EXPLANATORY MEMORANDUM TO

THE BLOOD SAFETY AND QUALITY (FEES AMENDMENT) REGULATIONS 2008

2008 No. 525

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of 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 This SI amends relevant regulations which set out the fees payable by hospital blood banks and blood establishments in relation to services the Medicines and Healthcare products Regulatory Agency (MHRA) undertakes as the Competent Authority acting on behalf of the Secretary of State for Health for regulating blood banks and establishments. It increases the fees payable by amounts ranging from 8% to 14%. The fees are targeted to ensure that actual costs for specific services are met through the fees charged in line with Treasury guidance on fees and charges. These changes are part of a package of fees changes covering all of the fees charged by MHRA for its services to different industry sectors.

3. Matters of special interest to the JCSI

3.1 Under the Regulations, the Secretary of State for Health is responsible for authorising and inspecting blood establishments, monitoring compliance of hospital blood banks and carrying out haemovigilance and is the Competent Authority for the purposes of the EC directives relating to the safety and quality of blood. The Secretary of State's functions are performed by the MHRA.

3.2 The MHRA is a Government Trading Fund and does not receive any central funding for this area of its work. Therefore, any work it does in relation to the performance of functions under the Regulations must be fully funded by fees charged for the work. The MHRA is also the UK medicines and devices regulator and is fully funded for its medicines regulatory work through fees charged to the pharmaceutical industry. The devices part of the work is mostly funded by central funds (via the Department of Health) because it does not have the ability to charge fees for all of its work. However, it does raise some funding directly through fees charged for specific services.

3.3 The fee increases in this instrument are made in order to ensure that the fees charged for each area of activity properly reflect the cost of that activity in line with Treasury guidance on fees and charges. There is no opportunity to fund this work from elsewhere (including central funds), no subsidies are available and it is not possible to cross-subsidise from other income.

4. Legislative background

4.1 This instrument amends regulation 22 of the Blood Safety and Quality Regulations 2005, in order to increase the fees payable by blood establishments and hospital blood banks, for the reasons given elsewhere in this memorandum.

5. Extent

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 By virtue of the Government Trading Funds Act 1973, the MHRA has an obligation to at least break even taking one year with another and to set fee levels to achieve this.

7.2 The fees charged by the MHRA are monitored and reviewed annually to ensure, as far as possible, that the fees charged for a particular service, reflect the cost of the work undertaken. This is in line with Treasury guidance on Fees and Charges. It has taken measures to deliver efficiencies and continues to do so. This instrument amends the level of fees charged by MHRA in order to ensure that the full cost of the work undertaken is recovered.

7.3 The cost of compliance associated with this instrument is estimated to be in the region of an additional £47k. In addition, the Agency is also proposing efficiency gains from within its current running costs. There are no associated recurring or non-recurring costs for those affected.

7.4 All hospital blood banks and blood establishments are affected – many of these are NHS bodies. All of these organisations have been consulted on the proposals to increase these fees. The formal consultation period lasted for 12 weeks, but relevant organisations were alerted before then that substantial increases would be proposed. We issued consultation notices to all relevant bodies and received 2 replies. These expressed concern at the impact the increases in inspection fees would have on the cost to the NHS and the National Blood Service. MHRA considered the responses, but it is unable to reduce the costs for this sector as it has no mechanism for recovering the shortfall and it is unable to cross-subsidise by increasing fees elsewhere. Many bodies are required to be inspected every two years and there was concern that if a full inspection was carried out with this frequency, the costs would be prohibitive. However, the Agency undertakes a risk-based approach to inspections and intends to target its inspections to specific areas of the organisation rather than undertake full inspections each time. This should keep costs down, particularly for compliant organisations.

7.5 The MHRA has no current proposals to consolidate any of the regulations amended by this instrument, although it continues to keep the matter under review

8. Impact

8.1 A full Impact Assessment has been prepared and is attached to the memorandum. Copies can also be obtained from Karen Salawu, Fees Policy Unit, Room 16-159 Market Towers, Tel: 020 7084 2216, e-mail: karen.salawu@mhra.gsi.gov.uk.

8.2 The impact on the public sector is that costs for blood banks and blood establishments will increase by around £47k in 2008/2009. The MHRA has considered the impact on these bodies but is unable to cross-subsidise the cost of this work from elsewhere. However, it is taking a risk-based approach to its responsibilities in this area which will mean that only necessary costs will be incurred and those establishments that are fully compliant will receive shorter inspections and therefore can expect to pay less. It is important that the work is properly resourced if it is to achieve the public health protection for which the inspection system was introduced.

