Dear Mr Macdonald

EU EXIT LEGISLATION

Thank you for your letter of 4th October 2018 inviting SNBTS’s comments with respect to:

- 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
- Blood Safety and Quality (Amendment) (EU Exit) Regulations

SNBTS is not able to comment specifically on the Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations as it does not operate in this area. However both the Blood Safety and Quality Regulations 2005 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 are transpositions of the relevant EU Directives into UK law. We believe that it is important that UK and EU law remain aligned in respect of the quality and safety of Substances of Human Origin (SoHO) in order to minimise any barriers to access to these vital human therapeutics.

The Committee will be mindful that SNBTS is also involved in the manufacture of Advanced Therapy Medicinal Products (ATMPs) which are governed directly by the EU ATMP Regulations 2017 and Eudralex, the collection of regulations governing medicinal products in the European Union. We believe it is also important that Scotland and the UK remain aligned with these regulations to ensure patient access to this new generation of therapeutic agents.

It is not for SNBTS to comment on the disposition of legal powers between the Scottish and UK Governments, however it is important from a business continuity perspective that, when necessary, we are able to source blood or tissue products from elsewhere in the UK and indeed that we are able to provide mutual support for patients elsewhere in the UK in times of need.
SNBTS has been offered the opportunity to comment on the Blood Safety and Quality (Amendment) (EU Exit) Regulations and the Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations and feel that the amendments proposed are proportionate and appropriate.

Thank you again for asking us to contribute.

With best wishes

Yours sincerely

Mary Morgan
Director

cc Prof Marc Turner, Medical Director, SNBTS.