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FROM THE BARONESS CHISHOLM OF OWLPEN
GOVERNMENT WHIP FOR THE DCMS, DFT AND DOH
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8 March 2018

Dear Judith

At the end of the debate on the Draft Human Fertilisation and Embryology (Amendment) Regulations 2018 and Draft Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018 on Tuesday 27 February you asked how many more health-related regulations that transpose EU legislation will be implemented before March 2019 and the likely total cost of this exercise to the NHS. I promised to write to you.

At this stage, we anticipate one further Statutory Instrument (SI) that transposes EU legislation in the health sphere.

The Human Medicines (FMD) (Amendment) Regulations 2018 on safety features to ensure protection of human health and patient safety apply the EU Delegated Regulation (EU2016/161) that supplements the EU Falsified Medicines Directive (FMD). The delegated regulation will be legally applied in all EU Member States on 9 Feb 2019, and therefore before the UK's Exit from the EU. We expect to be formally consulting on implementation by the end of April 2018.

As you are aware, impact assessments were published alongside the Regulations when they were laid in Parliament. As is standard practice, estimated costs are considered on an individual SI basis.

I hope you find this letter helpful. I will also place a copy in the House library.

Best wishes,
Carlyn

BARONESS CHISHOLM OF OWLPEN

Baroness Jolly
House of Lords