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 from outside the European Community, 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.

(2) A blood establishment shall keep such records of the information referred to in paragraph (1) above and such additional records as are necessary—

(a) for the identification of each single blood donation and each single blood unit and its components (including blood and blood components which are imported into the European Community); and

(b) to ensure full traceability to the point of delivery to a hospital,

for a period of not less than 30 years.