STATUTORY INSTRUMENTS

2019 No. 4

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

Amendment of the Blood Safety and Quality Regulations 2005

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(**1**);

(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.

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

(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 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.".