EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Blood Safety and Quality Regulations 2005 (S.I. 2005/50) ("the principal Regulations"), which implement Directive 2002/98/EC of the European Parliament and of the Council setting out the standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components(**1**) and related Commission Directives(**2**).

Regulation 2 amends regulation 22 of the principal Regulations to increase the fees payable by blood establishments and hospital blood banks or facilities in relation to authorisation, operation, and haemovigilance. The overall average fee increase is around 1%. It also introduces a new fee for applications under regulation 12(1) of the principal Regulations to make written representations to, or appear before and be heard by, a person appointed by the Secretary of State.

An impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ and copies have been placed in the libraries of both Houses of Parliament.

(**1**) OJNo. L33, 8.2.2003, p.30 to which amendments have been made by Regulation (EC) No. 596/2009 of the European Parliament and of the Council (OJ No. L188, 18.7.2009, p.14).
(**2**) Commission Directive 2004/33/EC (OJ No. L91, 30.3.2004, p.25), Commission Directive 2005/61/EC (OJ No. L256, 1.10.2005, p.32) and Commission Directive 2005/62/EC (OJ No. L256, 1.10.2005, p.41).