STATUTORY INSTRUMENTS

# 2009 No. 3307

# HEALTH AND SAFETY

## The Blood Safety and Quality (Modification) Regulations 2009

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| *Made - - - -* | *15th December 2009* |
| *Laid before Parliament* | *15th December 2009* |
| *Coming into force - -* | *16th December 2009* |

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 is the designated Minister for the purposes of that section in relation to health protection measures regulating the use of material of human origin(**b**).

### Citation, commencement, interpretation and duration

**1.**—(1) These Regulations may be cited as the Blood Safety and Quality (Modification) Regulations 2009 and shall come into force on 16th December 2009.

(2) In these Regulations "the principal Regulations" means the Blood Safety and Quality Regulations 2005(**c**);

(3) For the period from 16th December 2009 to 30th June 2010, the principal Regulations shall apply with the modifications specified in regulation 2 of these Regulations.

### Modification of regulation 7 of the principal Regulations

**2.** In regulation 7 of the principal Regulations (blood establishment requirements)—

(a) in paragraph (2)(d), before "apply" insert "except where paragraphs (2A) to (2C) applies,";

(b) after paragraph (2) insert—

"(2A) Where the conditions in paragraph (2B) are satisfied, a blood establishment shall apply the eligibility criteria for donors of blood and blood components in accordance with Part 3 of the Schedule (eligibility criteria for donors of whole blood and blood components) subject to the following modifications applying for the period in paragraph (2C)—

(a) in paragraph 1.2 (haemoglobin levels in donors blood), "125" is modified to "120" and "135" is modified to "130"; and

(b) in paragraph 2.2.1 (duration of deferral period), in relation to the entry for "Flu-like illness" the period in column 2 is modified from "2 weeks" to "1 week".

(2B) The conditions are that—

(**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 by section 3(3) of and Part 1 of Schedule 1 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.

(a) the latest "HPA Weekly National Influenza Report" published by the Health Protection Agency(**a**) states that—

(i) the weekly GP consultation rate for flu-like illness is equal to or greater than 200 cases for every 100,000 persons in the UK population; or

(ii) the weekly estimated incidence of flu-like illness is equal to or greater than 200,000 new cases a week; and

(b) the Secretary of State—

(i) is satisfied that there is a serious risk of shortage or an actual risk of shortage in the supply of blood and blood components directly due to the A(H1N1) influenza pandemic; and

(ii) has advised the blood establishment that the eligibility criteria for donors of whole blood and blood components may be modified in accordance with paragraph (2A).

(2C) For the purpose of paragraph (2A) the period shall begin on the date that the conditions in paragraph (2B) are satisfied and shall end on the date following the date on which the blood establishment has notified the Secretary of State that stock levels of blood and blood components for all groups are equal to or exceed 5 days supply.".

Signed by the authority of the Secretary of State for Health

*Gillian Merron*
Minister of State,
Department of Health

15th December 2009

(**a**) The Health Protection Agency was established under section 1 of the Health Protection Agency Act 2004 (c.17). The HPA Weekly National Influenza Report ("the Report") draws together many sources of information from across the UK to give an overall picture of influenza activity across the UK. The Report is published weekly on Thursday and is available from the Health Protection Agency's website www.hpa.org.uk.

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations modify the Blood Safety and Quality Regulations 2005 ("the principal Regulations"), which implement Directive 2002/98/EC of the European Parliament and of the Council setting out the standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components(**a**) and related Commission Directives.

Regulations 1 and 2 modify the principal Regulations to implement Commission Directive 2009/135/EC(**b**) ("the Directive") allowing temporary derogations to certain eligibility criteria for donors of whole blood and blood components in the context of any shortage in the supply caused by the influenza A(H1N1) pandemic. In particular these modifications provide that—

— when certain conditions are satisfied, a blood donation may be accepted from persons with slightly lowered blood haemoglobin levels and also from donors giving blood one week after symptoms of flu-like illness had ended;

— the conditions are that the levels of GP consultations for flu-like illness and incidence of flu-like illness in the UK population are above threshold level and the Secretary of State is satisfied that there are risks to the supply of blood and blood components due to the A(H1N1) influenza pandemic and has subsequently advised the blood establishment that the eligibility criteria for donors may be modified as described above;

— any modification of the eligibility criteria under these Regulations shall only apply for the period beginning from the date that the conditions are satisfied to the date after the date on which the blood establishment notifies the Secretary of State that levels of blood or blood components are equal to or exceed 5 days supply;

— in accordance with the Directive these Regulations shall cease to apply after 30th June 2010.

An Impact Assessment has not been prepared in respect of this instrument as it has negligible impact on the private and voluntary sectors. A Transposition Note in relation to the implementation of the Directive has been placed in the libraries of both Houses of Parliament and copies may be obtained from the Medicines and Healthcare products Regulatory Agency, Room 16-111 Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

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(**a**) OJ No. L33, 8.2.2003, p.30.
(**b**) OJ No. L288, 4.11.2009, p.7.

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