9. Contact

9.1 Sue Jones at MHRA Tel: 020 7084 2652 or e-mail: sue.jones@mhra.gsi.gov.uk can answer any queries regarding this instrument.

Summary: Intervention & Options

Department /Agency:	Title:	
MHRA	Impact Assessment of The Blood Safety and Quality (Fees Amendment) Regulations 2008	
Stage: Final	**Version:** 1	**Date:** 1 January 2008
Related Publications:		

Available to view or download at:

http://www.mhra.gov.uk

Contact for enquiries: Karen Salawu **Telephone:** 020 7084 2216

What is the problem under consideration? Why is government intervention necessary?

Changes are proposed to existing legislation governing levels of fees paid by blood banks and establishments in relation to the regulation of medicines. Fees are being increased overall in order to cover estimated unavoidable increases in costs for the Medicines and Healthcare products Regulatory Agency (MHRA) from April 2008. Under the Blood Safety and Quality Regulations 2005 the Secretary of State for Health is responsible for authorising and inspecting blood establishments, monitoring compliance of hospital blood banks and carrying out haemovigilance.

What are the policy objectives and the intended effects?

The objectives are to ensure the MHRA can recover its costs in relation to this work and thus continue its role to protect public heath.

What policy options have been considered? Please justify any preferred option.

1 Do not increase fees.

2. Increase fees to ensure only essential unavoidable costs can be met. Target increases/decreases as appropriate. This is our preferred option.

3.Increase fees across the board by inflation - but this would fail to reflect the actual costs associated with essential regulatory functions.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

Fees and costs are subject to ongoing monitoring and review throughout each year on a cyclical basis.

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

Dawn Primarolo .....Date: *27th February 2008*

Summary: Analysis & Evidence

Policy Option: 1	Description: Do not increase fees

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ NIL	
Average Annual Cost (excluding one-off)	
£ nil	

Description and scale of **key monetised costs** by 'main affected groups' This figure represents the status quo. On 2007/2008 fee levels, the budgeted income for MHRA blood related work is £590,000. All blood bank and blood establishments are liable for fees.

Total Cost (PV) **£ nil**

Other **key non-monetised costs** by 'main affected groups' If we implement this option, the MHRA will suffer a shortfall in funding with no other means to make up the difference. Recruitment would have to be stalled and performance is likely to suffer. Efforts to tackle other risks would be curtailed,with potential harm to public health and safety.

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£ NIL	
Average Annual Benefit (excluding one-off)	
£ nil	

Description and scale of **key monetised benefits** by 'main affected groups' Whilst the MHRA would be able to meet most of its commitments with a limited budget , it would be working with fees below actual costs. This would be contrary to Treasury guidance and against the Trading Fund.

Total Benefit (PV) **£ nil**

Other **key non-monetised benefits** by 'main affected groups' Lower costs for companies.The Agency would have to seek to make cuts. Its biggest cost is for staff costs and a freeze on recruitment for vacancies might be considered. But this is likely to result in areas of the Agency being undermanned. Performance would be affected and public health protection may suffer as a result.

Key Assumptions/Sensitivities/Risks Requirements of the Trading Fund Order to break even taking one year with another;. Treasury guidance on ensuring fees match costs; Responsibility to protect public health

Price Base Year	Time Period Years	**Net Benefit Range** (NPV) **£**	**NET BENEFIT** (NPV Best estimate) **£**

What is the geographic coverage of the policy/option?				UK	
On what date will the policy be implemented?				1 April 2008	
Which organisation(s) will enforce the policy?				MHRA	
What is the total annual cost of enforcement for these organisations?				£ N/A	
Does enforcement comply with Hampton principles?				Yes	
Will implementation go beyond minimum EU requirements?				No	
What is the value of the proposed offsetting measure per year?				£ N/A	
What is the value of changes in greenhouse gas emissions?				£ N/A	
Will the proposal have a significant impact on competition?				No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large	
Are any of these organisations exempt?	No	No	N/A	N/A	

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ NIL Decrease of £ NIL **Net Impact** **£** NIL

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Summary: Analysis & Evidence

Policy Option: 2	Description: Increase fees to ensure unavoidable cost increases for 08/09 are covered.

