EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Blood Safety and Quality Regulations 2005 ("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 and increases the fees payable by blood establishments and hospital blood banks or facilities in relation to authorisation, operation, and haemovigilance. It introduces new methods of calculating the rates, and new rates for inspections. The overall average fee increase is around 8%.

A full regulatory impact assessment of the effect that this instrument will have on the costs of the 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.
(**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).