EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (FEES AMENDMENTS) REGULATIONS 2009

SI 2009 No. 383

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 instrument amends the regulations which set out fees payable by the medical devices industry in relation to services provided by, and regulatory functions carried out by the MHRA in relation to medical devices on the UK market. It increases some of the fees payable (i.e. fees for assessment of clinical investigation applications and Notified and Conformity Assessment Body designation and monitoring); the overall effect is to increase these specific fees by an overall 3%.

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

3.1 Nearly all the costs relating to medical devices regulation work carried out by the MHRA as Competent Authority for the UK is publicly funded through a Service Level Agreement with DH. However, a small proportion of its funding comes from fees charged for specific areas of statutory work. The MHRA is a Government Trading Fund and the Agency must ensure that its income is sufficient, taking one year with another, to meet its expenditure. The MHRA recovers some of its costs for the medical devices and clinical investigation and Notified and Conformity Assessment Body functions referenced above. However it cannot be cross-subsidised for this or any of its other statutory functions by other income the Agency receives in relation to medicines regulation.

3.2 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. The Agency also charges for registration of some medical device manufacturers but as this fee continues to cover its costs no increase is proposed. The fee referred to in regulation 2(3) (d) is increased by £640 which is more than 3%. This increase takes account of the erroneous reduction of this particular fee made in regulation 2(3) (d) of the Medical Devices (Fees Amendments) Regulations 2008 (S.I. 2008/530).The Department took the decision not to amend the provision in question because during the fee period 2008 to 2009, it was unlikely that numerous applications for an application (which would attract this fee) would be made. The fee becomes payable where advice is required to be given in connection with quality, safety and clinical development at a meeting. In the fee period 2007 to 2008 only one such application had been received. The Department considered the matter carefully and took the view that it would not be cost effective to introduce an amending S.I. in respect of this one type of fee. The Department can confirm that to date no applications which would have attracted the pre-consultation fee in question have been made in the fee period 2008 to 2009.

3.3 The Agency undertakes a robust assessment of its fees and costs each year.

4. Legislative Context

4.1 This instrument amends: the Medical Devices (Consultation Requirements) (Fees) Regulations (S.I. 1995 No 449 as amended) as well as the Medical Devices Regulations (S.I. 2002 No 618 as amended) which is the subject of this Explanatory Memorandum.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom

6. European Convention on Human Rights

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 The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health. It carries out the functions of the Secretary of State, acting as the Competent Authority in relation to the regulation of medical devices. This instrument affects some of the medical devices functions of the Agency.

7.2 The costs for the work relating to medical devices regulation undertaken by the Agency are mostly met by funding from the Department of Health. In addition, 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 (where fees can be charged for work undertaken) to achieve this.

7.3 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. This instrument amends the level of some fees charged by MHRA for work in connection with the assessment of clinical trial applications and the designation and monitoring of UK Notified and Conformity Assessment Bodies in order to ensure that the full cost of the work undertaken is recovered.

7.4 The cost of compliance associated with this instrument is estimated to be around £8,000. There are no associated recurring or non-recurring costs for those affected. The total estimated income for MHRA for medical device related work in 2009/2010, taking into account the increased fees and anticipated volumes, is expected to be around £347,000.

- ***Consolidation***

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. Consultation outcome

8.1 All UK Notified and Conformity Assessment Bodies, relevant Trade Associations and all companies who had notified medical device clinical investigations to the Agency during the last four years have been consulted during a 12 week period on the proposals to increase these fees. An Impact Assessment has been prepared and is attached to the memorandum. Copies can also be obtained from Daniella Smolenska, Devices Policy, European and Regulatory Affairs Room 8/2 – A07 Market Towers, Tel: 020 7084 3363, e-mail: daniella.smolenska@mhra.gsi.gov.uk. The industry fully supports the MHRA's work in relation to medical devices regulation and there were only 3 responses to the consultation; of these one was in support and one was to express no comment on the proposal. The other was from a small start-up company asking whether the fees for clinical investigations are different for small companies compared to those for larger ones.

9. Guidance

9.1 This is a straight forward increase to fees and therefore guidance is not considered to be necessary.

10. Impact

10.1 The impact on business, charities or voluntary bodies mainly affects the medical device sector and notified bodies in relation to medical devices. However these effects are considered minimal.

10.2 The impact on the public sector is minimal.

10.3 An Impact Assessment is attached to this memorandum

11. Regulating small business

11.1 The legislation applies to small business. However when compared to the total development costs for a new medical device the impact of these fee increases are considered to be minimal.

12. Monitoring & review

12.1 The fees charged by MHRA are reviewed annually.

13. Contact

Rob Higgins at MHRA Tel: 020 7084 3185 or e-mail: rob.higgins@mhra.gsi.gov.uk any queries regarding this.