COSTS

ANNUAL COSTS	
One-off (Transition) **Yrs**	Description and scale of **key monetised costs** by 'main affected groups' Increased costs are targeted to specific fees at different levels to balance out cost recovery. Some are increased by more than the average, small number are frozen at current rates. Inspection fees are replaced by a standard daily rate based on actual time spent on site and cost.
£ . NIL	
Average Annual Cost (excluding one-off)	**Total Cost** (PV) **£ 47,000**
£ 47,000	

Other **key non-monetised costs** by 'main affected groups' None

BENEFITS

ANNUAL BENEFITS	
One-off **Yrs**	Description and scale of **key monetised benefits** by 'main affected groups' Some fees remain at 07/08 levels
£ NIL	
Average Annual Benefit (excluding one-off)	**Total Benefit** (PV) **£ nil**
£ nil	

Other **key non-monetised benefits** by 'main affected groups' Some fees are simplified through replacing individual inspection fees with a daily rate fee and some fees are frozen at current levels.

Key Assumptions/Sensitivities/Risks Requirements of the Trading Fund Order to break even taking one year with another;. Treasury guidance on ensuring fees match costs; Responsibility to protect public health.

Price Base Year	Time Period Years	**Net Benefit Range** (NPV) **£**	**NET BENEFIT** (NPV Best estimate) **£**

What is the geographic coverage of the policy/option?			UK	
On what date will the policy be implemented?			1 April 2008	
Which organisation(s) will enforce the policy?			MHRA	
What is the total annual cost of enforcement for these organisations?			£ N/A	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			No	
What is the value of the proposed offsetting measure per year?			£ N/A	
What is the value of changes in greenhouse gas emissions?			£ N/A	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ nil Decrease of £ nil **Net Impact** **£** nil

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Summary: Analysis & Evidence

Policy Option: 3	Description: Increase fees by inflationary rate (2.75% GDP deflator for 2008/9) across the board.

COSTS

ANNUAL COSTS	
One-off (Transition) **Yrs**	Description and scale of **key monetised costs** by 'main affected groups' All parts of the blood organisations are liable for fees. Costs would be raised by 2.75% across the board for every individual fee.
£ NIL	
Average Annual Cost (excluding one-off)	
£ 16,000	**Total Cost** (PV) **£ 16,000**

Other **key non-monetised costs** by 'main affected groups' The Agency would not be fully funded for the year, costs and fees would not be matched correctly contrary to the Treasury guidance and Trading Fund Order. Lack of funds could mean lack of resources to fully undertake responsibilities of the Agency, including protecting health.

BENEFITS

ANNUAL BENEFITS	
One-off **Yrs**	Description and scale of **key monetised benefits** by 'main affected groups' Increase in fees would be limited to inflationary rate rather than a higher than inflation rate (which represents true cost increases).
£ NIL	
Average Annual Benefit (excluding one-off)	
£ nil	**Total Benefit** (PV) **£ nil**

Other **key non-monetised benefits** by 'main affected groups'

Key Assumptions/Sensitivities/Risks Requirements of the Trading Fund Order to break even taking one year with another;. Treasury guidance on ensuring fees match costs; Responsibility to protect public health

Price Base Year	Time Period Years	**Net Benefit Range** (NPV) **£**	**NET BENEFIT** (NPV Best estimate) **£**

What is the geographic coverage of the policy/option?				UK	
On what date will the policy be implemented?				1 April 2008	
Which organisation(s) will enforce the policy?				MHRA	
What is the total annual cost of enforcement for these organisations?				£ N/A	
Does enforcement comply with Hampton principles?				Yes/No	
Will implementation go beyond minimum EU requirements?				Yes/No	
What is the value of the proposed offsetting measure per year?				£ N/A	
What is the value of changes in greenhouse gas emissions?				£ N/A	
Will the proposal have a significant impact on competition?				No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large	
Are any of these organisations exempt?	No	No	N/A	N/A	

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ nil Decrease of £ nil **Net Impact** **£** nil

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

Background

1.1 The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health. Under the Blood Safety and Quality Regulations 2005 the Secretary of State for Health is responsible for authorising and inspecting blood establishments, monitoring compliance of hospital blood banks and carrying out haemovigilance. These functions are carried out by the MHRA acting as the Competent Authority on behalf of the Secretary of State. The fees charged by the MHRA for these services are monitored and reviewed annually to ensure, as far as possible, that the fees charged reflect the cost of the work undertaken. This is in line with Treasury guidance on Fees and Charges.

