STATUTORY INSTRUMENTS

2006 No. 2013

The Blood Safety and Quality (Amendment) Regulations 2006

Amendment of regulation 8 of the principal Regulations

5.—(1) Regulation 8 of the principal Regulations (labelling of blood and blood components and traceability) is amended as follows.

(2) For paragraph (2) substitute—

"(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 into the European Community)—

(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.".

(3) After paragraph (2), insert the following paragraphs—

"(3) The records referred to in sub-paragraph (a) 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.".