Windsor Framework Democratic Scrutiny Committee

Minutes of Proceedings

22 May 2025

Meeting Location: Room 30

Present:

Ciara Ferguson MLA (Chairperson)

David Brooks MLA (Deputy Chairperson)

Declan Kearney MLA

Peter Martin MLA

Eóin Tennyson MLA

Present by Video:

Steve Aiken MLA

Jonathan Buckley MLA

Apologies:

Emma Sheerin MLA

In Attendance:

Jessica Jacques (Senior Assistant Clerk)

Christopher Dickison (Senior Assistant Clerk)

Oliver Bellew (Assistant Clerk)

Victoria Bourquin (Assistant Clerk)

Suzanne Walsh (Clerical Supervisor)

Damien Brown (Clerical Officer)

In Attendance by Video:

Carla Campbell (Clerical Supervisor)

Shelley Garner (Clerical Officer)

The meeting commenced at 10.01am in closed session.

1. **Apologies**

   As above.

2. **Declaration of Members' Interest**

   None.

3. **COM/2023/192 Proposal for a Directive on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC – Legal Advice**

   Caroline Byers, Legal Adviser, Assembly Legal Services, joined the meeting at 10.03am.

   The Committee considered the following proposed EU act:

   COM/2023/192 Proposal for a Directive on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC.

The Committee noted that the proposed EU act has not been notified to the Committee, but following a work planning exercise on 20 February 2025, the Committee agreed to gather evidence on the proposed EU act.

The Legal Adviser provided advice on whether it appears likely that the proposed EU act differs significantly (in whole or in part) from the content or scope of the EU act it is amending/replacing.

Eóin Tennyson MLA joined the meeting at 10.09am.

A question and answer session followed.

Agreed: The Committee agreed to continue its consideration of the proposed EU act in public session.

The Legal Adviser remained in the meeting for agenda item 4.

4. 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, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 – Legal Advice

The Committee considered the following proposed EU act:

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, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006.

The Committee noted that the proposed EU act has not been notified to the Committee, but following a work planning exercise on 20 February 2025, the Committee agreed to gather evidence on the proposed EU act.

The Legal Adviser provided advice on whether it appears likely that the proposed EU act differs significantly (in whole or in part) from the content or scope of the EU act it is amending/replacing.

Agreed: The Committee agreed to continue its consideration of the proposed EU act in public session.

The Legal Adviser left the meeting at 10.35am.

Agreed: The Committee agreed to move to public session at 10.35am.

The meeting commenced at 10.35am in public session.

5. Draft Minutes

Agreed: The Committee agreed the minutes of the meeting held on 15 May 2025.

6. Matters Arising

None.

7. COM/2023/192 Proposal for a Directive on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC – Departmental Oral Evidence

The Committee noted that the proposed Directive COM/2023/192 and proposed Regulation COM/2023/193 make up a package of legislative proposals to reform existing EU pharmaceutical legislation, and that the oral evidence session would cover the two proposed EU acts.

The following officials joined the meeting at 10.36am:

Sean Curley	Principal Pharmaceutical Officer, Department of Health

Aaron McKendry	Senior Principal Pharmaceutical Officer and Head of the Medicine Regulatory Group, Department of Health

The officials gave oral evidence on COM/2023/192 and COM/2023/193.

A question and answer session followed.

The evidence session was reported by Hansard.

The officials left the meeting at 11.08am.

The Committee noted that once the proposed EU acts are adopted and published in the Official Journal of the EU, and if they are notified to the Committee, it would have to make a decision on whether to hold an inquiry on each individual act.

Agreed: The Committee agreed to seek the views of stakeholders identified by RaISe via Citizen Space with a four-week deadline for response.

Agreed: The Committee agreed to request that the Department of Health provide a revised departmental assessment of impact when it has more information on the proposed EU Directive.

Agreed: The Committee agreed to ask RaISe to monitor the progress of the proposed EU Directive.

8. 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, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 – Departmental Oral Evidence

Agreed: The Committee agreed to seek the views of stakeholders identified by RaISe via Citizen Space with a four-week deadline for response.

Agreed: The Committee agreed to request that the Department of Health provide a revised departmental assessment of impact when it has more information on the proposed EU Regulation.

Agreed: The Committee agreed to ask RaISe to monitor the progress of the proposed EU Regulation.

The Chairperson left the meeting at 11.10am and the Deputy Chairperson assumed the Chair.

9. Correspondence

9.1 The Committee noted an update from the Executive Office regarding current proposed EU legislation relevant to Northern Ireland.

9.2 The Committee noted a copy of correspondence from the House of Lords Northern Ireland Scrutiny Committee to the UK Government regarding COM/2023/769 Proposal for a Regulation on the welfare of dogs and cats and their traceability.

9.3 The Committee noted a copy of correspondence from the House of Lords Northern Ireland Scrutiny Committee to the UK Government regarding Regulation (EU) 2024/1143 on geographical indications for wine, spirit drinks and agricultural products, as well as traditional specialities guaranteed and optional quality terms for agricultural products.

9.4 The Committee noted a copy of correspondence from the House of Lords Northern Ireland Scrutiny Committee to the UK Government regarding C/2024/0661 Commission Delegated Regulation on appropriate measures to ensure the effective and safe use of veterinary medicinal products.

9.5 The Committee noted a copy of correspondence from the House of Lords Northern Ireland Scrutiny Committee to the UK Government regarding its Explanatory Memorandum on COM/2024/43 Proposal for a Regulation as regards a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain in vitro diagnostic medical devices.

9.6 The Committee noted a copy of correspondence from the House of Lords Northern Ireland Scrutiny Committee to the UK Government regarding its Explanatory Memorandum on the European Commission Work Programme 2025.

9.7 The Committee noted a copy of correspondence from the House of Lords Northern Ireland Scrutiny Committee to the UK Government regarding

Regulation (EU) 2024/1252 establishing a framework for ensuring a secure and sustainable supply of critical raw materials.

9.8 The Committee noted a copy of correspondence from the House of Lords Northern Ireland Scrutiny Committee to the UK Government regarding Regulation (EU) 2023/2411 on the protection of geographical indications for craft and industrial products.

10. Chairperson's Business

Given that the Committee may need to meet during the summer recess to discharge its statutory functions, the Chairperson asked Members to notify the secretariat of the dates when they are unable to attend a Committee meeting during this period. The Chairperson reminded Members that arrangements for nominating substitute members are now in place.

11. Any other business

None.

12. Date, time, and place of next meeting

The next meeting will be held on Thursday 29 May 2025 at 10:00am in Room 30.

Agreed: The Committee agreed that, due to the public holiday on 26 May 2025, meeting papers should issue on Tuesday 27 May 2025.

The meeting was adjourned at 11.16am.

Ciara Ferguson, MLA

Chairperson, Windsor Framework Democratic Scrutiny Committee