



Department
of Health &
Social Care

*From the Lord Bethell
Parliamentary Under Secretary of State for Innovation (Lords)
39 Victoria Street
London
SW1H 0EU
Tel: 020 7210 4850*

Lord Kinnoull
Chair
European Union Committee
House of Lords
London
SW1A 0PW

16 October 2020

Dear Lord Kinnoull,

EM 5844/18: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU

5844/18 ADD 1: COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Strengthening of the EU Cooperation on Health Technology Assessment (HTA) Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU

5844/18 ADD 2: COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU

Thank you for your response regarding my letter sent on 4 August 2020 on the above documents.

You ask for an update on the progress of UK-EU negotiations on provisions for information sharing regarding clinical trials and pharmacovigilance.

At the time of writing, UK and EU negotiators are continuing discussions ahead of the European Council meeting on 15-16 October. As instructed by the Prime Minister, UK negotiators will continue to work intensively to bridge the gaps that remain between the two sides.

In these negotiations, the Government's priority has always been to ensure patients have access to safe and effective medicines and clinical trials. In its approach to negotiations, the UK sets out that the UK-EU Agreement should promote trade in goods by addressing regulatory barriers to trade between the UK and EU, while preserving each party's right to regulate, as is standard in free trade agreements. We are also seeking commitments to cooperate on pharmacovigilance and to develop a comprehensive confidentiality agreement with the European Medicines Agency. This should facilitate information sharing and enable regulators to act promptly to safeguard patient safety and public health, such as by responding to urgent adverse drug reactions. To further promote public health, we are also seeking to explore procedures relating to vaccines and other biological medicinal products, and clinical trials.

You also ask whether the draft UK-EU free trade agreement and medical products annex should include provision for information sharing relating to health technology assessments.

I do not believe this would be helpful. Firstly, there already exist informal networks between European Health Technology Assessment (HTA) bodies, such as the National Institute for Health and Care Excellence (NICE) and its European counterparts, that allow for information sharing.

Secondly, the benefits to NICE of a formal HTA information sharing provision would outweigh the obligations that would likely accompany such a provision. You are aware of our earlier concerns relating to the proposed EU regulation on HTA and the potential negative impact on the timeliness of NICE's HTAs.

NICE is working hard with the Medicines and Healthcare products Regulatory Agency (MHRA) and others on a compelling UK life science offer to support early patient access to effective and innovative medicines, and it needs to retain maximal flexibility and freedom to operate in order to do so.

Best Wishes,

A handwritten signature in dark ink, appearing to read 'Bethell', written in a cursive style.

Lord Bethell