EXPLANATORY MEMORANDUM TO

THE BLOOD SAFETY AND QUALITY (AMENDMENT) (No. 2) REGULATIONS 2005

2005 No. 2898

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1. These Regulations further amend the Blood Safety and Quality Regulations 2005
(SI 2005/50) ("the principal Regulations") to make a number of changes to the rules governing the operation of blood establishments (establishments which collect, process and test human blood and blood components) and hospital blood banks (hospital units which store, distribute, and perform compatibility tests on, blood and blood components for use in hospitals) . They also make further provision for fees payable by such bodies and persons operating laboratories which carry out tests on behalf of such bodies ("contract laboratories").

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1. The Joint Committee reported regulations 22 and 24 of the principal Regulations for making an unexpected use of an enabling power. The Department indicated in its memorandum to the Joint Committee of 14 February 2005 that its policy had been revised and the principal Regulations would be amended accordingly. The principal Regulations will be amended so that a blood establishment granted an authorisation before 8 November 2005, when the principal Regulations come fully into force, will not be required to pay a periodic fee until 8 November 2006. The fee will then be payable on 8th November in each subsequent year.

3.2. The principal Regulations imposed a periodic fee of £304 on a blood establishment in respect of its authorisation. These Regulations introduce an annual charge to a blood establishment of £375 to cover the costs to the Medicines and Healthcare products Agency (MHRA) of operating a system for the receipt and assessment of reports of serious adverse events and reactions associated with blood and blood components (an activity known as haemovigilance). This represents an annual fee increase of 123%. The

MHRA is a trading fund established under the Government Trading Funds Act 1973 and the Secretary of State is required under the provisions of the Act to ensure that the costs of the services provided by the Agency are met from its income. It was not possible to assess the costs to the Agency of operating a haemovigilance system before the principal Regulations came into force.

3.3. The Regulations also provide for a hospital blood bank to be charged the annual MHRA haemovigilance fee of £375, plus a further annual fee of £400 to cover the costs to the MHRA of operating a system for the receipt and assessment of the annual compliance report to the Secretary of State, which is a requirement under regulation 10 of the principal Regulations. The total additional annual charge of £775 to a hospital blood bank is required, as stated earlier, to enable the MHRA to operate within the terms of its Trading Fund and once again, it was not possible to assess the costs to the Agency of operating a system for monitoring the compliance of a hospital blood bank before the principal Regulations came into force.

4. Legislative Background

4.1 The principal Regulations were made under section 2(2) of the European Communities Act 1972 and transpose into UK law two European Directives (2002/98/EC and 2004/33/EC) relating to standards of quality and safety for the collection and testing of human blood and blood components, whatever their intended purpose, and their processing, storage and distribution when intended for transfusion. The Secretary of State is responsible for authorising and inspecting blood establishments, monitoring compliance of hospital blood banks and carrying out haemovigilance. The Secretary of State for Health has agreed that MHRA (an executive agency of the Department of Health) should perform these functions.

4.2 This instrument is being made: to ensure that a hospital blood bank carrying out the collection, testing and processing of blood or blood components can be authorised as a blood establishment; to ensure that the Secretary of State can require the removal of a "responsible person" under regulation 6 of the principal Regulations if they fail to carry out their duties adequately or at all; to alter the dates on which annual compliance reports under regulation 10 of the principal Regulations must be provided to the Secretary of State; to extend the protection against incrimination of a person's spouse under regulation 18(8) of the principal Regulations to civil partners; and to provide for additional fees payable by blood establishments, hospital blood banks and contract laboratories.

5. Extent

5.1. This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1. No statement is required.

7. Policy background

7.1. The UK supports the Directives and has been instrumental in their development and negotiation. Much of their content is already current practice in UK Blood Services and the NHS. The principal Regulations significantly improve the assurances available about the safety and quality of the blood supply.

7.2. 580 organisations and interested parties were consulted on the proposed amendments to the principal Regulations. 14 responses were received, of which 10 offered substantive comments:

7.2.1. There was a general recognition of the need for the MHRA's operational costs for compliance monitoring of hospital blood banks and haemovigilance to be met. There were no explicit objections to the proposed additional fees. A number of consultees from the NHS commented on the desirability of central funding for the implementation of the Regulations. One comment concerned the original assessment by the Department of Health that implementation of the principal Regulations could be achieved with minimal additional cost. The Department of Health has advised the NHS that the administrative, financial and operational impact of implementing the principal Regulations will vary from hospital to hospital and depend significantly on the extent to which each is compliant with current requirements and best practice. Central funding is not available for implementation or developments such as IT systems for the traceability of blood and blood components. The Welsh Assembly has also advised that central funding is not available and hospital blood banks should have been or be developing quality systems under the Pathology Modernisation/Diagnostic Services strategy in Wales.

