STATUTORY INSTRUMENTS

2019 No. 4

EXITING THE EUROPEAN UNION
HEALTH AND SAFETY

The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019

Made - - - - 8th January 2019

Coming into force in accordance with regulation 1

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018(**1**).

In accordance with paragraph 1(1) of Schedule 7 to that Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

Citation and commencement

1. These Regulations may be cited as the Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 and come into force on exit day.

Amendment of the Blood Safety and Quality Regulations 2005

2. The Blood Safety and Quality Regulations 2005(**2**) are amended as follows.

3. In regulation 1, in paragraph (3)—

(a) insert in the appropriate places the following definitions—

> ""good practice guidelines" means the 19th edition of the Good Practice Guidelines for Blood Establishments Required to Comply with Directive 2005/62/EC(**3**);";
>
> ""quality system" means the organisational structure, responsibilities, procedures, processes, and resources for implementing quality management and, for this purpose, "quality management" means the co-ordinated activities to direct

(**1**) 2018 c. 16.
(**2**) S.I. 2005/50. Relevant amendments are made by S.I. 2006/2013, 2009/3307, 2011/1043 and 2017/1320.
(**3**) https://www.edqm.eu/sites/default/files/goodpracticeguidelines-19th_edition_guide_preparation_use_qa_blood_components-december2016.pdf. Hard copies may be obtained from the Ministerial Correspondence and Public Enquiries Unit, Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU.

and control an organisation with regard to quality at all levels within the blood establishment;";

(b) in the definition of "third country" for "a Member State" substitute "the United Kingdom".

4. After regulation 1 insert—

"**Modification of provisions of the Annex to Commission Directive 2005/62/EC**

1A.—(1) For the purposes of these Regulations, the Annex to Commission Directive 2005/62/EC is to be read with the modifications specified in the following paragraphs.

(2) Paragraph 2.5 is to be read as if the reference to compliance with the Directives mentioned in that paragraph was a reference to compliance with the requirements which those Directives would require to be imposed if those Directives formed part of domestic law.

(3) Paragraph 4.3 is to be read as if the reference to—

(a) the requirements of Council Directive 93/42/EEC and Directive 98/79/EC were a reference to the requirements of the Medical Devices Regulations 2002(**4**);

(b) third countries were a reference to countries other than the United Kingdom.

(4) Paragraph 6.1.1 is to be read as if the reference to the requirements set out in Annexes II and III to Directive 2004/33/EC were a reference to the requirements set out in Parts 2 and 3 of the Schedule.

(5) Paragraph 6.2.2 is to be read as if the reference to third countries were a reference to countries other than the United Kingdom.

(6) Paragraph 6.3.2 is to be read as if the reference to the requirements set out in Annex IV to Directive 2002/98/EC were a reference to the requirements set out in regulation 7(7).

(7) Paragraph 6.3.3 is to be read as if the reference to a test mentioned in Annex IV to Directive 2002/98/EC were a reference to a test for the infections mentioned in regulation 7(7)(c).

(8) Paragraph 6.5.2 is to be read as if—

(a) the reference to requirements in Article 14 of Directive 2002/98/EC and Commission Directive 2005/61/EC were a reference to the requirements set out in regulation 8;

(b) the words "The label for a final blood component shall comply with the requirements of Annex III to Directive 2002/98/EC." were omitted.

(9) Paragraph 6.5.3 is to be read as if the reference to compliance with Article 7 of Directive 2004/33/EC were a reference to compliance with regulation 7(3) (in relation to labelling), regulation 8 and paragraph 3.2 of Part 4 of the Schedule.

(10) Paragraph 6.6.1 is to be read as if the reference to mandatory requirements set out in the Directive were a reference to the requirements set out in these Regulations.

(11) Paragraph 9.1 is to be read as if the reference to the standards set out in Annex V of Directive 2004/33/EC were a reference to the standards set out in Part 5 of the Schedule.

(12) Paragraph 9.2 is to be read as if the reference to regulatory requirements were a reference to the requirements in regulation 12B.

(13) Paragraph 10.1 is to be read as if for "according to approved procedures" there were substituted "and in accordance with the procedures required by the quality system established and maintained by the blood establishment".

