EXPLANATORY MEMORANDUM TO

THE BLOOD SAFETY AND QUALITY (AMENDMENT) REGULATIONS 2016

2016 No. 604

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 These Regulations amend the Blood Safety and Quality Regulations 2005 (S.I. 2005/50) ("the principal Regulations") to transpose Commission Directives 2014/110/EU and 2011/38/EU. These Directives allow testing for West Nile Virus ("WNV") as an alternative to a 28 day deferral period for prospective blood donors returning from WNV affected areas, and relaxed the quality control requirements for maximum pH values for platelets concentrates at the end of the shelf life.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments.

3.1 None.

Other matters of interest to the House of Commons

3.2 As this instrument is subject to the negative procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

4. Legislative Context

4.1 This Instrument transposes into UK law amendments made to Commission Directive 2004/33/EC ("the EU Blood Directive") by Commission Directives 2014/110/EU and 2011/38/EU.

4.2 The principle Regulations implement Directive 2002/98/EC of the European Parliament and Council setting out standards of quality and safety for the collection and testing of human blood and blood products, whatever their intended purpose, and their processing, storage and distribution when intended for transfusion. They also implement Commission Directive 2004/33/EC, which contains certain technical requirements relating to blood and blood components.

4.3 Part 3 of the Schedule to the Principal Regulations provides details of the eligibility criteria to be met by blood donors for a donation to be made to the UK blood establishments, including temporary deferral criteria for donors with an infectious illness or donors leaving an area where an infectious illness is present.

4.4 Part 5 of the Schedule sets out standards of safety and quality for the processing, storage and distribution of blood and blood components, including the minimum and maximum pH levels for units of platelets at the end of the shelf life.

4.5 These Regulations amend the principal 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.

5. Extent and Territorial Application

5.1 This instrument extends to all of the United Kingdom.

5.2 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

What is being done and why

7.1 The EU Blood Directive established a deferral period for prospective donors of 28 days after leaving an area where there is on-going transmission of WNV to humans. Directive 2014/110/EU amended this to give the option to apply a screening test for WNV as an alternative to the 28 day deferral period for people returning from WNV-affected areas. This increases supplies of donated blood from this donor pool if required.

7.2 WNV is a mosquito-borne virus, widely distributed in Africa and Western Asia, and has spread across the USA and Canada (since 2000) and many Northern European countries (since 2010). It is not present in the UK (except in occasional returning visitors from affected areas) as the UK does not currently have the resident type of mosquito to transmit it. Most human cases are either asymptomatic (76%) or result in only mild flu-like symptoms with full recovery, but 1 in 150-200 develop a more severe form of the disease which may culminate in fatal encephalitis, particularly in the elderly or immunosuppressed. WNV can be transmitted by blood transfusion as the virus is present in blood during infection, clearing by 28 days post-infection (hence the 28 day deferral period for blood donation for those who have visited affected areas).

7.3 The EU Blood Directive and UK Blood Safety and Quality Regulations 2005 required that travellers returning from an area with on-going transmission of WNV in humans should be deferred from blood donation for 28 days. There was no provision within this Directive for WNV testing in place of deferral. However, outbreaks in Europe from 2010 led to the implementation of testing in order to maintain a sufficient blood supply in some affected countries.

7.4 A risk assessment performed by the UK Blood Services in 2011 concluded that there was a risk of up to 2.65% of donors in the UK being deferred because of travel to a WNV affected area, and, as up to 30% of donors who are deferred never donate again, this was a potential risk to supply. NHS Blood and Transplant (NHSBT) therefore implemented WNV screening in 2012 to screen donors returning from WNV affected areas. An NHSBT review in 2015 concluded that the cost of new donor recruitment to replace lost donors as a result of deferral, if that measure were used alone, would be

approximately 7 times the cost of screening. The 2014 amendment to the 2005 Blood Directive, therefore, updates the regulations to allow WNV screening which already takes place in the UK.

7.5 The EU Blood Directive also set minimum and maximum pH (a figure for expressing the acidity or alkalinity of a solution) levels for units of platelets at the end of the shelf life. Directive 2011/83/EU removed the maximum pH value for all platelet concentrates. This means that platelets that exceed this pH level no longer need to be discarded, reducing the amount of stored platelets that are lost. Evidence shows that the function of platelets is not affected by a higher pH therefore the removal of the upper pH limit serves to prevent platelet from being discarded unnecessarily where there is no detriment to their quality.

7.6 Platelets are needed to help blood to clot and are used to prevent or treat bleeding in patients whose own platelets are not being produced in sufficient numbers, for example, patients who are having massive transfusion due to major haemorrhage when the level of platelets in the body could be diluted, or patients on chemotherapy for leukaemia. Platelets have only a 7 day shelf life between collection and transfusion because their functionality decreases during storage. Stocks therefore need to be constantly replaced. There needs to be a balance between having enough stock and therefore having the platelets available when required (sometimes urgently) and having too much stock so that they have to be discarded after 7 days. NHSBT is reimbursed by hospitals for the cost of each platelet unit issued to them and this cost is not recovered if the platelets are discarded. Reducing wastage is therefore beneficial to reduce healthcare costs and make the most of the donor's gift.

Consolidation

7.7 The changes made by this Instrument are small in scale, and the making of them has not changed the Department's position on whether the principal Regulations they amend require consolidation.

8. Consultation outcome

8.1 This only impacts on the Blood Transfusion Services and they have been consulted on the proposed changes and are content. As the amendments are technical in nature and a result of the need to keep up to date with EU legislative requirements, no wider consultation has been carried out in relation to these Regulations.

9. Guidance

9.1 This only impacts on the Blood Transfusion Services and guidance will be updated to reflect the change.

10. Impact

10.1 There is no impact on business, charities or voluntary bodies.

10.2 The impact on the public sector is negligible and deregulatory in nature.

10.3 An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

11.1 The legislation does not apply to activities that are undertaken by small businesses.

12. Monitoring & review

12.1 The Department monitors the implementation and efficient operation of the Regulations amended by this instrument.

13. Contact

13.1 Paul Holley at the Department of Health (Telephone: 0207210 5560 or email: paul.holley@dh.gsi.gov.uk).