7.2.2. Consultees suggested that small hospital blood banks could be charged reduced annual compliance and haemovigilance fees. This suggestion was considered to be impracticable because the fixed costs to the MHRA of operating compliance monitoring and haemovigilance systems are not related directly to the size and scale of operation of individual hospital blood banks.

7.2.3. Serious Hazards of Transfusion (SHOT) a professional enquiry service funded by the blood services of England and Wales, raised issues concerning its continuing role and funding under the new arrangements. The MHRA has developed a web-based reporting system for serious adverse events and reactions with blood and blood components, which facilitates SHOT reporting by incorporating SHOT questionnaires. This provides a single reporting route for UK haemovigilance and enables SHOT to review and extract data for detailed manipulation and analysis.

8. Impact

8.1. A Regulatory Impact Assessment is attached to this memorandum.

8.2. The impact on the public sector is that NHS hospital blood banks will be charged annual fees to cover the operational costs to the MHRA of the receipt and assessment of annual compliance reports, and for the operation of a haemovigilance system for the receipt and assessment of reports of serious adverse events and serious adverse reactions to blood and blood components.

9. Contact

9.1. Nigel Goulding at the Medicines and Healthcare products Regulatory Agency,
Tel: 020 7084 2131 or e-mail: nigel.goulding@mhra.gsi.gov.uk can answer any queries regarding the instrument.

FULL REGULATORY IMPACT ASSESSMENT

1) Title of proposal

Amendment of the Blood Safety and Quality Regulations 2005 (SI 2005/50) ("the Principal Regulations")

2) Purpose and intended effect of measure

a) Objectives

To amend and correct the Blood Safety and Quality Regulations 2005 and to introduce provisions for the Medicines and Healthcare products Regulatory Agency (MHRA) to charge fees for regulatory activities carried out on behalf of the Secretary of State. The proposed amendments are as follows:

i) Provision of authority to charge fees for the inspection of third party testing laboratories that carry out testing on behalf of blood establishments.

ii) To change the requirements for the periodic fee associated with the authorisation of a blood establishment. A blood establishment granted an authorisation before 8 November 2005, when the Principal Regulations come into force, will not be required to pay a periodic fee before 8 November 2006.

iii) To provide authority for the removal of the Responsible Person named on the authorisation of a blood establishment, where the individual in question has failed to carry out the responsibilities of a Responsible Person required under the Principal Regulations.

iv) To require the submission to MHRA, by every hospital blood bank in the United Kingdom, of a report confirming compliance with the provisions of the Principal Regulations. This report will be required on or before 31 December 2005 and then on the 30 April 2007 and thereafter. The reporting year is defined as the 12 month period ending 31 March with reports to be submitted no later than the end of April.

v) To provide the authority for MHRA to charge hospital blood banks or blood establishments that are operating as a blood banks an annual fee to cover the operational costs associated with the receipt and assessment of annual compliance reports and to charge hospital blood banks and blood establishments an annual fee to cover the operation of a haemovigilance system for the receipt and assessment of reports of serious adverse events and serious adverse reactions.

vi) To amend the Principal Regulations to clarify that hospital blood banks in addition to operating as such may register as blood establishments if they wish to continue to collect and/or processes blood or blood components.

vii) The current regulations provide that no person should be obliged to answer any questions or give any information to an inspector if to do so might incriminate him or his spouse. In line with recent changes in the law to introduce the concept of civil partnership it is proposed to extend the benefit of this provision to include answers or information which might incriminate civil partners

b) Background

i) The Blood Safety and Quality Regulations transpose into UK law two European Blood Safety Directives: Directive 2002/98/EC which sets standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components (and amends Directive 2001/83/EC) and Directive 2004/33/EC, which implements certain technical requirements of Directive 2002/98/EC.

ii) Two further (technical) Commission Directives implementing the haemovigilance[1] and quality systems requirements of Directive 2002/98/EC are still under negotiation and after adoption will require separate transposition into UK law by amending Regulations.

iii) The Principal Regulations require and provide for:

(1) Blood establishments (primarily the national blood services of England, Wales, Scotland and Northern Ireland - the "UK Blood Services") to be authorised and inspected, a process very similar to the existing arrangements operated by the MHRA under the Medicines Act. The Directive and the Regulations define a blood establishment as an organisation which collects and tests blood and blood components, whatever their intended purpose; and processes, stores and distributes blood and blood components when they are intended for transfusion.