1.2 The proposed amendments fulfil the obligation that the MHRA, a Government Trading Fund established under the Government Trading Fund Act 1973, is required to recover the full costs of the services it provides and cross subsidy is not permitted.

Objectives

2.1 These Regulations amend existing legislation in connection with the regulation of blood banks and other blood establishments. The proposal for 2007/2008 is to achieve full cost recovery of the work undertaken by the MHRA as the Competent Authority.

Rationale for Government intervention

3.1 The quality and safety of blood and blood products in the UK is already amongst the best in the world but their use, like most medicinal procedures, can never be free of risk. The implementation of SI 2005 (No 50) and subsequent amendments further improved the safety and quality of the blood supply.

Health Impact

3.2 Ultimately, if the MHRA were to be insufficiently resourced to carry out its responsibilities, the Agency could be unable to fulfil its obligations in relation to its role as Competent Authority and the protection of public health. The Agency, as a Trading Fund (TF), would be unable to sustain its financial position. Staff numbers would have to be cut to be able to break even taking one year with another as required by the TF Order. If the MHRA is not adequately resourced for the work it undertakes there could be a risk to human health in the long term through inadequate regulation and inspection of blood banks and blood establishments. This could occur, for example through bad clinical practices not being spotted and remedied and thus contaminated blood products being released for patient use.

Economic Impact

3.3 It is therefore important that the MHRA is able to gain sufficient income from fees to resource its functions effectively. However, it is also recognised that the Agency must carry out its responsibilities efficiently and in accordance with the Government's principles on Better Regulation, so that regulation is proportionate, targeted and risk-based. Hospital blood bank inspections are targeted according to assessed risk and will generally take place every few years.

3.4 The MHRA's main areas of work are the regulation of medicines and medical devices. It covers the cost of all the work carried out in relation to medicines regulation (and a small proportion of the work relating to devices regulation) through fees charged. It has an established fees system which regularly monitored and costed to ensure that fees charged for specific services are targeted accordingly.

3.5 The rationale behind these fee proposals is therefore to ensure a fee regime that enables the Agency to recover its costs, fulfil its role in safeguarding public health; and also uses the resources from fee income to target improvement in this area of the Agency's business.

4. Consultation

4.1 These proposals have been considered at length with Department of Health officials and with Treasury. Both have approved the proposals and are satisfied that the Agency is making every effort to match fees with costs and that these changes serve to ensure that this is the case. A 12 week public consultation exercise was carried out between October 2007 and January 2008. Two responses were specifically about these fees and expressed concern on the impact the increases would have on the cost the NHS and the National Blood Service of inspections.

5. Options

5.1 Three options for the main proposals have been identified:

Option 1 Do nothing option i.e. make no increases to fees. This is a "do nothing" option in the pure sense, although it would amount to a real terms cut in Agency funding, which would therefore leave the Agency significantly less well resourced in real terms than currently.
Option 2 Increase fees as proposed to cover costs
Option 3 Increase fees by an inflationary figure (2.75% - GDP deflator measure for 2008/9) across-the-board. As a measure of basic inflationary costs, this can be seen as a "do nothing" option

5.2 Option 1 would freeze most licensing costs at 2007/2008 levels. This would mean that the Agency would not be fully recovering the cost of this work.

5.3 Option 2 will ensure that the correct fee is charged to cover the cost of each area of work undertaken and ensure that MHRA's obligations as a Trading Fund to recover full costs of the service it provides without cross subsidy.

5.4 Option 3 would mean that costs were not targeted, nor would they recover fully the cost of the work undertaken.

6. Costs and Benefits

Sectors and groups affected

6.1 The NHS and other organisations that store or manufacture blood products would be affected.

- An NHS hospital blood bank requiring to pay annual haemovigilance fee, an annual compliance fee and has a short inspection in year would have paid £2,158 in 2007/2008 but for the same services in 2008/2009 would pay £3,570 – a difference of £1,412. Hospital blood bank inspections are targeted according to assessed risk and will generally take place every few years. The same hospital blood bank, if there were no inspection in year, would pay £1,118 in 2008/09 instead of £1,032 in 2007/8 – an increase of £86.

- A new establishment applying for an application for authorisation would have been charged £2,688 in 2007/2008, but would pay £2,927 in 2008/2009 – an increase of £239.