(**4**) S.I. 2002/618.

References to the requirements set out in the Annex to Commission Directive 2005/62/EC

1B. References in regulations 7, 9 and 13 to the requirements set out in the Annex to Commission Directive 2005/62/EC are to be read as a reference to the requirements which that Annex would require to be imposed if that Annex formed part of domestic law.".

5. In regulation 2—

(a) for the heading substitute "Scope of the Regulations";

(b) omit paragraph (1).

6. In regulation 6, in paragraph (2)(b), for the words from ", in an establishment" to the end of the sub-paragraph substitute—

"in one or more establishments authorised—

(i) under regulation 4; or

(ii) in a third country where the safety and quality standards for establishments authorised in that country are equivalent to those for establishments authorised in the United Kingdom under regulation 4,

to undertake activities related to the collection or testing (or both) of blood and blood components, or to their preparation, storage or distribution.".

7. In regulation 7—

(a) in paragraph (1)(b)—

(i) for "complies with the Community standards" substitute "meets the standards";

(ii) for "good practice guidelines set out in Article 2.2 of that Directive" substitute "the good practice guidelines";

(b) after paragraph (1) insert—

"(1A) For the purposes of paragraph (1)(b), references to the competent authority or to competent authorities in the Annex to Commission Directive 2005/62/EC must be read as references to the Secretary of State.";

(c) in paragraph (3)(a), for "into the European Union" substitute "from a third country".

8. In regulation 8—

(a) in paragraph (1), for "from outside the European Union" substitute "from a third country";

(b) in paragraph (2), for "into the European Union" substitute "from a third country".

9. In regulation 9—

(a) in paragraph (1)(b)—

(i) for "complies with the Community standards and requirements set out" substitute "meets the standards and requirements set out in";

(ii) for "good practice guidelines set out in Article 2.2 of that Directive" substitute "the good practice guidelines";

(b) after paragraph (1) insert—

"(1A) For the purposes of paragraph (1)(b), references to the competent authority or to competent authorities in the Annex to that Directive must be read as references to the Secretary of State.".

10. In regulation 13—

(a) omit "into the United Kingdom";

(b) in paragraph (a)—

(i) omit "Community";

(ii) after "2005/62/EC", insert "and for the purpose of this paragraph, references to the competent authority or competent authorities in the Annex to that Directive must be read as references to the Secretary of State".

11. Omit regulation 16A.

12. In regulation 23, in paragraph (1), for the words from "he shall" to the end of that paragraph substitute "he must notify blood establishments that those criteria must be adopted".

13. After regulation 23 insert—

"**Regulations relating to the quality and safety of blood and blood components**

23A.—(1) The appropriate authority may by regulations make provision in relation to—

(a) standards and requirements relating to a quality system for blood establishments, including provision amending regulations 7(1)(b) and 13(a) in so far as those provisions relate to those standards and requirements;

(b) information to be provided to donors of blood and blood components, including provision amending regulation 7(2)(a) and Part A of Part 2 of the Schedule;

(c) information to be obtained from donors of blood and blood components, including provision amending regulation 7(2)(b) and Part B of Part 2 of the Schedule;

(d) eligibility criteria for donors of blood and blood components, including provision amending regulation 7(2)(d) and Part 3 of the Schedule;

(e) storage, transport and distribution requirements, including provision amending regulation 7(3)(b) and paragraphs 1 and 2 of Part 4 of the Schedule;

(f) quality and safety requirements for blood and blood components, including provision amending regulation 7(3)(c) and Part 5 of the Schedule;

(g) traceability requirements, including provision amending regulation 8 and Part 6 of the Schedule;

(h) deferral criteria for donors of blood and blood components, including provision amending paragraphs 2.1 to 2.4 of Part 3 of the Schedule;

(i) the requirements applicable to autologous transfusions, including provision amending paragraph 3 of Part 4 of the Schedule; and

(j) the procedure for notifying serious adverse reactions and events and notification format, including provision amending regulation 12B and Parts 7 and 8 of the Schedule.

