EXPLANATORY MEMORANDUM TO

THE BLOOD SAFETY AND QUALITY (MODIFICATION) REGULATIONS 2009

2009 No. 3307

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

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 These Regulations amend the Blood Safety and Quality Regulations 2005 (SI 2005/50) ("the principal Regulations") to transpose Commission Directive 2009/135/EC. The Directive allows temporary relaxations of two eligibility criteria for blood donors in the context of a risk of shortage of blood and blood components caused by the influenza A(H1N1) pandemic.

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

3.1 This instrument will breach the 21 day rule for JCSI for Statutory Instruments.

3.2 There are several reasons for this. To begin with the Directive evolved out of discussions in the 3rd quarter of 2009 between the European Commission and Member States about the risks to the supply of blood and blood components in the event of the A(H1N1) pandemic taking hold. This led to a meeting in late October 2009 during which the Commission was able to outline its proposals and the relevant criteria to be applied in relaxing the eligibility criteria for blood donation to take place. Member States voted in favour of these proposals and the Directive was adopted on 3rd November 2009 as an emergency measure in order to protect public health. Until the point at which Member States were aware of the conditions that would apply there was no practical information which would have assisted the Department in preparing the Regulations.

3.3 It was necessary to liaise with relevant bodies and with devolved administrations and there have been some drafting issues which have regrettably delayed the instrument being made earlier.

3.4 These measures need to be transposed into national law by the 31st December 2009 at the latest in accordance with the Directive. This means that it is now not possible to implement the Directive within the timescales normally required by both JCSI and the Merits Committee.

3.5 Although these provisions have not been necessary thus far, the UK blood establishments ("UKBTS") may need to make use of the relaxations in donor criteria before 31st December 2009 if the A(H1N1) influenza pandemic

produces shortages of blood and blood components. It is therefore necessary to have the Regulations in place as soon as possible so that UKBTS are able to deal with that eventuality.

3.6 These provisions will help ensure that given the uncertainties about the rate and extent of H1N1 influenza infection across the United Kingdom, UKBTS may implement the temporary relaxation of these two donor acceptance criteria, quickly should the need arise, in order to maintain the supply of blood and blood components.

4. Legislative Context

4.1 The principal Regulations were made under section 2(2) of the European Communities Act 1972 and transpose into UK law four European Directives (2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC) relating to standards of quality and safety for the collection and testing of human blood and blood components, whatever their intended purpose, and their processing, storage and distribution when intended for transfusion.

4.2 Under the principal Regulations the Secretary of State is responsible for authorising and inspecting blood establishments, monitoring compliance of hospital blood banks and carrying out haemovigilance. The Secretary of State for Health has agreed that the Medicines and Healthcare products Regulatory Agency (MHRA) an executive agency of the Department of Health should perform these functions.

4.3 This instrument is being made in accordance with the provisions of Directive 2009/135/EC. 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 UKBTS. The measures in this instrument will ensure that during the influenza A(H1N1) pandemic if certain conditions apply, two of the eligibility criteria for donations of blood for donors can be relaxed to help avoid shortages of blood and blood components.

4.4 The instrument provides for the temporary measures to be lifted once stock levels reach a specified level again. However in accordance with the Directive these cannot apply after 30th June 2010.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

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 instrument transposes into UK law Commission Directive 2009/135/EC of 3 November 2009, which came into force on 5 November 2009. Member States are required to transpose and bring into force the Directive by 31 December 2009. A transposition note is attached at Annex 1.

7.2 The Directive is an urgent temporary measure intended to assist in the maintenance of stocks of blood and blood components during the 2009/2010 influenza A (H1N1) pandemic and applies until 30 June 2010.

7.3 The Directive allows temporary relaxations of two eligibility criteria for blood donors in the context of a risk of shortage of blood and blood components caused by the influenza A (H1N1) pandemic. The temporary relaxations reduce the minimum acceptable haemoglobin levels in donors' blood to no less than 120g/l for females (down from 125g/l) and 130g/l for males (down from 135g/l). Also, the deferral period during which a donation of blood should not be accepted from a person who has recovered from flu-like symptoms is reduced to 7 days after recovery from such symptoms (down from 14 days).

- ***Consolidation***

7.4 The principal Regulations came into force on 8 February 2005 and have been amended subsequently by instruments transposing Commission Directives 2005/61/EC and 2005/62/EC also by instruments implementing MHRA fee changes, miscellaneous amendments and corrections. The European Commission has identified and is currently considering further amendments to blood Directive 2004/33/EC, which will require transposition, and in view of this it is difficult to commit to a specific timescale for future consolidation of the principal Regulations.