Summary: Intervention & Options

Department /Agency:	Title:	
Medicines and Healthcare products Regulatory Agency (MHRA)	**Impact Assessment of THE MEDICAL DEVICES (FEES) REGULATIONS 2009**	
Stage: Final	**Version:** 2	**Date:** 21 January 2009
Related Publications:		

Available to view or download at:

http://www.mhra.gov.uk

Contact for enquiries: Mrs Daniella Smolenska **Telephone:** 0207 084 3363

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

These Regulations amend existing legislation relating to the fees charged to the medical device industry and notified bodies in connection with MHRA's regulatory activities with regard to medical devices in the United Kingdom. The proposal for 2009/2010 is to achieve full cost recovery. Following a rigorous costing exercise, the proposal is to increase individual fees by differential amounts according to how closely current fee levels match the actual cost of the related activity. Proposed fees therefore vary, with some (ie registration) remaining the same.

What are the policy objectives and the intended effects?

The MHRA is required to recover its costs for its routine regulatory activities with regard to Medical Devices. The fees charged by the MHRA are monitored and reviewed 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.

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

Option 1 - increase fees as proposed to cover costs. This is our preferred option.

Option 2 - make no changes.

Option 3 - increase fees by an inflationary figure across-the-board

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

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: ***26th January 2009***

Summary: Analysis & Evidence

Policy Option: 1	Description: Increase fees as proposed to cover costs

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition) **Yrs**	
£	
Average Annual Cost (excluding one-off)	
£ 8000	**Total Cost** (PV) **£ 8000**

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

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups'
One-off **Yrs**	
£	
Average Annual Benefit (excluding one-off)	
£	**Total Benefit** (PV) **£**

Other **key non-monetised benefits** by 'main affected groups' - MHRA fully funded to enable it to fulfil current functions without loss of quality, companies receiving prompt and effective service and protection of public health by ensuring proper and timely review of clinical investigation reviews and Notified Body activity.

Key Assumptions/Sensitivities/Risks

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?				1/4/09
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 **Minimal**	Small **Minimal**	Medium **Minimal**	Large **Minimal**
Are any of these organisations exempt?	No	No	N/A	N/A

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

Increase of £ N/A Decrease of £ N/A **Net Impact** £ N/A

Key: **Annual costs and benefits:** **(Net) Present**

Summary: Analysis & Evidence

Policy Option: 2	Description: Make no Changes

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition) **Yrs**	
£	
Average Annual Cost (excluding one-off)	
£ 0	**Total Cost** (PV) **£ 0**

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

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups'
One-off **Yrs**	
£	
Average Annual Benefit (excluding one-off)	
£	**Total Benefit** (PV) **£**

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

Key Assumptions/Sensitivities/Risks

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?				1/4/09	
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 **0**	Small **0**	Medium **0**	Large **0**	
Are any of these organisations exempt?	No	No	N/A	N/A	

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

Increase of £ N/A Decrease of £ N/A **Net Impact** £ N/A

Key: **Annual costs and benefits:** **(Net) Present**

Summary: Analysis & Evidence

Policy Option: 3	Description: Increase fees by an inflationary figure across-the-board

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition) **Yrs**	
£	
Average Annual Cost (excluding one-off)	
£ 15000	**Total Cost** (PV) **£ 15000**

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

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups'
One-off **Yrs**	
£	
Average Annual Benefit (excluding one-off)	
£	**Total Benefit** (PV) **£**

Other **key non-monetised benefits** by 'main affected groups' - MHRA over funded to enable it to fulfil current functions.

Key Assumptions/Sensitivities/Risks The figure is based on an inflationary figure of 4.4%.

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?				1/4/09
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 **Minimal**	Small **Minimal**	Medium **Minimal**	Large **Minimal**
Are any of these organisations exempt?	No	No	N/A	N/A

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

Increase of £ N/A Decrease of £ N/A **Net Impact** £ N/A

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 Fees have been charged by MHRA for certain activities it undertakes under the Medical Devices Directives since 1995. These activities include review of clinical investigations, designation and monitoring of UK Notified Bodies (NBs) and registration of UK manufacturers of In Vitro Diagnostics (IVDs), class I and custom made devices as well as assemblers and sterilizers. Please note that we are only allowed to charge fees to secure 100% cost recovery and not to make a profit or to subsidise the cost of other activities. Fees will need to be increased as salary and other overhead costs are projected to increase in 2009/10.

1.2 The overall increase in income to maintain full cost recovery is likely to be about £8000. Up from about £339000 (current projection for 08/09) to about £347000 (09/10). These figures have been produced based on the Agency's current costing model.

2. Options

2.1 Three options for the main proposals have been identified:

Option 1 - increase fees as proposed to cover costs.

Option 2 - make no changes.

Option 3 - increase fees by an inflationary figure across-the-board.

