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 Commission Directive 2004/33/EC(**2**), which contains certain technical requirements relating to blood standards.

Regulation 2 substitutes, in regulation 1(3) of the principal Regulations, a new definition of "blood establishment". The amendment has the effect that a person responsible for management of a hospital blood bank may also be a blood establishment for the purposes of the principal Regulations, if the hospital blood bank is carrying out activities which require an authorisation under regulation 3 of those Regulations (in particular, the collection, testing and processing of blood and blood components).

Regulation 3 amends regulation 6 of the principal Regulations, so as to enable the Secretary of State to require a blood establishment to remove a person acting as a "responsible person" under that regulation, if he considers that they are failing to carry out their duties adequately or at all.

Regulation 4 amends regulation 10 of the principal Regulations, so as to provide that the date on or before which a hospital blood bank must provide a report under that regulation, in relation to the reporting year 1st April 2005 to 31st March 2006, is 31st December 2005, and in relating to each subsequent reporting year, on 30th April following the end of that year.

Regulation 5 amends regulation 18(8) of the principal Regulations. Regulation 18(8) provides that the provision of regulation 18(7) making it an offence for a person to obstruct, or fail to comply with any requirements made of him by, an inspector acting under the Regulations shall not require a person to answer any question if it would incriminate his or her spouse. The amendment extends the protection against incrimination to civil partners (i.e. persons in a civil partnership).

Regulation 6 amends regulation 22 of the principal Regulations, which relates to fees payable in respect of blood establishments and hospital blood banks. In particular, regulation 6 provides: that blood establishments and hospital blood banks shall pay an annual haemovigilance fee of £156 for the reporting year 2005/6 and £375 in subsequent years; that hospital blood banks shall pay an annual fee of £400; for fees payable in respect of inspections of laboratories which carry out testing of blood or blood components on behalf of blood establishments or hospital blood banks; and that for blood establishments granted an authorisation before 8th November 2005 (the date the regulations are to apply to establishments previously licensed under the Medicines Act 1968), the first annual fee will be payable on 8th November 2006 and annually thereafter.

The increase in total annual fees payable by blood establishments by 2007 is 123% (from £304 to £679). The increase for hospital blood banks is from no fee to £775 by 2007 (or £400 if also authorised as a blood establishment).

A full regulatory impact assessment of the effect that these Regulations 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. Copies of the assessment have been placed in the library of each House of Parliament.

(**1**) OJNo. L33, 8.2.2003, p.30.
(**2**) OJ No. L191, 30.3.2004, p.25.