EXPLANATORY MEMORANDUM TO

THE MEDICINES (PRODUCTS FOR HUMAN USE) (FEES) REGULATIONS

2010 No. 551

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 revokes and re-enacts in consolidation form current legislation, which sets out fees payable by the pharmaceutical industry in relation to services provided by, and regulatory functions carried out by, the MHRA in relation to medicines for human use.

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

3.1 The Agency wishes to explain that there is a reduction in two types of fee – Major Variation (Type II) Complex Group Application where the UK is a Concerned Member State and for a 'National Type II Major Variation Complex Group Application for a UK national variation application, both from £10,099 to £9,738. This is deliberate and intended to amend the provision in a new Statutory Instrument which came into force in January 2010. The Agency on further reflection took the decision not to amend the provision in question when the error in the fee was discovered. This was because during the fee period Jan 2010 to March 2010, it was unlikely that numerous applications for these two types of application (which would attract the fee in question) would be made.

3.2 The Agency considered the matter carefully and took the view that it would not be cost effective to introduce an amending S.I. in respect of these two types of fee. As a consequence a policy decision not to amend the fee was made. We can confirm that to date no applications which would attract the fees in question have been made.

4. Legislative Context

4.1 This instrument revokes and re-enacts in consolidation form the Medicines (Products for Human Use–Fees) Regulations 2009 (SI No 389); revokes The Medicines (Products for Human Use)(Amendments relating to Fees for Variations) Regulations 2009 (SI No 3222) and amends the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (SI 1994 No 105 as amended). The instrument is made to change the fees payable in accordance with the provisions of those regulations (although one or two are frozen e.g. Capital fees for Person Appointed Hearings still set at £10,000 and penalty fees for late payment of periodic fees).

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 This instrument revokes and re-enacts in consolidated form the Medicines (Product for Human Use-Fees) Regulations 2009 which set out fees payable by the pharmaceutical industry in relation to services provided by, and regulatory functions carried out by, the MHRA in relation to medicines for human use. It applies generally applies fees changes with an overall average of 1%. The principle changes in the Regulations are:

- A new fee category for new Marketing Authorisations applications in European Decentralised procedures will be introduced where the UK is the Reference Member State and the application is submitted under Article 10c of Directive 2001/83 (simple application) colloquially referred to as 'informed consent'; and

- A new daily rate fee for risk assessments which do not lead to an inspection of a site.

7.2 The MHRA does not receive any central funding for the medicines element of its work. This is fully funded by fees paid by the industry. The MHRA is a Government Trading Fund and the Agency must therefore ensure that its income is sufficient, taking one year with another, to meet its expenditure.

7.3 The fee increase is set at these rates for several reasons:

- to reflect Treasury guidance on fees and charges which advises that actual costs should be taken into account;
- to cover essential unavoidable costs for the Agency in carrying out its regulatory functions (such as accommodation costs, increasing utilities costs, retention and recruitment of staff in assessing applications);
- to further improve efficiency and promptness in handling of applications; and
- to ensure that the MHRA can effectively carry out its responsibilities to safeguard public health.

The fee changes 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 has a large number of different fees specific to different areas of work. Some fees are one-off capital fees (e.g. for a new licence application), some are charged for each time an activity takes place (e.g. fees for variations to existing licences), and others are annual fees that are intended to cover the costs of activity such as ongoing drug safety monitoring and enforcement. This instrument also makes miscellaneous minor drafting amendments for clarification from last year.

- ***Consolidation***

7.4 No consolidation, other than what has already been consolidated is anticipated.

8. Consultation outcome

8.1 Over 2000 letters were posted alerting interested organisations to the consultation on the MHRA website. A total of 8 responses were received (6 from industry associations, 2 companies) all in support of the proposals. The general themes of the responses were;

- Welcome greater transparency and detail of proposals and the opportunity for early discussions on proposals,
- Supportive of MHRA's role and general rational for increases and the need to be adequately funded to carry out its work.

9. Guidance

9.1 Guidance and information regarding fees payable by the pharmaceutical industry can be found on the MHRA website at www.mhra.gov.uk.

10. Impact

10.1 An 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.

10.2 The impact on the public sector is minimal. The changes to fees mainly affect the private sector pharmaceutical industry. However, some NHS bodies, and academic research bodies will be affected by the increases in some fees.

11. Regulating small business

11.1 The legislation applies to small business. It is recognised that although regulatory fees represent a relatively small element in the annual outgoings of a small pharmaceutical business, it is likely to represent a greater proportion of their outgoings than for larger businesses. The MHRA operates a number of provisions to assist smaller companies, such as reduced fees for certain small companies, lower periodic fees for products with low turnover, and extended terms of payment of a number of capital fees.

11.2 The Agency will consider further assistance and targets small businesses in it consultation process each year. However, reduced fees below costs incurred would lead to cross subsidisation from fees paid by other companies, so it is not possible to offer general fee reductions for smaller companies.

12. Monitoring & review

12.1 The changes in the fees aim to achieve full cost recovery for the MHRA, please refer to the attached Impact Assessment for further details.

