



Llywodraeth Cymru
Welsh Government

WRITTEN STATEMENT BY THE WELSH GOVERNMENT

TITLE **The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019**

DATE **22 November 2018**

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

The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 (“the Regulations”)

The [retained EU] Law which is being amended

The regulations will amend:

- The Blood Quality and Safety Regulations 2005

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

This SI confers powers on the Secretary of State and Welsh Ministers in relation to certain quality and safety standards and technical requirements relating to the collection, testing, processing, storage and distribution of blood and blood components. There is no effect on the Assembly’s legislative competence or Welsh Ministers’ executive competence.

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 arising from the UK leaving the European Union relating to Blood Quality and Safety:

Regulation 13 amends the Blood Quality and Safety Regulations 2005 to insert a new section regarding provisions in relation to setting standards and requirements in respect of blood and blood components collected and tested for the purpose of and use in autologous transfusion; including establishing standards and specifications for a quality system to be

carried out by a blood establishment; standards of quality and safety for the collection, testing, processing, storage and distribution of blood and blood components; traceability requirements; notification of serious adverse reactions and events; and various other technical requirements.

The new regulation states that the 'appropriate authority' may by regulations make provisions 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.

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

<http://www.legislation.gov.uk/ukdsi/2019/9780111174814/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.