EXPLANATORY MEMORANDUM TO

THE BLOOD SAFETY AND QUALITY (FEES AMENDMENT) REGULATIONS 2010

2010 No. 554

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. Purpose of the instrument

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.

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

3.1 None.

4. Legislative Context

4.1 This instrument amends regulation 22 of the Blood Safety and Quality Regulations 2005 (S.I.2005/50), in order to increase the fees payable by blood establishments and hospital blood banks, for the reasons given elsewhere in this memorandum**.**

5. Territorial Extent and Application

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 negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- ***What is being done and why***

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 It applies generally applies fees changes with an overall average of 1%. There is one principle changes in the Regulations:

- To extend the payment of the fee of £10,000 for Persons Appointed hearings in relation to requests for a hearing in respect of blood establishments and blood banks in order to fully recover the costs involved. There is a significant amount of work involved in setting up a PA meeting, and in paying for a panel of appropriate skilled and experienced members to consider these appeals..

7.4 The cost of compliance associated with this instrument is estimated to be in the region of an additional £23,836. 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.

- ***Consolidation***

7.5 The Department does not intend to consolidate the Blood Safety and Quality Regulations 2005.

8. Consultation outcome

8.1 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 no replies.

9. Guidance

9.1 Guidance and information on these Regulations is available on the MHRA website at: www.mhra.gov.uk If the guidance is to be amended/updated before April please say so.

10. Impact

10.1 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.

11. Regulating small business

11.1 There are no ‘small’ businesses’ as such involved in these areas of work.

12. Monitoring & review

12.1 These regulations are amended each year to achieve full cost recovery of the work undertaken by the MHRA as the Competent Authority

13. Contact

13.1 Tracy Murray at MHRA Tel: 020 7084 2329 or e-mail: tracy.murray@mhra.gsi.gov.uk can answer any queries regarding this instrument.

Summary: Intervention & Options

Department /Agency:	Title:	
Medicines and Healthcare products Regulatory Agency (MHRA)	**Impact Assessment of The Blood Safety and Quality (Fees Amendment) Regulations 2010**	
Stage: Final	**Version:** 2	**Date: 1 February 2010**
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 by the UK Competent Authority for Blood. Fees are being increased overall in order to cover estimated unavoidable increases in costs for the Medicines and Healthcare products Regulatory Agency (MHRA - UK Competent Authority for Blood and blood prodcuts) from April 2010. 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. This is our preferred option.

3.Increase fees across the board by inflation (CPI at 1.8% as of August 2009). This would over recover estimated costs associated with essential regulatory functions for 2010/2011.

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 Consultation 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:

Mike O'Brien.....Date: ***10th February 2010***

Summary: Analysis & Evidence

Policy Option: 1	Description: Do not increase fees

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition) **Yrs**	This figure represents the status quo. The Agency would be working with fees below actual costs.
£ NIL	
Average Annual Cost (excluding one-off)	
£ nil	**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. Efforts to tackle other risks could be curtailed,with potential harm to public health and safety.

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups'
One-off **Yrs**	No benefits
£ NIL	
Average Annual Benefit (excluding one-off)	
£ nil	**Total Benefit** (PV) **£ nil**

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

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 2010	
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:** **(Net) Present**

Summary: Analysis & Evidence

Policy Option: 2	Description: Increase fees to ensure unavoidable cost increases are covered.

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition) **Yrs**	Fees are proposed to be increased by 1% in order to cover the estimated cost increases for MHRA for 2010/2011.
£ . NIL	
Average Annual Cost (excluding one-off)	
£ 23,836	**Total Cost** (PV) **£ 23,836**

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

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups'
One-off **Yrs**	Although it has not been monetised, the MHRA will be able to carry out its functions as UK Competent Authority for Blood and Blood Products.
£	
Average Annual Benefit (excluding one-off)	
£	**Total Benefit** (PV) **£**

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

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 2010	
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**

Summary: Analysis & Evidence

Policy Option: 3	Description: Increase fees by inflationary rate across the board.

COSTS

ANNUAL COSTS	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 1.8% across the board for every individual fee.
One-off (Transition) **Yrs**	
£ NIL	
Average Annual Cost (excluding one-off)	
£ 24,027	**Total Cost** (PV) **£ 24,027**

Other **key non-monetised costs** by 'main affected groups' The Agency would be over recovering aginst its costs which would be contrary to the Treasury guidance and Trading Fund Order.

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups' None
One-off **Yrs**	
£ 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 2010	
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**

[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.]

1. Background

1.1 The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health. The Agency is the UK regulator for medicines and also medical devices. 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 also 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.

2. Objectives

2.1 These Regulations amend existing legislation in connection with the regulation of blood banks and other blood establishments. The proposal for 2010/2011 is to achieve full cost recovery of the work undertaken by the MHRA as the Competent Authority.

3. 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.

Economic Impact

3.3 The Agency, as a Trading Fund (TF), would be unable to sustain its financial position. Staff numbers may have to be cut to be able to break even taking one year with another as required by the TF Order.

3.4 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.

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.

4.2 A 12 week public consultation exercise was carried out with letters being issued to over 2000 companies, individuals, industry associations and licence and Marketing Authorisation holders who were likely to be affected by the proposals or interested in them. A nil response was received.

5. Options

5.1 Three options for the main proposals have been identified:

Option 1 Do nothing option i.e. makes no increases to fees. This is a "do nothing" option.

Option 2 Increase fees as proposed to cover costs.

Option 3 Increase fees by an inflationary figure (1.8% as at August 2008) across-the-board.

6. Costs and Benefits

Sectors and groups affected

6.1 The NHS and other organisations that store or manufacture blood products would be affected for example;

- 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 £13,302 in 2009/2010 but this would be £13,435 in 2010/2011, still only a 1% increase.

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 are proposed to be increased by 1%.

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.

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 2010. The new fees will be advertised on the MHRA's website and all those affected will be 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 2010/2011.

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