Department of Health (DoH) response to DSC follow up query on EU Pharmaceutical Reforms – May 2026

The Committee has asked the Department to clarify the date on which full technical analysis of the provisionally agreed text on the proposed EU Pharma Reform package (COM/2023/192 and COM/2023/193), will be completed.

A 'full' technical analysis of the provisionally agreed text on the proposed EU Pharma package should be considered in two parts, with completion dates differing.

The first part includes the collaborative work that has been ongoing between the Department, the Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency (MHRA). This analysis will culminate in the production of a UK Government explanatory memorandum (UKG EM). Although there is a provisionally agreed text the Department anticipates completion of the UKG EM to be aligned with the publication of the finalised text in the Official Journal of the EU, currently expected in October 2026. The Department will provide Members with an update to the assessments of impact once this has been shared.

Regarding a completion date for the 'full' analysis, there is now a recognition that other aspects of the technical analysis are likely to continue beyond publication of the finalised text in the Official Journal of the EU and throughout the 24-months implementation period. For example, the finalised EU proposed text includes provisions to introduce electronic patient information leaflets for all medicines and medicine licence holders must make them available. The MHRA has already launched the 'Patient Information Project' which aims to explore ways to increase medicines information accessibility, trust and making it fit for the future, with the use of electronic information leaflets being considered. This project has a three-phase approach to delivery with a work plan and phase three anticipated to be complete between 2027-28. However, as the EU will provide further details regarding electronic patient information leaflets in forthcoming Implementing Acts, an ongoing analysis on those acts, such as setting common standards and formats for electronic leaflets, will need to be considered alongside the project.

This means the Department cannot provide a definitive date when the overall 'full' technical analysis will be complete. However, the Department wants to assure Members that the technical analysis that will be used to construct the UKG EM and thus provide the Committee with an update on the assessments of impact will be shared when complete as highlighted above.

The Department endeavours to update the Committee on any further developments as soon as practicable.

From: +Windsor Framework Committee Public Email <WindsorFramework.Committee@niassembly.gov.uk>
Sent: 30 April 2026 15:21
To: TEO Democratic Scrutiny Committee [redacted]
Cc: DoH DSC Admin [redacted]
Subject: WFDSC - DoH - COM/2023/192 and COM/2023/193

Good afternoon,

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

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

At it's meeting today, 30 April 2026, the DSC considered the Department of Health's response in relation to the provisionally agreed texts of the two abovementioned proposed EU acts. This states that the department's original assessments of impact remain unchanged until a full technical analysis is completed.

The Committee agreed to ask, in the first instance, for confirmation of when this analysis will be completed. **The Committee would be grateful for a response providing this confirmation by Friday 15 May 2026.**

The Committee also requests a copy of that technical analysis, once it has been completed.

Regards