STATUTORY INSTRUMENTS

2005 No. 50

The Blood Safety and Quality Regulations 2005

Labelling of blood and blood components and traceability

8.—(1) A blood establishment shall ensure that the label on each unit of blood or blood component supplied by it, or imported by it **[**F1 from a third country**]**, shall contain the following information—

(a) the official name of the component;

(b) the volume or weight or number of cells in the component, as appropriate;

(c) a unique numeric or alphanumeric donation indication;

(d) the name of the producing blood establishment;

(e) the ABO Group, except in the case of plasma intended only for fractionation;

(f) the Rh D Group, either Rh D positive or Rh D negative, except in the case of plasma intended only for fractionation;

(g) the date or time of expiry, as appropriate;

(h) the temperature of storage;

(i) the name, composition and volume of any anticoagulant and any additive solution.

[F2(2) A blood establishment shall maintain, in relation to all blood and blood components collected or prepared by it (including blood and blood components which are imported by it **[**F3from a third country**]**)—

(a) records of the information referred to in paragraph (1) above;

(b) the records referred to in Part A of Part 6 to the Schedule; and

(c) such other records as are necessary to ensure full traceability of blood and blood components and identification of each single donation, unit and component.**]**

[F4(3) The records referred to in sub-paragraph (a) **[**F5of paragraph (2)**]** shall be maintained—

(a) in an appropriate and readable storage medium, and

(b) for a period of not less than 30 years.

(4) A blood establishment shall ensure that the traceability system in place in the blood establishment enables the tracing of blood and blood components to their location and processing stage.

(5) A blood establishment shall have in place a system to uniquely identify each donor, each blood unit collected and each blood component prepared, whatever its intended purpose, and the facilities to which a given unit of blood or blood component has been delivered.”.

(6) A blood establishment shall ensure, when it issues a unit of blood or blood components for transfusion, that the facility to which the unit of blood is issued has in place a procedure to verify that each unit of blood issued has been transfused to the intended recipient or, if not transfused, to verify its subsequent disposition.**]**

Textual Amendments

F1 Words in reg. 8(1) substituted (31.12.2020) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/4), regs. 1, **8(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Reg. 8(2) substituted (31.8.2006) by The Blood Safety and Quality (Amendment) Regulations 2006 (S.I. 2006/2013), regs. 1(1), **5(2)**

F3 Words in reg. 8(2) substituted (31.12.2020) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/4), regs. 1, **8(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F4 Reg. 8(3)-(6) inserted (31.8.2006) by The Blood Safety and Quality (Amendment) Regulations 2006 (S.I. 2006/2013), regs. 1(1), **5(3)**

F5 Words in reg. 8(3) inserted (1.5.2008) by The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 (S.I. 2008/941), regs. 1(1), **7**

Changes to legislation:
There are currently no known outstanding effects for the The Blood Safety and Quality Regulations 2005, Section 8.