Department of Health & Social Care

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Dear Simon,

Thank you for the opportunity to update the Northern Ireland Affairs Committee on 26 November regarding medicines and the Northern Ireland Protocol. Further to that meeting, I am writing to you on behalf of both myself and the Chancellor of the Duchy of Lancaster to provide an update on the agreed flexibilities for regulation under the Falsified Medicines Directive and importation requirements and to outline the Departments' Portfolio on the Northern Ireland Protocol.

As you are aware, the Ireland/Northern Ireland Specialised Committee agreed on 5 November on the need for additional time to enable industry to make the required adaptations for medicines under the Protocol. The co-chairs of the EU-UK Joint Committee, the UK Chancellor of the Duchy of Lancaster, Rt Hon Michael Gove, and European Commission Vice-President Maroš Šefčovič, have since reached an agreement in principle on the outstanding issues on implementation of the Withdrawal Agreement, which includes confirming the agreement on the 12-month phased approach for medicines under the Protocol.

Further details of this are set out in the Government's 10 December Command Paper. Published alongside it was the draft unilateral declarations by the European Union and the United Kingdom of Great Britain and Northern Ireland in the Withdrawal Agreement Joint Committee on human and veterinary medicines. The Joint Committee will meet tomorrow to formalise these arrangements, including both parties making their respective declarations.

We have worked closely with industry at each stage: to determine the impacts, and the timeframes they need to make the required changes; including, engagement with trade bodies in the lead up to the release of detailed guidance. The Medicines and Healthcare products Regulatory Agency (MHRA) released this guidance on 11 December, providing industry with additional information and clarity on the supply of medicines into Northern Ireland including for Investigational Medicinal Products for clinical trials. Further guidance on marketing authorisation holder (MAH) and qualified person responsible for pharmacovigilance (QPPV) will be released shortly.

We are committed to supporting industry and continuing to work with them on the longer-term arrangements, and towards preparedness for 1 January 2022. We continue engagement via a series of webinars, and regular, established meetings with industry. The New Deal for Northern Ireland announced by the Northern Ireland Secretary also included

specific account of further support for the industry in adapting to the requirements of the Protocol, with additional details to be announced in due course.

More broadly, my Department and officials are well prepared for the end of the transition period and delivery of the Northern Ireland Protocol. As agreed in the recent meeting with the Committee, an overview of the Departments' EU Exit portfolio and the policy areas which are impacted by the Northern Ireland Protocol are outlined in the annex. We continue to ensure the Department has the appropriate resourcing levels in place to manage response incidents including across the concurrent risks of Covid-19 and Winter.

I look forward to the ratification of the medicine's declaration in the 5th Withdrawal Agreement Joint Committee, which is a key mitigation to ensure the supply of medicines to Northern Ireland.

It was a pleasure to attend the session of the Committee - I look forward to returning in the future!

Yours ever, Ed

EDWARD ARGAR MP

DHSC EU Exit Portfolio and governance

The policy areas in the portfolio which are impacted and preparing for the implementation of the Protocol are shaded in teal.