

To: [REDACTED]
Assistant Assembly Clerk
Windsor Framework Democratic Scrutiny Committee (DSC)

Ref. DSC 136/25

Sent by email: windsorframework.committee@niassembly.gov.uk

09th June 2025

Re. 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

Dear [REDACTED]

We would like to thank the Democratic Scrutiny Committee for seeking our views in relation to the above proposed EU acts, and specifically whether application/non-application would have a significant negative impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist.

We note the laudable objectives outlined for COM/2023/192 and COM/2023/193 -including to ensure the quality, safety and efficacy of medicinal products for patients; to make sure all patients have timely and equitable access to safe, effective and affordable medicines; enhance security of supply and access of medicines; and make medicines more environmentally sustainable.

Beyond these high-level EU proposals, in the absence of any DoH explanatory guidance which outlines what changes this is likely to mean to Health and Social Care in a Northern Ireland setting, it is difficult for us to a) seek the views of our members on these proposals, and b) provide considered feedback on what the implications could be from a dentistry perspective.

We are of course happy to engage in future if and when more detail on the practical implications in Health and Social Care in Northern Ireland becomes available.

Yours sincerely

[REDACTED]

[REDACTED]
Northern Ireland Director



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

Ref: DSC 136/25

23 May 2025

██████████
Northern Ireland Director, British Dental Association

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