1 November 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

I am writing further to my letter of 16 October and your discussions in Committee on 23 October regarding these proposed UK-wide Regulations which address ‘deficiencies’ which will occur in the existing Regulations in these areas when the UK leaves the European Union, particularly in the event of a ‘No-Deal’ Brexit.

I understand that some concerns were raised in the Committee’s discussions regarding whether or not the Scottish Government has received up to date drafts of these Regulations from the UK Government and that the Committee has written to Ministers at the UK Department of Health and Social Care (DHSC) to seek further clarification on this.

I can confirm that, whilst the drafts of all three Regulations are still being finalised by DHSC in advance of being laid, the Scottish Government has now seen near final drafts of all three SIs. We are therefore satisfied that we have sufficient information at this stage.

As I said in my notification letter of 28 September regarding these draft Regulations, we must respond to the UK Government’s preparations for a ‘No-Deal’ scenario as best we can, despite the inevitable widespread damage and disruption that would cause. It is our unwelcome responsibility to ensure that devolved law continues to function on and after EU withdrawal. It is therefore perhaps worth clarifying that, if the Scottish Government did take forward these EU Exit Regulations in relation to Scotland where these cover devolved...
matters and address the implications of EU exit, those Regulations could not differ substantially from the UK-wide Regulations as the EU Withdrawal Act 2018 only permits limited changes to the existing Regulations in order to enable EU exit. While some concerns have been raised by the Committee regarding possible impacts of a ‘No-Deal’ Brexit, for example in relation to guaranteeing that stem cells can continue to be exported to the EU as they are now, Scottish regulations would unfortunately not be any more able to address that issue than UK-wide ones if we find ourselves in the situation where there is no deal agreed between the UK Government and the EU. In the event of a ‘No-Deal’ scenario, neither Scottish nor UK-wide Regulations could require other EU Member States or the European Commission to take a particular approach, for example in relation to UK exports.

I hope this is helpful in clarifying the latest position regarding these Regulations and will allow the Committee to proceed in approving the notification.

Yours sincerely,

Joe Fitzpatrick

JOE FITZPATRICK