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 [M1].

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.

Marginal Citations

M1 2018 c. 16.

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.

Commencement Information

I1 Reg. 1 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**) see reg. 1

Amendment of the Blood Safety and Quality Regulations 2005

2. The Blood Safety and Quality Regulations 2005 [M2] are amended as follows.

Commencement Information

I2 Reg. 2 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M2 S.I. 2005/50. Relevant amendments are made by S.I. 2006/2013, 2009/3307, 2011/1043 and 2017/1320.

[F1 3. In regulation 1, in paragraph (3)—

(a) after the definition of "qualified health professional" insert —

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

(b) for the definition of "third country", substitute—

""third country" means—

(a) in relation to the import of blood or blood components into Great Britain, a country other than the United Kingdom; and

(b) in relation to the import of blood or blood components into Northern Ireland, a country other than Northern Ireland or a member State;".**]**

F1 Reg. 3 substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **3**

Commencement Information

I3 Reg. 3 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

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 **[F2**as they apply in relation to Great Britain**]**, 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 **M3**;

(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 ".

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

1B. References in regulations 7, 9 and 13 **[**[F3], as they apply in relation to Great Britain,**]** 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.".

F2 Words in reg. 4 inserted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **4(a)**

F3 Words in reg. 4 inserted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **4(b)**

Commencement Information

I4 Reg. 4 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M3 S.I. 2002/618.

[[F4]**5.** In regulation 2—

(a) for the heading substitute "Designation of the competent authority for Northern Ireland and scope of the Regulations";

(b) for paragraph (1) substitute—

"(1) The Secretary of State is designated the competent authority in relation to Northern Ireland for the purposes of the Directive.".**]**

F4 Reg. 5 substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **5**

Commencement Information

I5 Reg. 5 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

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

[F5"—

(i) in relation to Great Britain, in one or more establishments authorised under regulation 4, or in a country where the safety and quality standards for establishments authorised in that country are equivalent to those for establishments authorised under regulation 4, to undertake activities relating to the collection or testing (or both) of blood and blood components, or to their preparation, storage or distribution;

(ii) in relation to Northern Ireland, in one or more establishments authorised in a member State, or under regulation 4, to undertake such activities."**]**.

F5 Words in reg. 6 substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **6**

Commencement Information

I6 Reg. 6 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

7. In regulation 7—

[F6(a) for paragraph (1)(b) substitute—

"(b) establish and maintain a quality system for blood establishments—

(i) in relation to Great Britain, that is based on the principles of good practice, which meets the standards and requirements set out in the Annex to Commission Directive 2005/62/EC and which gives effect to the Good Practice Guidelines for Blood Establishments Required to Comply with Directive 2005/62/EC published in the 20th edition of the Guide to the preparation, use and quality assurance of blood components;

(ii) in relation to Northern Ireland, that is based on the principles of good practice, which complies with the Community standards and requirements set out in the Annex to Commission Directive 2005/62/EC 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;";**]**

(b) after paragraph (1) insert—

"(1A) **[**F7In relation to Great Britain, 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 ".

F6 Reg. 7(a) substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **7(a)**

F7 Words in reg. 7(b) substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **7(b)**

Commencement Information

I7 Reg. 7 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

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 ".

Commencement Information

I8 Reg. 8 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

9. In regulation 9—

[F8(a) for paragraph (1)(b) substitute—

"(b) establish and maintain a quality system for the hospital blood bank—

(i) in relation to Great Britain, that is based on the principles of good practice, which meets the standards and requirements set out in the Annex to Commission Directive 2005/62/EC and which gives effect to the Good Practice Guidelines for Blood Establishments Required to Comply with Directive 2005/62/EC published in the 20th edition of the Guide to the preparation, use and quality assurance of blood components;

(ii) in relation to Northern Ireland, that is based on the principles of good practice, which complies with the Community standards and requirements set out in the Annex to Commission Directive 2005/62/EC 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;";**]**

(b) after paragraph (1) insert—

"(1A) **[**F9In relation to Great Britain, 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.".

F8 Reg. 9(a) substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **8(a)**

F9 Words in reg. 9(b) substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **8(b)**

Commencement Information

I9 Reg. 9 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

10. In regulation 13—

[[F10](a) in the heading, for "the United Kingdom" substitute "Great Britain";

(aa) for the opening words substitute—

"Any person who imports blood or blood components into Great Britain from a third country must ensure that each unit which they import—";**]**

(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 ".

