STATUTORY INSTRUMENTS

2016 No. 604

HEALTH AND SAFETY

The Blood Safety and Quality (Amendment) Regulations 2016

Made - - - -	*24th May 2016*
Laid before Parliament	*27th May 2016*
Coming into force - -	*18th July 2016*

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**a**).The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to health protection measures regulating the use of material of human origin(**b**).

Citation, commencement and interpretation

1. These Regulations may be cited as the Blood Safety and Quality (Amendment) Regulations 2016 and shall come into force on 18th July 2016.

Amendment of the Schedule to the Blood Safety and Quality Regulations 2005

2.—(1) The Schedule to the Blood Safety and Quality Regulations 2005(**c**) is amended as follows.

(2) In Part 3 (eligibility criteria for donors of whole blood and blood components), in the table in paragraph 2.2.1, for the entry for West Nile Virus (WNV) substitute—

"West Nile Virus (WNV) (*)	28 days after leaving a risk area of locally acquired West Nile Virus unless an individual Nucleic Acid Test (NAT) is negative"

(3) In Part 5 (quality and safety requirements for blood and blood components), in the table in paragraph 2, in the column headed "acceptable results for quality measures", in each place it appears, for "6.4–7.4 corrected for 22°C, at the end of the shelf life" substitute "Minimum 6.4 corrected for 22°C, at the end of the shelf life".

(**a**) 1972 c. 68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and section 3(3) of and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c.7).
(**b**) S.I. 2004/3037.
(**c**) S.I. 2005/50, to which there are amendments not relevant to these Regulations.

Signed by the authority of the Secretary of State for Health.

Jane Ellison,
Parliamentary Under-Secretary of State
Department of Health

24th May 2016

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Blood Safety and Quality Regulations 2005 (S.I. 2005/50) ("the 2005 Regulations") in order to implement Commission Directive 2014/110/EU amending Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations and Commission Implementing Directive 2011/38/EU amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life.

Regulation 2(2) amends Part 3 of the Schedule to the 2005 Regulations in order to transpose the changes made to Annex III to Directive 2004/33/EC by Directive 2014/110/EU. This allows testing for West Nile Virus as an alternative to a 28 day deferral period for blood donors returning from West Nile Virus affected areas.

Regulation 2(3) amends Part 5 of the Schedule to the 2005 Regulations in order to transpose the changes made to Annex V to Directive 2004/33/EC by Directive 2011/38/EU. This relaxes the quality control requirements for maximum pH values for units of platelets at the end of the shelf life.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, public or voluntary sectors is foreseen. A Transposition Note in relation to the implementation of the Directives is published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk. Copies may also be obtained from the Medicines and Healthcare products Regulatory Agency, 151 Buckingham Palace Road, Victoria, London, SW1W 9SZ.

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