STATUTORY INSTRUMENTS

## 2006 No. 2013

## The Blood Safety and Quality (Amendment) Regulations 2006

## Amendment of regulation 1 of the principal Regulations

**2.** In regulation 1 of the principal Regulations (citation, commencement and interpretation), in paragraph (3)—

(a) for the definition of "health service hospital", substitute—

"health service hospital" means a hospital owned or managed by a health service body;";

(b) for the definition of "independent hospital", substitute—

""independent hospital"-

- (a) in England and Wales, has the same meaning as in section 2 of the Care Standards Act 2000(1),
- (b) in Scotland, has the same meaning as in section 2 of the Regulation of Care (Scotland) Act 2001(2), and
- (c) in Northern Ireland, has the same meaning as in article 2 of the Health and Personal Social Services (Quality, Improvement and Regulation)(Northern Ireland) Order 2003(3)
- (c) for the definition of "registered person", substitute—

""registered person" means the person registered as the manager of an independent hospital, a care home or an independent clinic following an application to be registered as such pursuant to—

- (a) section 12(3) of the Care Standards Act 2000,
- (b) section 7(1) of the Regulation of Care (Scotland) Act 2001, or
- (c) article 13(1) of the Health and Personal Social Services (Quality, Improvement and Regulation)(Northern Ireland) Order 2003"; and
- (d) insert, in the appropriate alphabetical places, the following definitions—

""biomedical research institution" means any body which carries out biomedical research;

"care home"—

- (a) in England and Wales, has the same meaning as in section 3 of the Care Standards Act 2000,
- (b) in Scotland, has the same meaning as in section 2 of the Regulation of Care (Scotland) Act 2001, and

<sup>(</sup>**1**) 2000 c.14.

<sup>(</sup>**2**) 2001 asp. 8.

<sup>(3) 2003</sup> N. 431( N.I).

(c) in Northern Ireland, has the same meaning as in article 2 of the Health and Personal Social Services (Quality, Improvement and Regulation)(Northern Ireland) Order 2003;

"Commission Directive 2005/62/EC" means Commission Directive 2005/62/EC of 30th September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments(4);

"facility" means-

- (a) a hospital,
- (b) any other facility or service owned or managed by a health service body,
- (c) a care home,
- (d) an independent clinic,
- (e) a manufacturer, or
- (f) a biomedical research institute;

"imputability" means the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused, or that a serious adverse reaction in a donor can be attributed to the donation process;

"independent clinic"-

- (a) in England and Wales, has the same meaning as in section 2 of the Care Standards Act 2000,
- (b) in Scotland, has the same meaning as in section 2 of the Regulation of Care (Scotland) Act 2001, and
- (c) in Northern Ireland, has the same meaning as in article 2 of the Health and Personal Social Services (Quality, Improvement and Regulations)(Northern Ireland) Order 2003;

"issue" means the provision of blood or blood components by a blood establishment or a hospital blood bank for transfusion to a recipient;

"manufacturer" means a person who-

- (a) holds a licence under section 8(2) of the Medicines Act 1968(5) to manufacture medicinal products;
- (b) holds an authorisation to manufacture an investigational medicinal product granted pursuant to regulation 36 of the Medicines for Human Use (Clinical Trials) Regulations 2004(6); or
- (c) falls within the definition of "manufacturer" in paragraph (1) of regulation 2 of the Medical Devices Regulations 2002(7);

"person responsible for the management of a facility" means-

- (a) in the case of a hospital, facility or service which is owned or managed by an NHS body, that body,
- (b) in the case of an independent hospital, an independent clinic or a care home, the registered person,

<sup>(4)</sup> O.J. L 256 1.10.2005 p 14.

<sup>(5) 1968</sup> c. 67, relevant amendments to section 8 have been made by S.I. 2004/1031, 2005/50 and 2789.

<sup>(6)</sup> S.I. 2004/1031.

<sup>(7)</sup> S.I. 2002/618 relevant amending instruments are S.I. 2003/1697 and 2005/2759.

(c) in the case of a manufacturer or a biomedical research institution, the manufacturer or biomedical research institution;

"person responsible for the management of a reporting establishment" means a blood establishment, the person responsible for the management of a facility or the person responsible for the management of a hospital blood bank;

"recipient" means a person who has been transfused with blood or blood components;

"reporting establishment" means the blood establishment, the hospital blood bank or the facility where the transfusion takes place;

"third country" means any country other than a Member State; and

"traceability" means the ability to trace each individual unit of blood or blood component from the donor to its final destination (whether this is a recipient, a manufacturer of medicinal products or disposal) and from its final destination back to the donor;".