

Draft Regulations laid before Parliament under paragraphs 1 and 8F of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2020 No. 0000

**EXITING THE EUROPEAN UNION
HEALTH AND SAFETY**

**The Blood Safety and Quality
(Amendment) (EU Exit) Regulations 2020**

*Made - - - - - ***
Coming into force in accordance with regulation 1*

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 8(1) and 8C of the European Union (Withdrawal) Act 2018(1).

A draft of this instrument has been approved by a resolution of each House of Parliament, in accordance with paragraphs 1 and 8F(2) of Schedule 7 to the European Union (Withdrawal) Act 2018.

Citation and commencement

1. These Regulations may be cited as the Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020 and come into force immediately before IP completion day.

Amendment of the Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019

2. The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019(3) are amended as follows.

Substitution of regulation 3

3. For regulation 3 substitute—

“3. In regulation 1, in paragraph (3)—

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

(1) 2018 c. 16. The European Union (Withdrawal) Act 2018 was amended by the European Union (Withdrawal Agreement) Act 2020 (c. 1) (“the 2020 Act”); section 8C was inserted by section 21 of that Act.
(2) Paragraph 8F was inserted by paragraph 51 of Schedule 5 to the 2020 Act.
(3) S.I. 2019/4.

““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;”.

Amendment of regulation 4

4. In regulation 4—

- (a) in regulation 1A as inserted by regulation 4, in paragraph (1), after “these Regulations” insert “as they apply in relation to Great Britain”;
- (b) in regulation 1B as inserted by regulation 4, after “and 13” insert “, as they apply in relation to Great Britain,”.

Substitution of regulation 5

5. For regulation 5 substitute—

“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.”.

Amendment of regulation 6

6. In regulation 6, for the inserted text substitute—

“—

- (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.”.

Amendment of regulation 7

7. In regulation 7—

(a) for paragraph (a) substitute—

“(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⁽⁴⁾;
 - (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) in paragraph (1A) inserted by paragraph (b), for the words “For the purposes of” substitute “In relation to Great Britain, for the purposes of”.

Amendment of regulation 9

8. In regulation 9—

(a) for paragraph (a) substitute—

“(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) in paragraph (1A) inserted by paragraph (b), for the words “For the purposes of” substitute “In relation to Great Britain, for the purposes of”.

Amendment of regulation 10

9. In regulation 10, for paragraph (a) substitute—

“(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—”;

(4) https://www.edqm.eu/sites/default/files/medias/fichiers/Blood/good_practices_guidelines_for_blood_establishments-blood_guide_20th_may_2020.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.

Insertion of regulation 10A

10. After regulation 10, insert—

“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.”.”.

Substitution of regulation 11

11. For regulation 11, substitute—

“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.”.”.

Substitution of regulation 12

12. For regulation 12 substitute—

“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).”.”.

Amendment of regulation 13

13. In regulation 13—

- (a) for the opening words substitute “After regulation 23ZA, as inserted by regulation 12(2), insert”;
- (b) in regulation 23A as inserted by regulation 13—
 - (i) in paragraph (1), for the opening words substitute “An appropriate authority in Great Britain may by regulations make provision in relation to—”;
 - (ii) for paragraph (1)(a) substitute—
 - “(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;”;
 - (iii) in paragraph (1)(e), for “regulation 7(3)(b)” substitute “regulations 7(3)(b), 9(1)(h)”;
 - (iv) in paragraph (1)(g), for “regulation 8” substitute “regulations 8, 9(1)(e)”;
 - (v) omit paragraph (3)(d);
 - (vi) for paragraph (3)(e) substitute—
 - “(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”;
- (c) in regulation 23B as inserted by regulation 13, omit paragraph (3);
- (d) omit regulation 23F as inserted by regulation 13.

Substitution of regulation 14

14. For regulation 14 substitute—

“**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](#).”.”.

Address
Date

Name
Parliamentary Under Secretary of State
Department for Health and Social Care

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers in sections 8(1) and 8C 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, and in order to give effect to the Protocol on Ireland/Northern Ireland in the withdrawal agreement, respectively.

They amend the Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/4) so as to enable the provision amended by those Regulations to continue to operate effectively in light of the Ireland/Northern Ireland Protocol following IP completion day.

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