#### STATUTORY INSTRUMENTS

## 2019 No. 4

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

### 7. In regulation 7—

[F1(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) [F2In 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".

### **Textual Amendments**

- F1 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)
- 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**

I1 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

Changes to legislation:
There are currently no known outstanding effects for the The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019, Section 7.