Department for International Trade

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The Rt Hon. the Lord Kakkar
House of Lords
London
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13th September 2018

Dear Lord Kakkar,

Thank you for your active engagement in the debate during the second reading of the Trade Bill, and your interest on the Government's position on the Clinical Trials Regulation. As promised in the debate, I am writing to you to give details of the Government's approach and to set out our plans to implement the regulation following the UK's departure from the European Union.

The EU's new Clinical Trials Regulation (CTR) is expected to be implemented during 2020 and would therefore apply to the UK under the terms of the time-limited implementation period. However, if the new regulation does not come into force during the implementation period, we will take steps without delay to ensure UK law remains aligned with those parts of the EU's CTR legislation that are within the UK's control.

However, there are two aspects of the Regulation which sit outside the UK's control. These are the use of a single shared central IT portal and participation in the single assessment model. The UK's participation in both of these aspects of the Regulation is dependent on a negotiated agreement between the UK and the EU. We cannot pre-empt these negotiations, nor can we provide further guarantees of action by the UK which might disadvantage our negotiating position.

I hope you find this helpful. I am copying this letter to Lord Stevenson of Balmacara and Lord Purvis of Tweed, and a copy of this letter will be placed in the libraries of both houses.

Yours ever,

Baroness Fairhead

Minister of State for Trade and Export Promotion

Department for International Trade