**Department of Health (DoH) response to DSC on EU Pharmaceutical Reforms – April 2026**

The Committee has asked the Department to review the previously submitted assessment of impact given the publication in early March 2026 of the provisionally agreed text on the proposed EU Pharma Reform package (COM/2023/192 and COM/2023/193).

Previous assessments and evidence provided to the Committee indicated that an assessment could not be provided until the full technical details of these proposals were fully understood. Members were also provided with assurances that the Department is working collaboratively with the Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency (MHRA) to fully understand the implications of the EU Pharma Reform package in Northern Ireland as the proposals progressed and texts became available. The Department wants to assure the Committee that this work continues in earnest following the publication of the provisionally agreed text, and the Department understands a revised UK Government explanatory memorandum is currently being developed and will be shared with the Committee once finalised.

Although a comprehensive update cannot be provided at this stage, the Department is aware that Members had previously raised concerns about the reclassification of antimicrobials as prescriptions only medicines. The Department would like to highlight that the recently published text contains an update which would address these concerns. The update, as it stands, will **exempt Northern Ireland** specifically from this requirement for antimicrobials- "*Directive on the Union code relating to medicinal products for human use*", Chapter XVII, Art. 209, (3a)- *"Article 51(1)(e) shall not apply to and in the United Kingdom in respect of Northern Ireland".*

The Department also wants to reassure Members that the two significant amendments to pharma legislation previously agreed between the UK Government and the EU that ensure the long-term supply of medicines into Northern Ireland will continue to apply following the publication of this text. This means the MHRA will continue to authorise medicines for Northern Ireland and supplies can continue to be supplied from Great Britain without additional regulatory importation controls.

Additionally, Members may be interested in the Department's current understanding in relation to the estimated timelines for the publication of these reforms in the Official Journal of the EU. While there is no formal date for a final plenary vote to ratify the proposed text ahead of publication, the Chair of the relevant European Parliament committee has publicly indicated that European Parliament approval is targeted for October '*at the earliest'*. We would therefore expect publication in late 2026 but will keep this under review. Following publication, the Department understand that there will be a 24-month implementation period.

The information and updates outlined above may provide some reassurance to Members regarding concerns previously raised, but the Department can confirm that the initial assessment of impact remains unchanged at this stage

until the full technical analysis is complete. The Department remains committed to updating Members as soon as practicable.