(2) Hospital blood banks to establish systems for quality management and haemovigilance and the MHRA to have powers to monitor compliance. A hospital blood bank is defined in the Directive and the Regulations as any unit within a hospital which stores and distributes and may perform compatibility tests on, blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities. The Regulations do not require authorisation or routine inspection of blood banks. However, inspections of blood banks "for cause" may be carried out by the MHRA. Any blood banks or blood establishments that are operating as blood banks are required

[1] Haemovigilance consists of a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients and the epidemiological follow-up of donors.

to submit an annual report to MHRA which sets out what systems they have in place to ensure compliance with their obligations under the regulations

(3) Blood establishments and hospital blood banks to report to the MHRA any serious adverse events[2] or serious adverse reactions[3] related to blood and blood components.

iv) The Principal Regulations came into force on 8 February 2005; however, they will not apply fully until 8 November 2005. From that date, under the Regulations, the Secretary of State will be responsible for authorising and inspecting blood establishments, monitoring compliance of hospital blood banks and carrying out haemovigilance. These functions will be performed by the MHRA.

v) The Principal Regulations already contain provisions for blood establishments to be charged fees for authorisations, routine inspections and non routine inspections and for hospital blood banks to be charged for non routine "for cause" inspections. The amending Regulations will add provisions to charge fees for:

(1) The inspection of third party testing laboratories.
(2) The receipt and assessment of annual compliance reports from hospital blood banks or blood establishments that are operating as blood banks.
(3) The receipt and assessment of reports of serious adverse events and serious adverse reactions from hospital blood banks and blood establishments (to be charged on an annual fee basis).

c) Rationale for Government Intervention

The UK is under an obligation to transpose European Directives into national legislation. Failure to transpose fully, or within the required timescales, could result in the European Commission taking infraction proceedings against the UK. This could result in the UK being subject to financial penalties whilst it remains in breach of its obligations as an EU Member State.

In the Regulatory Impact Assessment for the Principal Regulations (available at: http://www.dh.gov.uk/assetRoot/04/10/80/12/04108012.pdf) the quality and safety of blood and blood components were described as being amongst the best in the world; nevertheless, the use of blood and blood components, like most other medical procedures was never free of risk. Whilst the UK sought to establish as safe a system as possible, it was recognised that 100%

[2] A serious adverse event is defined as an unintended occurrence associated with the collection, testing processing, storage and distribution of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.

[3] A serious adverse reaction is defined as an unintended response in a donor or in a patient associated with the collection or transfusion of blood components that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity.

certainty was unachievable. It was considered that the Principal Regulations should significantly improve the assurances available about the safety and quality of the blood supply.

The proposed amendments to the Principal Regulations fulfil the following:

i) The requirement that the MHRA, a Trading Fund established under the Government Trading Funds Act 1973, is required to recover the costs of the services it provides; for instance, by charging direct fees.
ii) The need to ensure that blood establishment periodic fees do not become due until 12 months after the coming into force date of the Principal Regulations.
iii) The need to ensure that a Responsible Person, who has failed to carry out his responsibilities under the Principal Regulations, can be removed from a blood establishment authorisation.

3) Consultation

a) Within Government

i) The European Blood Safety Directives and the Principal Regulations were subject to formal consultation and Parliamentary scrutiny. The proposed amending Regulations make certain changes which are considered desirable to more effectively implement the requirements of the directive and to ensure that appropriate fees are charged for the various types of regulatory activity provided for by the regulations

b) Public Consultation

i) A formal 9 week public consultation exercise was carried out between 1 August 2005 and 30 September 2005 (MLX 327); the consultation included a partial RIA. 580 organisations and interested parties were consulted.

ii) 14 responses were received from consultees, of which 10 offered substantive comments. Respondees were based in hospital blood banks in the NHS, the private sector, the blood service and another government department. 2 consultees restricted their comments to the proposed Amending Regulations; the remainder also commented to a greater or lesser degree on the scope and implementation of the Principal Regulations.

