EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Blood Safety and Quality Regulations 2005 ("the principal Regulations"). The principal Regulations implement Directive 2002/98/EC of the European Parliament and Council setting out the standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components ("the Directive")(**1**) They also implement Commission Directive 2004/33/EC(**2**), which contains certain technical requirements relating to blood and blood components.

These Regulations further amend the principal Regulations to implement Commission Directive 2005/61/EC(**3**) and Commission Directive 2005/62/EC(**4**) which contain further technical requirements with regard to blood and blood components.

Regulation 2 amends regulation 1 of the principal Regulations to insert further definitions and to amend some of the definitions in the principal Regulations.

Regulation 3 amends regulation 3 of the principal Regulations to provide that the import of blood or blood components from a country outside the European Community may only be undertaken by a blood establishment or by a licensed manufacturer of medicines or a manufacturer of medical devices.

Regulation 4 amends regulation 7 of the principal Regulations to provide that the quality system maintained by blood establishments must comply with the requirements of Commission Directive 2005/62/EC and to require that blood establishments retain records of serious adverse events.

Regulation 5 amends regulation 8 of the principal Regulations to impose further requirements on blood establishments with regard to traceability (the tracing of individual blood donations from donor to recipient and vice versa) in accordance with the requirements of Commission Directive 2005/61/EC.

Regulation 6 amends regulation 9 of the principal Regulations to impose further requirements on hospital blood banks with regard to traceability in accordance with the requirements of Commission Directive 2005/61/EC, and to provide that the quality system maintained by hospital blood banks must comply with the requirements of Commission Directive 2005/62/EC.

Regulation 7 inserts new regulations 12A and 12B into the principal Regulations. Regulation 12A requires that facilities which receive blood (i.e care homes, independent clinics, hospitals and other NHS facilities and services, manufacturers of medicines and medical devices and biomedical research institutes) keep certain records. Regulation 12B requires that facilities which undertake blood transfusions report adverse events and reactions to the blood establishment from which the blood involved in the adverse incident was received, and to the Secretary of State.

Regulation 8 amends regulation 13 of the principal Regulations to provide that any person who imports blood and blood components imported into the European Community must ensure that that blood and those blood components have been prepared to equivalent standards to those set out in Commission Directive 2005/62/EC.

Regulations 9 and 10 extend the Secretary of State's obligations regarding inspection and record keeping, respectively, to include facilities. Regulation 11 imposes an obligation on the Secretary of

(**1**) OJ L 33, 8.2.2003, p30.
(**2**) OJ L91, 30.3.2004, p25.
(**3**) OJ L 256, 1.10.2005, p.32.
(**4**) OJ L 256, 1.10.2005, p 41.

State to notify details of serious adverse reactions and events to the competent authorities of other Member States in appropriate cases.

Regulations 12 to 14 amend regulations 17, 18 and 22 of the principal Regulations to provide, respectively, that the Secretary of State shall have power of entry into a facility, that breach of the obligations placed on facilities by regulations 12A and 12B shall be a criminal offence and that a fee shall be payable by a facility in respect of heamovigilance (except where a facility has made arrangements with a hospital blood bank that the blood bank will report adverse incidents on the facility's behalf) and for an inspection under these Regulations. Haemovigilance is the monitoring of serious adverse incidents by the Secretary of State in order to ensure that potentially contaminated products are removed from the distribution chain.

Regulation 15 provides for the Schedule to the principal Regulations to be amended to include certain technical requirements relating to haemovigilance.

A full Regulatory Impact Assessment of the effect that this instrument will have on the costs of business, and a Transposition Note in relation to the implementation of Directives 2005/61/EC and 2005/62/EC have been placed in the libraries of both Houses of Parliament and copies may be obtained from Department of Health, Area 530, Wellington House, 133-155 Waterloo Road London SE1 8UG.