



Llywodraeth Cymru
Welsh Government

WRITTEN STATEMENT BY THE WELSH GOVERNMENT

TITLE **The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2020**

DATE **15 October 2020**

BY **Rebecca Evans MS, Minister for Finance and Trefnydd**

SO30C – SI laid in Parliament which amends legislation in a devolved area

The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2020 – affirmative

Policy Overview of the SI

This SI amends the Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 (“the 2019 Regulations”) which were made last year 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 SI applies to the whole of the UK and is due to come into force immediately before implementation period completion date (11pm 31 December 2020).

The SI amends the 2019 Regulation so as to enable the provisions amended by those Regulations to continue to operate effectively in light of the Northern Ireland Protocol following the implementation period.

There is no policy divergence between the Welsh Government and UK Government in relation to this SI.

The Law which is being amended

- Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019

The purpose of the amendments

The relevant provisions of the SI are to implement 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. The provisions restrict the changes being made by the 2019 Regulations to Great Britain (GB), meaning that the current law remains in place for Northern Ireland.

The SI and accompanying Explanatory Memorandum, setting out the effect of each amendment is available here:

[The Human Tissue \(Quality and Safety for Human Application\) \(Amendment\) \(EU Exit\) Regulations 2020](#)

Any impact the SI may have on the Senedd's legislative competence and/or the Welsh Ministers' executive competence

The SI amends an EU Exit SI in relation to human tissue quality and safety. The SI has no impact on the Welsh Ministers' executive competence or the Senedd's legislative competence. The SI does not involve the transfer of any functions to or from the Welsh Ministers nor does it confer any new functions on the Welsh Ministers.

Why consent was given

There is no divergence between the Welsh Government and the UK Government (Department of Health and Social Care) on tissue 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.