8. Consultation outcome

8.1 The MHRA consulted between 5 February 2009 and 20 March 2009 on a wide range of changes to legislation in anticipation of the influenza A (H1N1) pandemic. Included in the consultation package were proposals concerning blood and blood components for temporary relaxations of two reporting obligations in the principal Regulations. These reporting obligations were purely national and did not implement any European provisions. This consultation pre-dated the European Commission's current legislative initiative, which culminated on 28 October 2009, in a unanimous vote in favour of the relaxations by the Blood Regulatory Committee representing the opinion of all Member States. In view of the need for an urgent response to the potential impact of the influenza A (H1N1) pandemic on blood supplies, it is not practicable to carry out another public consultation.

9. Guidance

9.1 The UKBTS has been fully involved since the outset in developing a UK response to the influenza A(H1N1) pandemic and its potential impact on the supply of blood and blood components. The UKBTS are fully aware and supportive of the temporary relaxations.

10. Impact

10.1 The impact on business, charities or voluntary bodies is negligible.

10.2 The impact on the public sector is unlikely to go beyond existing expenditure on blood donor recruitment and retention publicity campaigns by the UKBTS.

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

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 The instrument will implement in the UK European provisions permitting temporary relaxations in blood donor eligibility criteria in response to the influenza A(H1N1) pandemic and its potential impact on the supply of blood and blood components. If certain specified conditions are met and under the authority of the Secretary of State, the UKBTS may implement the relaxations if they are necessary to maintain stocks of blood and blood components. The UKBTS will notify the MHRA when they apply these relaxations. These provisions will apply until 30 June 2010 after which time donor eligibility criteria will revert to those in place before the coming into force of this instrument.

13. Contact

13.1 Nigel Goulding at the Medicines and Healthcare products Regulatory Agency Tel: 020-7084-2131 or email: nigel.goulding@mhra.gsi.gov.uk can answer any queries regarding the instrument.

Annex 1

Transposition Note

The Blood Safety and Quality (Modification) Regulations 2009 transpose Commission Directive 2009/135/EC of 3 November 2009 allowing temporary derogation to certain eligibility criteria for whole blood and blood components donors laid down in Annex III to Directive 2004/33/EC in the context of a risk of shortage caused by the Influenza A(H1N1) pandemic.

These Regulations do not go beyond what is necessary to implement the Directive, including making consequential changes to domestic legislation to ensure its coherence in the area to which they apply.

Articles	Objectives	Implementation	Responsibility
1.1	Provides that member states confronted with a risk of shortage in the supply of blood and blood components directly due to the A(H1N1) Influenza pandemic may on a temporary basis provide for derogations from the requirements of Directive 2004/33/EC (Directive on certain technical requirements for blood and blood components) that – (a) the minimum levels of haemoglobin necessary in a donors blood are reduced from 125 g/l to 120 g/l for women and from 135 g/l to 130 g/l or men; (b) the deferral period after which a person may give blood after being cleared of flu-like symptoms is reduced from 14 days to 7 days.	The criteria relating to donors of blood and blood components is set out in regulation 7(2)(d) and Part 3 to the Schedule of the Blood Safety and Quality Regulations 2005 (S.I. 2005/50), "the principal Regulations". New paragraph (2A) in regulation 2(b) of the Blood Safety and Quality Regulations 2009 will modify the principal Regulations so that the derogations in Directive 2009/135/EC can apply when certain conditions are satisfied.	Secretary of State
1.2	The implementation of the derogations shall be subject to conditions including the criteria and methodology as to when	New paragraph (2B) in regulation 2(b) of the Blood Safety and Quality Regulations 2009 provides the conditions necessary	As above

	the derogations will be necessary and when the derogations will cease to apply.	for the derogation to apply. New paragraph (2C) in the same regulation also identifies how the period over which the derogation applies is to be determined.	
2.1	Provides for member states to transpose the Directive by 31 December 2009.	Regulation 1(3) of the Blood Safety and Quality Regulations 2009 provides for the Directive to come into force on 15th December 2009.	As above
3	Provides for the Directive to apply until 30 June 2010.	Regulation 1(3) of the Blood Safety and Quality Regulations 2009 provides that the transposed provision shall apply until 30 June 2010.	As above