

From: DoH DSC Admin

Sent: 25 November 2025 09:19

To: DSC

Subject: DoH Input: DSC/20a/2025 - Request for departmental assessment of impact - COM-2023-224 - Compulsory Licensing for Crisis Management

Windsor Framework Democratic Scrutiny Committee,

Thank you for considering the Department of Health's previously submitted impact of assessment at your meeting of 6 November 2025, please see below responses to your follow up requests:

Q: The DSC agreed to request an updated assessment of impact on the [provisionally agreed text](#) of the proposed EU act (including any input from the UK Government that may be required).

A: In preparing the previously submitted impact of assessment template for the Committee the Department based the assessment on the referenced provisionally agreed text. Our assessment was made in collaboration with UK Government colleagues in both the Department of Health and Social Care (DHSC) and the Intellectual Property Office (IPO). Our position and current understanding remain unchanged.

Q: The DSC also agreed to request confirmation from the Department that the proposed EU act, if published and implemented, would not disrupt access to UK-produced medicines and vaccines in Northern Ireland.

A: The Department is awaiting the finalised version of this EU proposal. However, as outlined in the Department's previous assessment, an updated amendment to the proposal means an EU-wide compulsory licence would not apply in Northern Ireland if adopted. If the EU-wide compulsory licence under the amendment to Regulation (EC) 816/2006 does not apply in Northern Ireland, then only a national compulsory licence granted by the UK competent authority could apply across the UK. Therefore, the Department's current understanding is that EU-wide compulsory licences granted under the proposed EU Act should not change NI's access to medicines and vaccines that are available in the UK.