# 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

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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:

D Lennard ..... Date: 26/1/09

# 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: Constant Prices (Net) Present Value

# 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: Constant Prices (Net) Present Value

# 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

# 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.]

## 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 |

# Annexes