iii) There was a general recognition of the need for the MHRA's operational costs for compliance monitoring of hospital blood banks and haemovigilance to be met and there were no explicit objections to the proposed additional fees. A number of consultees from the NHS commented on the desirability of central funding for the implementation of the Regulations. One comment concerned the original assessment by the Department of Health that implementation of the principal Regulations could be achieved with minimal additional cost. The Department of Health

has advised the NHS that the administrative, financial and operational impact of implementing the principal Regulations will vary from hospital to hospital and depend significantly on the extent to which each is compliant with current requirements and best practice. Additional central funding is not available for implementation or developments such as IT systems for the traceability of blood and blood components. The Welsh Assembly has also advised that central funding is not available and hospital blood banks should have been or be developing quality systems under the Pathology Modernisation/Diagnostic Services strategy in Wales.

iv) Consultees suggested that small hospital blood banks could be charged reduced annual compliance and haemovigilance fees. This suggestion was considered to be impracticable because the fixed costs to the MHRA of operating compliance monitoring and haemovigilance systems are not related directly to the size and scale of operation of individual hospital blood banks.

v) Serious Hazards of Transfusion (SHOT) a professional enquiry service funded by the blood services of England and Wales, raised issues concerning its continuing role and funding under the new arrangements. The MHRA has developed a web-based reporting system for serious adverse events and reactions with blood and blood components, which facilitates SHOT reporting by incorporating SHOT questionnaires. This provides a single reporting route for UK haemovigilance and enables SHOT to review and extract data for detailed manipulation and analysis.

vi) The comments received have been reflected in this RIA where appropriate.

4) Options

a) Option 1 - Do nothing. The proposed amendments clarify and amend the Principal Regulations further. The MHRA would be in breach of the terms of its Trading Fund Order if it did not recover the costs of providing regulatory services as the Competent Authority under the Directive and Regulations. Therefore, to do nothing is not an option.

b) Option 2 – Amend the Principal Regulations only in respect of the periodic fee for blood establishments. This option would ensure equity in respect of the periodic fee for blood establishments, but would not address the remaining issues. This option, as with Option 1, could result in a breach of the Trading Fund Order

c) Option 3 – Amend the Principal Regulations and introduce further amendments to address the other issues identified above and provide authority for MHRA to levy fees for services as required by the MHRA Trading Fund Order. This is the preferred option, as it amends the Principal Regulations to ensure that the system of regulation established in the principal regulations will work more effectively, and, ensures MHRA is able to comply with the Government Trading Funds Act 1973. It removes the possibility of a breach of the MHRA Trading Fund Order

5) Cost and Benefits

a) Sectors and groups affected

i) Public Sector

(1) The UK Blood Service

The UK Blood Service will be affected by the proposed amendments concerning blood establishments: the change of date for when periodic fees become payable and the power for a Responsible Person to be removed from an authorisation for failing to discharge his duties and the annual fee associated with the operation of a haemovigilance system for reports of serious adverse events and serious adverse reactions.

(2) Hospital blood banks in the NHS

Hospital blood banks in the NHS will be affected by: the requirement to submit their first compliance report to MHRA by 31 December 2005 and the MHRA annual fee associated with the receipt and assessment of this report and with the receipt and assessment of reports of serious adverse events and serious adverse reactions. Also, hospital blood banks that obtain authorisations as blood establishments will be affected by the amendments described in paragraph (i)(1).

(3) Transplant Centres

Transplant centres taking preoperative autologous donations of blood or blood components (not of stem cells or bone marrow which are not covered by the directive), will need to obtain authorisations as blood establishments if they wish to continue to undertake such activity and will therefore be affected by the amendments described in paragraph (i)(1).

ii) Private Sector

(1) Private hospital blood banks

Blood banks in private hospitals will be affected as described in paragraph (i)(2).

