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 corrects an error in regulation 12B of the principal Regulations, which imposes requirements on blood establishments, hospital blood banks and facilities where blood transfusion takes place to report serious adverse reactions and events. Regulation 2 ensures that such establishments, blood banks and facilities must make an annual report to the Secretary of State on serious adverse events using the format specified in Part 8 of the Schedule to the Regulations.

Regulation 3 corrects cross-references in regulation 16 of the principal Regulations (records to be kept by the Secretary of State), so as to ensure that the obligation to keep records of notifications of serious adverse reactions and events by blood establishments, hospital blood banks and transfusion facilities applies to notifications made under regulation 12B.

Regulation 4 amends regulation 22 of the Regulations and increases the fees payable by blood establishments and hospital blood banks in relation to authorisation, operation, haemovigilance and inspection. The overall average fee increase is around 40%.

A full regulatory 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.
(**2**) Commission Directive 2004/33/EC (OJ No. L91, 30.3.2004), 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).