STATUTORY INSTRUMENTS

2017 No. 1320

HEALTH AND SAFETY

The Blood Safety and Quality (Amendment) Regulations 2017

Made - - - -	*20th December 2017*
Laid before Parliament	*22nd December 2017*
Coming into force - -	*15th February 2018*

The Secretary of State has been designated for the purpose of section 2(2) of the European Communities Act 1972(**a**) in relation to health protection measures regulating the use of material of human origin(**b**).

The Secretary of State for Health makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Blood Safety and Quality (Amendment) Regulations 2017 and come into force on 15th February 2018.

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

Amendment of regulation 7 of the principal Regulations

2. In regulation 7 of the principal Regulations (blood establishment requirements), in paragraph (1)(b), after "Commission Directive 2005/62/EC(**d**)" insert "and which gives effect to the requirements in respect of the use of good practice guidelines set out in Article 2.2 of that Directive(**e**)".

Amendment of regulation 9 of the principal Regulations

3. In regulation 9 of the principal Regulations (hospital blood bank requirements), in paragraph (1)(b), after "Commission Directive 2005/62 EC" insert "and which gives effect to the requirements in respect of the use of good practice guidelines set out in Article 2.2 of that Directive".

(**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 Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c. 7).
(**b**) S.I. 2004/3037.
(**c**) S.I. 2005/50; relevant amending instruments are S.I. 2006/2013, S.I. 2008/941 and S.I. 2011/1043.
(**d**) OJ L No 256, 01.10.2005, p 41.
(**e**) Paragraph 2 of Article 2 of Commission Directive 2005/62/EC was substituted by Article 1 of Commission Directive (EU) 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments.

Signed by authority of the Secretary of State for Health.

Jackie Doyle-Price
Parliamentary Under-Secretary of State,
Department of Health

20th December 2017

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Blood Safety and Quality Regulations 2005 ("the principal Regulations") to implement Commission Directive (EU) 2016/1214(**a**) ("the 2016 Directive") which amends Directive 2005/62/EC which contains technical requirements relating to blood establishments.

Regulation 2 amends regulation 7 of the principal Regulations to provide that the quality system maintained by blood establishments must incorporate good practice guidelines of the type mentioned in Article 2.2 of the 2005 Directive, as amended by the 2016 Directive. A model for such guidelines have been jointly developed by the European Commission and the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe and published by the Council of Europe(**b**).

Regulation 3 makes a similar amendment to regulation 9 of the principal Regulations for hospital blood banks.

A full impact assessment has not been produced for this instrument as no, or no significant impact, on the private, voluntary or public sectors is foreseen.

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(**a**) OJ No L 199, 26.07.2016, p 14.
(**b**) This can be found at: :https://www.edqm.eu/sites/default/files/goodpracticeguidelines-19th_edition_guide_preparation_use_qa_blood_components-december2016.pdf

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