Llywodraeth Cymru
Welsh Government

WRITTEN STATEMENT
BY
THE WELSH GOVERNMENT

TITLE **The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019**

DATE **22 November 2018**

BY **Julie James AM, Leader of the House and Chief Whip**

The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 ("the Regulations")

The Law which is being amended
The Regulations will amend:

(a) the Human Tissue Act 2004
(b) the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006; and
(c) the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

Any impact the SI may have on the Assembly's legislative competence and/or the Welsh Ministers' executive competence
This SI contains provisions which enable the Welsh Ministers to exercise functions in relation to Wales without encumbrance. It also contains provisions whereby the Welsh Ministers could provide consent to the Secretary of State to exercise functions in relation to Wales on their behalf.

Functions transferred to the Secretary of State with consent would constitute functions of a Minister of the Crown for the purposes Schedule 7B to Government of Wales Act 2006. This therefore may be a relevant consideration in the context of the Assembly's competence to legislate in the future in these areas.

The purpose of the amendments
The purpose of the amendments is to correct deficiencies in legislation relating to human tissues arising from the UK leaving the European Union.

Regulation 3 amends the Human Tissue (Quality and Safety for Human Application) Regulations 2007 to insert a new section relating to the traceability, quality and safety of imports, notification of serious adverse events and reactions, and various technical

requirements. The new regulation states that the ‘appropriate authority’ may prescribe the requirements in these areas. The appropriate authority is defined in relation to Wales as the Welsh Ministers or the Secretary of State acting with the consent of the Welsh Ministers. These regulations would set the procedures for ensuring that all tissues and cells procured, processed, stored or distributed in the UK, all relevant data relating to products and materials coming into contract with those tissues and cells, can be traced from the donor to the recipient and vice versa and technical requirements, including licensing or authorisation of tissue establishments; quality systems; training; and other areas.

The SI and accompanying Explanatory Memorandum, setting out the effect of each amendment is available here:
http://www.legislation.gov.uk/ukdsi/2019/9780111174821/contents

Why consent was given
There is no divergence between the Welsh Government and the UK Government on the policy for the correction. Therefore, making separate SIs in Wales and England would lead to duplication, and unnecessary complication of the statute book. Consenting to a UK wide SI ensures that there is a single legislative framework across the UK which promotes clarity and accessibility during this period of change. In these exceptional circumstances, the Welsh Government considers it appropriate that the UK Government legislates on our behalf in this instance.

A Statutory Instrument Consent Memorandum has also been laid in the National Assembly in respect of the amendments to the Human Tissue Act 2004.