- An existing large sized blood establishment paying an annual haemovigilance fee and receiving an inspection in year (assuming it would be a 5 day inspection) would pay £13,585 in 2007/2008 but this would be £12,728 in 2008/2009, a decrease of £857.

Benefits

6.2 The key benefit is the protection of public health in ensuring the safety and quality of the supply of blood in the UK. In addition stakeholders will continue to see benefit from improvements in service levels from the MHRA.

Costs

6.3 The MHRA reviews it fees on an annual basis and makes proposals for changes to take place in April each year. Individual fees for blood establishments increase on a range between 8% and 14%. This year the MHRA proposed the introduction of a daily rate for inspection which will apply to blood banks and establishments. We are proposing to replace existing inspection fees with a new scheme based on daily rates. This is an important part of our broader move to more risk-based inspections, which will focus our inspection work on those companies and facilities judged to be higher risk. Currently, there are around 35 different MHRA inspection fees for different types of inspection (including blood establishments and blood banks), all based loosely on the average time spent on site by the inspector. The new daily rate replaces the existing structure. The costing will be more transparent for organisations and companies that are fully compliant are likely to be inspected less and thus costs will reduce. Although there is a requirement to inspect some blood establishments on a 2-yearly cycle, the inspections will be focused in sample areas rather than full inspections being undertaken each year which should ensure that inspection costs for compliant establishments will reflect the work being undertaken.

6.4 There are no associated policy costs or administration costs from these proposals. These regulations implement an increase in fees that already exist. There are therefore no associated additional administration costs for companies as there are no new fees or new procedures being implemented.

Impact on Small Business

6.5 These regulations will impact on all organisations within this sector equally. There are no "small businesses", as such, involved in this area of work but NHS and other public health organisations will be affected by these regulations. The increase in income for the MHRA from the whole of this sector in 2008/2009, using estimated projections of numbers of inspections is around £47k over the amount charged through fees in 2007/08.

7. Competition Assessment

7.1 The market for the supply of human blood and blood products – including its collection, testing and processing, storage and distribution of human blood and blood components has been studied by the National Audit Office (NAO). It is not believed that these proposals will increase any existing barriers to entry and harmonisation. The Regulations introduce no change in existing UK practice.

8. Equality Impact Assessment:

8.1 An initial Equality Impact screening assessment has been carried out, which has shown that a full assessment is not required as the proposed policy has no disproportionate impact on race or other relevant equalities. The proposed policy will not have any disproportionate impact on rural populations.

9. Enforcement, Sanctions, and Monitoring

9.1 These Regulations will be enforced by the Competent Authority through a system of licensing, inspection and compliance verification. Breaching these provisions would constitute an offence. The Finance Division of the Agency is responsible for raising invoices and collecting revenue for the Agency. There are certain sanctions where some fees are paid late. The MHRA monitors and assesses costs against fees on an annual basis and proposals for change are made through a consultative process and are subject to parliamentary approval. The MHRA is working to improve its efficiency and the introduction of more risk-based inspections ensures that compliant bodies are not inspected unnecessarily. More compliant bodies will have lower costs.

10. Implementation and delivery plan

10.1 The new fees will apply to relevant MHRA services undertaken on or after the 1st April 2008. The new fees will be advertised on the MHRA's website and all those affected have been made aware through the consultation exercise that changes are imminent.

11. Post-implementation review

11.1 The new fees and the anticipated income through estimated volumes have been matched with the Agency's budget plan for 2008/2009.

11.2 MHRA fee levels are subject to continuous rigorous monitoring and review with a view to making annual amendments (where necessary) to ensure that, as far as possible, the cost of the work undertaken by the MHRA is reflected in the fees charged to industry, NHS and other establishments. In addition, the Agency is seeking efficiencies from within its working practices to provide a better standard of service from within current resources.

12. Summary and Recommendations

12.1 Option 2 best achieves the objective of ensuring that costs reflect the actual cost of the work undertaken by the MHRA. It will allow the MHRA to undertake its responsibilities for protecting public health. It will help to target resources.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	Yes	No
Sustainable Development	Yes	No
Carbon Assessment	Yes	No
Other Environment	Yes	No
Health Impact Assessment	Yes	No
Race Equality	Yes	No
Disability Equality	Yes	No
Gender Equality	Yes	No
Human Rights	Yes	No
Rural Proofing	Yes	No

Annexes