16th October 2018

Dear Lewis,

The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations, the Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations and the Blood Safety and Quality (Amendment) (EU Exit) Regulations

EU EXIT LEGISLATION – PROTOCOL WITH SCOTTISH PARLIAMENT

Thank you for your letter of 3 October regarding the three proposed EU exit SIs listed above. As is described in the notification, these Regulations only make amendments to the statute book to cover the possibility of a ‘no-deal’ EU exit. They do not however make changes to the existing procedures or safety standards in relation to the donation and transplantation or transfusion of human organs, tissues and cells, or blood.

You asked about the proposed regulation-making powers within these SIs and which powers to make regulations we anticipate will sit with UK Ministers and which with devolved administrations. I should clarify that, following discussions with the UK Department of Health and Social Care, it has been agreed that in all three of the proposed Regulations, any regulation-making powers would be conferred on both devolved administration Ministers and the Secretary of State for Health and Social Care.

This would mean that in each case the SIs will permit Regulations to be made either by Scottish Ministers or, subject to Scottish Ministers providing consent to this, by the Secretary of State. This will ensure there is future flexibility, enabling UK-wide Regulations to be progressed by the Secretary of State for Health and Social Care where it makes sense to do so and there is agreement between the four UK administrations. However, it will also enable the Scottish Government to bring forward its own Regulations in cases where this is
considered appropriate, for example where the Scottish position may be different from other parts of the UK.

I hope this is helpful in clarifying how we anticipate that these SIs will provide for regulation-making powers to be exercised in relation to Scotland.

JOE FITZPATRICK