2.2 Option 1 will increase costs in relation to fees, to all parts of the sector by around £8000 overall. The new fees being introduced will ensure that adequate resources can be given to issues affecting public health. Overall the increase and the new fees will target costs better and ensure that the Agency is remunerated adequately for the work it undertakes. It will also help to ensure adequate resources and thus better service can be provided.

2.3 Option 2 would freeze costs at existing levels. This would hamper the Agency's ability to maintain its operation. It would create a position where costs would be running at a level above income and would result in a deficit. If the Agency were not resourced adequately there could be a long-term risk to public health. There would also be a direct impact on companies in terms of the speed and efficiency with which work were dealt with.

2.4 Option 3 would overcharge for the Agency carrying out its work by about £7000.

3. Business sectors affected

3.1 UK Notified and Conformity Assessment Bodies (7 in total) and sectors of the medical device industry involved in carrying out clinical investigations for regulatory purposes in the UK.

4. Public Consultation

4.1 These proposals have the approval of HM Treasury and of the Department of Health Minister's, who are responsible for the work of the Agency. A 12 week public consultation on the proposals began on 14th October 2008 and ended on 6th January 2009. Details of the consultation documents were posted on the Agency's web page and in addition copies of the consultation package were sent to all UK Notified and Conformity Assessment Bodies, relevant Trade Associations and all companies who had notified clinical trials with the Agency during the last four years. The Agency received only 3 responses to the consultation; of these one was in support and one was to express no comment on the proposal. The other was from a small start-up company asking whether the fees for clinical investigations are different for small companies compared to those for larger ones; for which there is currently no distinction. The end result being that the proposed costs have not needed to be amended as a result of the consultation.

5. Costs for a "typical" business

5.1 It is not possible to identify a "typical" business. Businesses will range from a small "one-man-band" manufacturer such as a dental laboratory to multi-million pound international manufacturing businesses. Due to the fact that registration costs are being maintained at the same level (£70) it is unlikely that small businesses will be affected unless they are intending to carry out a clinical investigation (An increase in £140 for a new product;). The additional costs for Notified Bodies, estimated at £3000, will be split between the 7 UK Notified Bodies, which in turn is likely to be passed on to their clients which total in the thousands. There is unlikely to be any activity with regard to Conformity Assessment Bodies but the fees have been updated just in case.

5.2 Some examples of potential costs are:

- A large innovative company that makes 3 high risk and 2 low risk clinical investigation applications will pay £18760 in fees in 2009/2010 compared to £18300 in 2008/2009. The sum payable in fees is likely to comprise only a very small part of the development costs of such products.

- A small start up company that makes 1 low risk clinical investigation application will pay £3020 compared to £3000 in 2008/2009. The sum payable in fees is likely to comprise only a minor part of the development costs of the product.

- A typical Notified Body with around 400 clients designated under 1 directive that is subject to surveillance and witnessed audit and makes 1 extension to scope application during the year will pay about £13400 in 2009/2010 compared to £13000 in 2008/2009 (Excluding travel and subsistence).

6. Total costs

6.1 The total cost of MHRA's chargeable regulatory activity with regard to medical devices is estimated to be around £347000 which represents the total estimated income in 2009/2010 from fees raised. This will be an additional cost of about £8000 to the Medical Device sector. It is not possible to predict the total income with any certainty as in any one year, the income will depend on the volume of registrations and clinical investigations received.

7. Competition Assessment

7.1 We do not anticipate that the proposed increases are likely to have any significant impacts for competition in any of the affected markets. MHRA fees expenditure represents a relatively small proportion of the annual outgoings of all the affected firms, and this will continue to be the case following implementation of the proposed increases. In the light of these factors, we consider that proposed increases will not be sufficient to result in any significant change to the structure of competition in the affected markets.

8. Small Firms' Impact Test

8.1 The registration fee is the one that is likely to affect small businesses the most but this fee has been kept the same. The only fee increases which could impact to a limited amount is the increase in clinical investigation fees; however out of about the 60 applications received each year only a very small number are from small businesses. The increase of a maximum of £140 pounds in the regulatory fees are a fairly insignificant cost in the design of a medical device (eg costs of undertaking the study, pre-clinical testing, initial design etc).

8.2 The smaller notified bodies have a correspondingly shorter, and lower frequency of, audit and the fees for the smallest notified body are likely to be about £4750 in 2009/2010 compared to £4600 in 2008/2009 (excluding travel and subsistence).

9. Health Impact Assessment

9.1 Maintenance in the protection of public health by ensuring proper and timely review of clinical investigation reviews and Notified Body activity.

10. Legal Aid, Sustainable Development, Carbon assessment, other Environment, Race Equality, Disability Equality, Gender Equality, Human Rights and Rural Proofing

10.1 As this is simply an increase in existing fees the regulations will have no effect on these issues.

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