(2) The provision that may be made in regulations under paragraph (1) includes provision to modify, or further modify, the Annex to Commission Directive 2005/62/EC as it applies by virtue of these Regulations.

(3) In paragraph (1), "appropriate authority" means—

(a) in relation to England, the Secretary of State;

(b) in relation to Wales—

(i) the Welsh Ministers; or

(ii) the Secretary of State acting with the consent of the Welsh Ministers;

(c) in relation to Scotland—

(i) the Scottish Ministers; or

(ii) the Secretary of State acting with the consent of the Scottish Ministers;

(d) in relation to Northern Ireland—

(i) the Department of Health in Northern Ireland;

(ii) the Secretary of State acting with the consent of that Department;

(e) in relation to the whole of the United Kingdom, the Secretary of State acting with the consent of the Welsh Ministers, the Scottish Ministers and the Department of Health in Northern Ireland.

Scope and nature of powers

23B.—(1) Regulations made by the Secretary of State or the Welsh Ministers under regulation 23A are to be made by statutory instrument.

(2) For regulations made under regulation 23A by the Scottish Ministers, see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010(**5**) (Scottish statutory instruments).

(3) Any power of the Department of Health in Northern Ireland to make regulations under regulation 23A is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979(**6**).

(4) Any power in regulation 23A to make regulations includes power to make—

(a) different provision for different purposes;

(b) consequential, supplementary, incidental, transitional, transitory or saving provision.

Scrutiny of regulations made by the Secretary of State

23C.—(1) Except as specified in paragraph (2), a statutory instrument containing regulations made by the Secretary of State under regulation 23A is subject to annulment in pursuance of a resolution of either House of Parliament.

(2) A statutory instrument containing regulations made under regulation 23A(1)(h) may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.

Scrutiny of regulations made by the Welsh Ministers

23D.—(1) Except as specified in paragraph (2), a statutory instrument containing regulations made by the Welsh Ministers under regulation 23A is subject to annulment in pursuance of a resolution of National Assembly for Wales.

(2) A statutory instrument containing regulations made under regulation 23A(1)(h) may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, the National Assembly for Wales.

Scrutiny of regulations made by the Scottish Ministers

23E.—(1) Except as specified in paragraph (2), regulations made by the Scottish Ministers under regulation 23A are subject to the negative procedure (see section 28 of the Interpretation and Legislative Reform (Scotland) Act 2010 ("the 2010 Act") (instruments subject to the negative procedure)).

(**5**) 2010 asp 10.
(**6**) S.I. 1979/1573 (N.I. 12).

(2) Regulations made by the Scottish Ministers under regulation 23A(1)(h) are subject to the affirmative procedure (see section 29 of the 2010 Act (instruments subject to the affirmative procedure)).

Scrutiny of regulations made by the Department of Health in Northern Ireland

23F.—(1) Except as specified in paragraph (2), regulations made by the Department of Health in Northern Ireland under regulation 23A are subject to negative resolution within the meaning of section 41(6) of the Interpretation Act (Northern Ireland) 1954(**7**) (definitions for parliamentary purposes) as if they were a statutory instrument within the meaning of that Act.

(2) Regulations may not be made by that Department under regulation 23A(1)(h) unless a draft of the regulations has been laid before and approved by a resolution of the Northern Ireland Assembly.".

14. In Part 3 of the Schedule, in paragraph 1, for "the quality management provisions in Articles 11, 12 and 13 of Directive 2002/98/EC" substitute "the requirements in regulation 7".

Signed by authority of the Secretary of State for Health and Social Care.

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

8th January 2019

(**7**) 1954 c. 33.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers in section 8(1) of the European Union (Withdrawal) Act 2018 (c.16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a) and (g) of that Act) arising from the withdrawal of the United Kingdom from the European Union.

They amend the Blood Safety and Quality Regulations 2005 (S.I. 2005/50) relating to the safety and quality of blood and blood components; both so as to make necessary amendments to enable those Regulations to continue to operate after the withdrawal of the United Kingdom from the European Union and to enable the appropriate authority to make regulations relating to the safety and quality of blood and blood components.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.