(2) Private Transplant Centres

Transplant centres in the private sector taking preoperative autologous donations, that obtain authorisations as blood establishments will be affected by the amendments described in paragraph (i)(3).

b) Benefits

i) The Principal Regulations and the Amending Regulations transpose and implement the European Blood Directives. The intention of these Directives is to ensure that all EU citizens have assured access to blood and blood components of uniformly high standards of safety and quality.

ii) The Amsterdam Treaty of 1997 gave the European Union a mandate to pass laws on the quality and safety of blood, human tissues and cells and human organs used in medical treatment (Article 152 of the EC Treaty). The Commission put forward its first legislative proposals in late 2000 and the Blood Directive 2002/98/EC was passed by the European Parliament and Council in January 2003.

iii) The Blood Directive sets EU-wide quality and safety standards for the collection, testing, processing, storage and distribution of human blood and blood components. The measures put in place comprehensive and legally binding standards for blood and blood derivatives from donor to patient and for related medical applications.

iv) The 2003 Directive gives the Commission a mandate to pass implementing measures. A first set of technical implementing measures (Directive 2004/33/EC) was adopted by the Commission in March 2004. Two further sets of implementing measures (Directives 2005/61/EC and 2005/62EC were adopted on 30 September 2005 followed consultations with Member State authorities and health experts over the past year.

v) EU countries need to be able to import blood and blood derivatives from each other to enable them to cope with shortages or dramatic surges in demand at national level (e.g. in case of a major disaster). Having a common set of high standards helps facilitate cooperation between healthcare systems. It also helps give Europeans confidence that if they go for treatment in another EU country they will be properly protected from blood born diseases. Day to day quality control of blood and regulation of organisations collecting, processing or storing blood still takes place at national and regional level.

vi) The proposed amendments correct and clarify the Principal Regulations in respect of blood establishment periodic fees, the date by which hospital blood banks will be required to submit their first compliance report and will enable hospital blood banks who wish to continue the collection and processing of blood and blood components to apply for authorisations as blood establishments.

vii) Public health is further safeguarded by the inclusion of a power to remove from a blood establishment authorisation a Responsible Person who has failed to carry out his responsibilities. The holder of the designation Responsible Person is pivotal, under the Directive and the Regulations, to the safety and quality of the blood and blood components supplied by a blood establishment.

viii) Third party contract laboratories, providing testing services to blood establishments, will be charged an appropriate fee for such inspections.

ix) The receipt and assessment by MHRA of annual reports from hospital blood banks or blood establishments that are operating as blood banks is a key element in monitoring compliance with the Principal Regulations, as is a haemovigilance system for the receipt and assessment of serious adverse events and serious adverse reactions. The MHRA has developed a web-based system for the reporting of these events and reactions. This will benefit reporters by facilitating and simplifying reporting and reducing the administrative burden. The Directive does not require authorisation and routine inspection of hospital blood banks. However, it does require hospital blood banks or blood establishments that are operating as blood

banks to comply with certain provisions of the Directive. The UK has implemented this provision by means of the requirement for annual compliance reports, which are assessed and followed up as necessary by the MHRA

c) Costs

i) The Regulatory Impact Assessment prepared in 2004, in association with the Principal Regulations, discussed the costs of the implementation of the European Blood Safety Directives. The scope of the current assessment is restricted to the costs attributable to the proposed amendments.

ii) Options 1 and 2 would not create any additional costs to blood establishments and hospital blood banks.

iii) The additional costs attributable to Option 3 amendments are estimated as:

(1) Inspections of third party laboratories carrying out testing on behalf of blood establishments (There are no more than 10) : £2,000 to £4,000 per laboratory per inspection. The size of the fee will vary with the range of testing activities undertaken. These fees are the same as those charged by the MHRA for similar inspections of contract laboratories under The Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2004 No. 666. The total inspection costs over a 2 year period are estimated to be in the range of £20,000 to £40,000.

(2) There are approximately 400 hospital blood banks in the UK, the majority are within the NHS, with about 40 in the private sector. Both the NHS and the private sector will be charged an annual compliance fee of £775 per blood bank. This fee is calculated to cover the operational costs to the MHRA of the receipt and assessment of annual compliance reports from hospital blood banks and the operation of the haemovigilance system for the receipt and assessment of reports of serious adverse events and adverse reactions. The MHRA has developed a pro forma compliance report for hospital blood banks to complete and return, which they will be required to do in the first instance by 31 December 2005. The Agency has also developed an on-line system for the reporting of serious adverse events and serious adverse reaction to blood and blood components. The total cost to hospital blood banks of the compliance monitoring and haemovigilance services is estimated to be £310,000 PA.

(3) There are currently 4 blood establishments which will be charged an annual fee of £375 for the operation of the operation of a haemovigilance system for reports of serious adverse events and serious adverse reactions. A blood establishment that is operating as blood bank will be charged an annual fee for the receipt and assessment of annual compliance reports. The total cost to these blood establishments for the haemovigilance service will be £1,500 PA.

