



Northern Ireland  
Assembly

# Research and Information Service Briefing Note

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22<sup>nd</sup> August 2025

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## **Windsor Framework Democratic Scrutiny Committee**

### **Status Update**

**Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC.**

**RaISe**

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 22<sup>nd</sup> May 2025, the DSC made a decision to monitor [Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC.](#)

The proposal aims to modernise and simplify the EU's pharmaceutical legislation by establishing a single Union code for medicinal products, improving access to safe and effective medicines, supporting innovation, and strengthening regulatory oversight while repealing outdated directives.

The proposed Directive is being put forward alongside a Regulation concerning EU procedures for the authorisation and supervision of human medicinal products – [COM\(2023\)193](#).

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 defined their negotiating mandates and have entered into informal trilogue discussions to work towards a compromise. The first trilogue meeting took place on 17 June 2025, and the Danish Presidency is expected to confirm the timing of the second round in early September. The Presidency has indicated its objective of securing an agreement before the end of the year.

Should progress be achieved, the institutions may conclude an early second reading agreement in the latter half of 2025. In such a case, the Council would first adopt the compromise text as its first reading position. The European Parliament would then adopt the text, with any agreed amendments, at second reading.

Following this, the Regulation would be formally published in the EU Official Journal and subsequently enter into force.

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