



Northern Ireland
Assembly

Research and Information Service Briefing Note

Paper 00/000

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NIAR-145-2025

Windsor Framework Democratic Scrutiny Committee

Status Update

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL 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.

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This information is provided to Members of the Legislative Assembly (MLAs) in support of their duties, and is not intended to address the specific circumstances of any particular individual. It should not be relied upon as professional legal advice, or as a substitute for it.

1 Background

At its meeting on 22nd May 2025, the DSC made a decision to monitor [Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL 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 proposal aims to streamline and modernise EU procedures for the authorisation and supervision of human medicinal products, while reinforcing the role and governance of the European Medicines Agency and consolidating legislation into a single framework.

The proposed Regulation is being presented alongside a Directive setting out the EU code for human medicinal products – [COM\(2023\)192.](#)

The proposal is progressing through the “ordinary legislative procedure” established under the Lisbon Treaty.

2 Status Update

Both the Council and the European Parliament have now set their negotiating positions and are engaged in informal trilogue discussions to reach a compromise. The first trilogue took place on 17 June 2025, and the Danish Presidency is expected to confirm the date of the second round in early September. The Presidency has stated its intention to secure an agreement before the end of the year.

If achieved, these negotiations could result in an early second reading agreement in the second half of 2025. Any compromise text would first require formal adoption by the Council as its first reading position, followed by adoption with any amendments by the European Parliament at second reading.

Once adopted, the Regulation would be published in the Official Journal and subsequently enter into force.

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