(4) 53 transplant centres (approximately 50 NHS and 3 private sector) that may take preoperative autologous donations of blood or blood components have been contacted. Currently none of these transplant centres have indicated that they will require a blood establishment authorisation. Those that do and are not also a blood establishment will be subject to an annual fee of £375 for the operation of a haemovigilance system for reports of serious adverse events and serious adverse reactions. The majority of the 50 NHS transplant centres are already counted within the 400 hospital blood banks in the UK. If a transplant centre is in a hospital with a blood bank only one annual fee of £375 would chargeable. These costs are likely to be included in the estimate at paragraph (2) above.

6) Small Firms Impact Test

The Regulatory Impact Assessment prepared in 2004 was unable to identify any small businesses likely to be affected by the Principal Regulations and therefore stage 1 of the Small Firms Impact Test was not carried out. This approach was agreed with the Small Business Service. This assessment will adopt a similar approach. However, if any of the organisations consulted feel this may not be the case then we invite them to contact us to discuss.

7) Competition Assessment

The 2004 Regulatory Impact Assessment reported that the market for the supply of blood and blood components including the collection, testing processing, storage and distribution, based on a study conducted by the National Audit Office, was run on a monopoly basis by the UK Blood Service. Hospital blood banks were identified as being run by NHS Trusts and by private hospitals. No significant changes were identified from existing practice in the UK and implementation of the Directives via the Principal Regulations was not seen to increase existing barriers for new entry into the market. No other concerns were identified and the conclusion reached was that a further detailed assessment was unnecessary. This assessment will adopt a similar approach.

8) Enforcement, sanctions and monitoring

The Principal Regulations, as amended, will be enforced by the Secretary of State, through a system of authorisation, inspection, compliance monitoring and haemovigilance. Breaches of the Principal Regulations are criminal offences. Directive 2002/98/EC requires member states to submit annual reports to the European Commission, which could result in reviews of the Directive and consequential amendments to the Principal Regulations.

9) Implementation and delivery plan

The Principal Regulations, came into force on 8 February 2005 and will apply fully from 8 November 2005. It is intended that the amending Regulations shall also come into force on 8 November 2005. As a result, the MHRA will have the authority to charge fees for: inspecting third party testing laboratories; receiving and assessing hospital blood bank compliance reports; and operating a haemovigilance service. The Amending Regulations will clarify: when fees become payable; when reports must be submitted; the eligibility of hospital blood banks to apply for blood establishment status; the non-incrimination of civil partners; and provide the power for the removal from a blood establishment authorisation of a "responsible person" who has failed to carry out his responsibilities under the Principal Regulations.

The MHRA has engaged with stakeholders to raise awareness of the coming into force of the Principal Regulations and the proposals contained in the Amending Regulations. The MHRA has organised seminars and meetings around the UK and information has been posted on the Agency website.

10) Post-implementation review

The MHRA will review, on a regular basis, the costs of operating systems for authorisation, inspection, compliance monitoring and haemovigilance under the Regulations. The Agency is required under the terms of its trading fund to ensure that the full costs of providing these services are recovered.

11) Summary and Recommendations

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1	No benefits were identified for this option.	The MHRA would be in breach of the terms of its Trading Fund Order if it did not recover the costs of providing regulatory services as the Competent Authority under the Directive and Regulations.
2	This option would ensure equity in respect of the periodic fee for blood establishments.	The periodic fee of £304 for blood establishments would not become payable to the MHRA before 8 November 2006. However, this option would leave the Principal Regulations uncorrected and could also result in a breach of the MHRA Trading Fund Order
3	Clarification and correction of the Principal Regulations. Provision of authority for MHRA to levy fees for services as required by the	The preferred option. It amends the Principal Regulations to ensure that the system of regulation established in the Principal Regulations will work

	MHRA Trading Fund Order.	more effectively, and, ensures MHRA is able to comply with the Government Trading Funds Act 1973. The total additional costs associated with the Amending Regulations are estimated to be in the range of £321,500 to £331,500 per annum.

The Government recommends option 3. This option not only corrects and clarifies the Principal Regulations; it also protects public health by strengthening the legislation.

12) Declaration

I have read this Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed: Caroline Flint

Date: 14th October 2005

Parliamentary Under Secretary of State for Public Health
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