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STATUTORY INSTRUMENTS

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**2007 No. 604**

**HEALTH AND SAFETY**

**The Blood Safety and Quality (Amendment) Regulations 2007**

*Made* - - - - 28th February 2007

*Laid before Parliament* 7th March 2007

*Coming into force* - - 1st April 2007

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(1) and section 56(1) and (2) of the Finance Act 1973(2).

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(3).

The Treasury has consented to the making of these Regulations as required by section 56(1) of the Finance Act 1973.

**Citation, commencement and interpretation**

1.—(1) These Regulations may be cited as the Blood Safety and Quality (Amendment) Regulations 2007 and shall come into force on 1st April 2007.

(2) In these Regulations, “the principal Regulations” means the Blood Safety and Quality Regulations 2005(4).

**Amendment of regulation 12B of the principal Regulations**

2. In regulation 12B of the principal Regulations (requirement to report serious adverse reactions and events), in paragraph (4), for sub-paragraph (c) substitute the following sub-paragraph—

“(c) submits a complete report to the Secretary of State on serious adverse events in any calendar year by no later than 1st April in the following calendar year, using the format set out in Section C of Part 8 of the Schedule.”.

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(1) 1972 c.68. Under section 57(1) of the Scotland Act 1998 (c.46), despite the transfer to Scottish Ministers of functions in relation to implementing obligations under Community law in relation to devolved matters, the functions of the Secretary of State in relation to implementing these obligations continues to be exercisable by him as regards Scotland.

(2) 1973 c.51.

(3) S.I. 2004/3037.

(4) S.I. 2005/50, as amended by S.I. 2005/1098 and 2898 and 2006/2013.

### **Amendment of regulation 16 of the principal Regulations**

3. In regulation 16 (records to be kept by Secretary of State)—
- (a) in paragraph (1), in sub-paragraph (c), for “regulation 7(1)(e)” substitute “regulation 12B”;
  - and
  - (b) in paragraph (2), in sub-paragraph (a), for “regulation 9(1)(f)” substitute “regulation 12B”.

### **Amendment of regulation 22 of the principal Regulations**

4.—(1) Regulation 22 of the principal Regulations (fees) shall be amended as follows.

- (2) In paragraph (2)—
- (a) in sub-paragraph (a), for “£2,444” substitute “£2,688”;
  - (b) in sub-paragraph (b), for “£400” substitute “£449”; and
  - (c) in sub-paragraph (c), for “£304” substitute “£387”.
- (3) In paragraph (2A), in sub-paragraph (b), for “£375” substitute “£432”.
- (4) In paragraph (3)—
- (a) in sub-paragraph (a), for “£8,729” substitute “£13,153”;
  - (b) in sub-paragraph (b), for “£5,557” substitute “£8,402”;
  - (c) in sub-paragraph (c), for “£2,698” substitute “£4,120”;
  - (d) in sub-paragraph (d), for “£1,518” substitute “£2,353”;
  - (e) in sub-paragraph (e), for “£4,048” substitute “£6,143”; and
  - (f) in sub-paragraph (f), for “£7,590” substitute “£11,449”.
- (5) In paragraph (3A), for “£400” substitute “£600”.
- (6) In paragraph (3C), in sub-paragraph (c), for “£375” substitute “£432”.
- (7) In paragraph (5)—
- (a) in sub-paragraph (a), for “£759” substitute “£1,126”;
  - (b) in sub-paragraph (b), for “£2024” substitute “£3,071”; and
  - (c) in sub-paragraph (c), for “£3795” substitute “£5,724”.
- (8) In paragraph (5B)—
- (a) in sub-paragraph (a), for “£2,000” substitute “£2,996”;
  - (b) in sub-paragraph (b), for “£3,000” substitute “£4,494”; and
  - (c) in sub-paragraph (c), for “£4,000” substitute “£5,992”.
- (9) In paragraph (5C)—
- (a) in sub-paragraph (a), for “£500” substitute “£750”;
  - (b) in sub-paragraph (b), for “£1,250” substitute “£1,875”; and
  - (c) in sub-paragraph (c), for “£2,000” substitute “£3,000”.

Signed by authority of the Secretary of State for Health

28th February 2007

*Caroline Flint*  
Minister of State  
Department of Health

We consent,

28th February 2007

*Frank Roy and Claire Ward*  
Two of the Lords Commissioners of Her  
Majesty's Treasury

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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## EXPLANATORY NOTE

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

These Regulations further amend 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<sup>(5)</sup> and related Commission Directives<sup>(6)</sup>.

Regulation 2 corrects an error in regulation 12B of the principal Regulations, which imposes requirements on blood establishments, hospital blood banks and facilities where blood transfusion takes place to report serious adverse reactions and events. Regulation 2 ensures that such establishments, blood banks and facilities must make an annual report to the Secretary of State on serious adverse events using the format specified in Part 8 of the Schedule to the Regulations.

Regulation 3 corrects cross-references in regulation 16 of the principal Regulations (records to be kept by the Secretary of State), so as to ensure that the obligation to keep records of notifications of serious adverse reactions and events by blood establishments, hospital blood banks and transfusion facilities applies to notifications made under regulation 12B.

Regulation 4 amends regulation 22 of the Regulations and increases the fees payable by blood establishments and hospital blood banks in relation to authorisation, operation, haemovigilance and inspection. The overall average fee increase is around 40%.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ and copies have been placed in the libraries of both Houses of Parliament.

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<sup>(5)</sup> OJNo. L33, 8.2.2003, p.30.

<sup>(6)</sup> Commission Directive [2004/33/EC](#) (OJ No. L91, 30.3.2004), Commission Directive [2005/61/EC](#) (OJ No. L256, 1.10.2005, p.32) and Commission Directive [2005/62/EC](#) (OJ No. L256, 1.10.2005, p.41).