F10 Reg. 10(a)(aa) substituted for reg. 10(a) (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **9**

Commencement Information

I10 Reg. 10 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[[F11]**10A.** After regulation 13 insert—

"**Import of blood and blood components into Northern Ireland**

13A. Any person who imports blood or blood components into Northern Ireland from a third country must ensure that each unit which they import—

(a) has been prepared in accordance with standards equivalent to the standards and requirements set out in the Annex to Commission Directive 2005/62/EC; and

(b) meets standards of quality and safety equivalent to those laid down in Part 5 of the Schedule.".**]**

F11 Reg. 10A inserted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **10**

Commencement Information

I11 Reg. 10A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[[F12]**11.** For regulation 16A substitute—

"**Requirement that the Secretary of State communicate certain information in respect of Northern Ireland to other competent authorities**

16A. The Secretary of State must, in respect of Northern Ireland, communicate to the competent authorities of member States such information as is appropriate with regard to serious adverse reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded.".".**]**

F12 Reg. 11 substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **11**

Commencement Information

I12 Reg. 11 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F13 12.—(1) In regulation 23—

(a) at the end of the heading insert "in relation to Great Britain";

(b) in paragraph (1), for the words from "he shall" to the end of that paragraph substitute "the Secretary of State must, in relation to Great Britain, notify blood establishments that those criteria must be adopted.".

(2) After regulation 23 insert—

"**Specific epidemiological situations in relation to Northern Ireland**

23ZA.—(1) Where the Secretary of State is aware of a specific epidemiological situation, such as an outbreak of a disease, which may affect the safety of blood donations, and as a result of which the Secretary of State considers that specific deferral criteria for the collection of blood donations should be adopted, the Secretary of State must in relation to Northern Ireland—

(a) notify blood establishments that those criteria must be adopted; and

(b) notify the Commission of—

(i) the epidemiological situation; and

(ii) the additional deferral criteria which blood establishments are required to adopt in relation to it pursuant to sub-paragraph (a).

(2) A blood establishment shall adopt and comply with any criteria for additional tests notified to them by the Secretary of State pursuant to paragraph (1).".**]**

F13 Reg. 12 substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **12**

Commencement Information

I13 Reg. 12 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

13. [F14 After regulation 23ZA, as inserted by regulation 12(2), insert**]**—

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

23A.—(1) **[**F15An appropriate authority in Great Britain may by regulations make provision in relation to—**]**

[F16(a) standards and requirements relating to a quality system for blood establishments and hospital blood banks, including provision amending regulations 7(1)(b), 9(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 **[**F17regulations 7(3)(b), 9(1)(h)**]** 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 **[**F18regulations 8, 9(1)(e)**]** 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;

F19(d) . . . . . .

[F20(e) in relation to the whole of Great Britain, the Secretary of State acting with the consent of the Welsh Ministers and the Scottish Ministers**]**

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 [M4] (Scottish statutory instruments).

[F21](3) . . . . . .

(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)).

(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)).

. [F22] . . . . . ".

F14 Words in reg. 13 substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **13(a)**

F15 Words in reg. 13 substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **13(b)(i)**

F16 Words in reg. 13 substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **13(b)(ii)**

F17 Words in reg. 13 substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **13(b)(iii)**

F18 Words in reg. 13 substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **13(b)(iv)**

F19 Words in reg. 13 omitted (31.12.2020 immediately before IP completion day) by virtue of The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **13(b)(v)**

F20 Words in reg. 13 substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **13(b)(vi)**

F21 Words in reg. 13 omitted (31.12.2020 immediately before IP completion day) by virtue of The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **13(c)**

F22 Words in reg. 13 omitted (31.12.2020 immediately before IP completion day) by virtue of The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **13(d)**

Commencement Information

I14 Reg. 13 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M4 2010 asp 10.

[F23 14. In Part 3 of the Schedule, in paragraph 1, for the sentence beginning with "All such cases" substitute—

"All such cases must be clearly documented and subject to—

(a) in relation to Great Britain, the requirements in regulation 7;

(b) in relation to Northern Ireland, the quality management provisions in Articles 11, 12, and 13 of Directive 2002/98/EC.".**]**

F23 Reg. 14 substituted (31.12.2020 immediately before IP completion day) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1304), regs. 1, **14**

Commencement Information

I15 Reg. 14 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

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

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.

Changes to legislation:
There are currently no known outstanding effects for the The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019.