STATUTORY INSTRUMENTS

2019 No. 4

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

U.K.

13. **[**F1After regulation 23ZA, as inserted by regulation 12(2), insert**]**—

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

23A.—(1) **[**F2An appropriate authority in Great Britain may by regulations make provision in relation to—**]**

[F3(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 **[**F4regulations 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 **[**F5regulations 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;

F6(d) . . . . . .

[F7(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 M1 (Scottish statutory instruments).

F8(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)).

. [F9] . . . . . ”.

Textual Amendments

F1 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)**

F2 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)**

F3 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)**

F4 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)**

F5 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)**

F6 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)**

F7 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)**

F8 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)**

F9 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

I1 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

M1 2010 asp 10.

Changes to legislation:
There are currently no known outstanding effects for the The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019, Section 13.