

UK MINISTERS ACTING IN DEVOLVED AREAS

180 - Quality & Safety of Organs Intended for Transplant (Amendment) (EU Exit) Regs 2020

Laid in the UK Parliament: 8 October 2020

Sifting

Subject to sifting in UK Parliament?	No
Procedure:	Draft affirmative
Date of consideration by the House of Commons European Statutory Instruments Committee	NA
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	NA
Date sifting period ends in UK Parliament	NA
Written statement under SO 30C:	Paper 52
SICM under SO 30A (because amends primary legislation)	Human Tissue Act 2004 (section 32)- SICM(5)32

Scrutiny procedure

Outcome of sifting	NA
Procedure	Draft affirmative
Date of consideration by the Joint Committee on Statutory Instruments	21/10/2020
Date of consideration by the House of Commons Statutory Instruments Committee	Not known
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	20/10/2020

Background

These Regulations are proposed to be made by the UK Government pursuant to sections 8(1) and 8C of the European Union (Withdrawal) Act 2018.

Summary

These Regulations form part of a suite of four instruments (the '2020 Instruments'). The 2020 Instruments together give effect to the Ireland/Northern Ireland Protocol (the 'Protocol') in the Withdrawal Agreement, for the safety and quality of blood and blood components, organs, tissues and cells, and reproductive cells (gametes and embryos) for treating patients.

The Protocol sets out the EU law that will continue to apply to and in Northern Ireland ('NI') after the end of the Implementation Period. NI must continue to meet the requirements of such legislation for as long as the Protocol is in force. The suite of four instruments, including these

Regulations, make the changes needed to allow NI to meet those requirements.

Four previous instruments were made in 2019 (the ‘2019 Instruments’) to ensure that, upon leaving the EU, the UK would maintain the current safety and quality standards for blood, organs, tissues and cells. The 2019 Regulations were made with the consent of the Welsh Ministers as part of the corrections exercise for a no-deal EU Exit in 2019 to ensure the statute book continued to function correctly. The 2019 Instruments also made amendments to reflect EU Member States becoming third countries to the UK. The 2020 Instruments restrict the changes made by the 2019 Instruments to Great Britain only. Therefore the current law will remain in place for NI.

These Regulations amend the Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 so as to enable the provisions amended by those Regulations to continue to operate effectively in light of the Protocol.

Statement by Welsh Government

Legal Advisers agree with the statement laid by the Welsh Government dated 15 October 2020 regarding the effect of these Regulations.

Intergovernmental Agreement on the European Union (Withdrawal) Bill

The above summary and the content of the Explanatory Memorandum to these Regulations confirm their effect.

Legal Advisers do not consider that any significant issues arise under paragraph 8 of the Memorandum on the European Union (Withdrawal) Bill and the Establishment of Common Frameworks in relation to these Regulations.

Consent motion under Standing Order 30A.10

The Welsh Government laid a Statutory Instrument Consent Memorandum (SICM) in respect of these Regulations on 15 October 2020, because the Regulations amend primary legislation within the legislative competence of the Senedd (in this case, section 32 of the Human Tissue Act 2004).

However, the Welsh Government is not proposing to table a motion to debate the SICM in Plenary (as stated by the Minister for Health and Social Services, in a letter to the Chair dated 15 October 2020).