiny
Committee (DSC)

Ref: DSC 140/25

23 May 2025

██████████
Chief Executive, Medicines and Healthcare Products Regulatory Agency

Issued via email to: ██████████

Dear ██████████

[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](#)

At its meeting on 22 May 2025, the Windsor Framework Democratic Scrutiny Committee (DSC) agreed to seek views from stakeholders on the two abovementioned proposed EU acts.

The DSC is gathering views to put it in a more informed position should the published acts be notified to it by Cabinet Office. [Read more about the Committee process here.](#)

Specifically, the DSC is seeking your views on whether applying/not applying each act would have a significant negative impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist.

Should you wish to provide views on the **proposed Directive COM/2023/192**, you can do so via Citizen Space at the following link: [COM/2023/192](#)

Should you wish to provide views on the **proposed Regulation COM/2023/193**, you can do so via Citizen Space at the following link: [COM/2023/193](#)

The DSC requests that you circulate the surveys widely within your membership.

Please note that both surveys will close on **19 June 2025**.

Yours sincerely,

██████████

██████████ Assistant Assembly Clerk
Windsor Framework Democratic Scrutiny Committee