

STATUTORY INSTRUMENT CONSENT MEMORANDUM

The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020

1. This Statutory Instrument Consent Memorandum is laid under Standing Order (“SO”) 30A.2. SO30A prescribes that a Statutory Instrument Consent Memorandum must be laid and a Statutory Instrument Consent Motion may be tabled before the Senedd if a UK Statutory Instrument (SI) makes provision in relation to Wales amending primary legislation within the legislative competence of the Senedd.
2. The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (“the 2020 Regulations”) were laid before Parliament on 12 October 2020 and are now being laid before the Senedd. The 2020 Regulations can be found at:

[The Quality and Safety of Organs Intended for Transplantation
\(Amendment\) \(EU Exit\) Regulations 2020](#)

Summary of the Statutory Instrument and its objective

3. This SI amends the Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (“the 2019 Regulations”) which was made last year, with the consent of the Welsh Ministers, to correct deficiencies in legislation arising from the UK leaving the European Union relating to organ safety and quality.
4. This SI will amend the 2019 Regulations so as to enable the provisions amended by those Regulations to continue to operate effectively in light of the Northern Ireland Protocol following Implementation Period completion day (11 pm 31 December 2020).

Relevant provision to be made by the SI

5. The SI amends the 2019 Regulations. The 2019 Regulations (regulation 2) amend provision in the Human Tissue Act 2004. The effect therefore is that provision in the Human Tissue Act 2004 is consequently amended.
6. Section 32 of the Human Tissue Act 2004 is amended to reflect the Northern Ireland Protocol, under which Northern Ireland will be treated both as if it were a Member State (subject to the modifications to EU law made by the Northern Ireland Protocol), and as a constituent part of the UK.
7. It is the view of the Welsh Government that the provisions described in paragraph 6 above fall within the legislative competence of the Senedd in so far as they relate to the organ safety and quality.

Why it is appropriate for the SI to make this provision

8. There is no divergence between the Welsh Government and the UK Government (Department of Health and Social Care) on organ safety and quality policy. The SI amends the 2019 Regulations that were made on an England and Wales basis, with the consent of the Welsh Ministers, as part of the corrections exercise for a no-deal EU Exit to ensure the statute book continued to function correctly. Therefore, making separate SIs in Wales and England would lead to duplication, and unnecessary complication of the statute book. Consenting once again to a UK wide SI ensures that there is a single legislative framework across the UK which promotes clarity and accessibility for patients and providers. In these exceptional circumstances, the Welsh Government considers it appropriate that the UK Government legislates on our behalf in this instance.

Vaughan Gething MS
Minister for Health and Social Services

15 October 2020