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 Medicines (Products for Human Use – Fees) Regulations 2010**	
Stage: Final	**Version: 2**	**Date: 1 February 2010**
Related Publications: 'MHRA Regulatory Fees – proposals for 1 April 2010' consultation document (MLX363)		

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 the pharmaceutical industry, some NHS and other public bodies in relation to the regulation of medicines. Fees income is being increased by 1% overall (which is less than current inflation: CPI at 1.8 in August 2009) in order to cover estimated unavoidable increases in costs for the Medicines and Healthcare products Regulatory Agency (MHRA) from April 2010. The MHRA protects public health by ensuring that all medicines and medical devices placed on the UK market are safe, of good quality, and, where appropriate, efficacious.

What are the policy objectives and the intended effects?

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

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

1. Do nothing.

2. Increase individual fees to ensure unavoidable costs can be met, but ensure full cost recovery is achieved. This is our preferred option

3. Increase fees across the board by inflation (CPI at 1.8 as of August 2009) – however, this would mean fees would not reflect real costs. CPI is not an accurate indicator of the MHRA's cost base.

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:

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

Summary: Analysis & Evidence

Policy Option: 1	Description: Do nothing

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition) **Yrs**	This figure represents the status quo. All holders of manufacturers', wholesale dealers' licences, marketing authorisations and herbal and homoeopathic registrations are liable for fees.
£	
Average Annual Cost (excluding one-off)	
£	**Total Cost** (PV) **£**

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

If we implement this option, MHRA will be operating at below cost without the ability to rely on any other funding (there is no central Government funding for medicines work). It would restrict the Agency's ability to meet its regulatory requirements, for example, tackling counterfeit medicines, or handling adverse reactions, and could be a risk to public health.

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups'
One-off **Yrs**	Although there would be small benefits for companies as they would be paying 2009 fee charges, the MHRA would be able to meet most of its commitments with a limited budget , it would be working with fees below actual costs.
£ 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) **£ NIL**

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 for 2010/11 are covered.

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups' Increased costs to each individual fee by 1%. All holders of manufacturers' and wholesale dealers'licences and Marketing Authorisations are liable for fees.
One-off (Transition) **Yrs**	
£ NIL	
Average Annual Cost (excluding one-off)	
£1m	**Total Cost** (PV) **£1m**

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

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups' Although it has not been monetised, the MHRA can continue to meet all obligations to protect public health.
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 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, Implementing Better Regulation benefits.

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 & Evidenc

Policy Option: 3	Description: Increase fees by inflationary ra 2009) across the board.

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups' All companies' costs would be increased by a greater amount than required for MHRA to operate.
One-off (Transition) **Yrs**	
£ NIL	
Average Annual Cost (excluding one-off)	
£ 1.8m	**Total Cost** (PV) **£ 1.8m**

Other **key non-monetised costs** by 'main affected groups' The Agency would be over funded for the year, costs and fees would not be matched correctly contrary to the Treasury guidance and Trading Fund Order. Companies would not benefit from implementation of Better Regulation initiatives.

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups'.
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/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**

[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. It acts on behalf of the Ministers comprising the Licensing Authority (as described in the Medicines Act 1968 as amended[1]), in the regulation of the parts of the pharmaceutical industry concerned with medicines for human use.

1.2 The MHRA is a Government Trading Fund and, as such, is fully funded for its medicines regulatory function by fees in connection with the manufacture, sale and supply of medicines. 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. Under the terms of the Trading Funds Acts, the MHRA has a financial objective to at least break even taking one year with another and to set fee levels to achieve this, after taking account of HM Treasury's requirement to earn 3.5% return on capital employed in real terms.

1.3 The Agency has a large number of different fees specific to relevant areas of medicines work (a full list of the current fees and proposed new fees are listed in Annex A of the consultation document).

Objectives

1.4 These proposed Regulations will consolidate existing legislation for the majority of fees charged by the MHRA in connection with the regulation of medicinal products for human use and medical devices in the United Kingdom incorporating changes proposed for 1 April 2010. (Medical devices are affected by these proposals only in respect of consultations for drug/device combinations. A separate IA has been prepared for proposals for changes to medical devices regulatory fees.) The proposal for 2010/2011 is to achieve full cost recovery of the work undertaken.

1.5 The Agency also intends that, through the implementation of these fee proposals, it will support its broader objectives and priorities, including:

- Ensuring that the Agency is adequately funded to fulfil its responsibilities for public health protection;
- Improving efficiency and promptness in the handling of licence applications and variations, including through incentivising companies to move to the international standard for electronic working (eCTD);
- Ensuring that the Agency has sufficient funding to recruit and retain the staff it needs, in licence assessment and other areas;
- Ensuring that fee levels reflect fairly the costs related to that activity, without cross-subsidy;
- Enabling the Agency to respond effectively to the threat posed by counterfeit medicines, through proactive intelligence, investigation and enforcement work;
- Supporting “Better Regulation” activities, including risk-based inspections, simplified regulatory processes, and revised and consolidated legislation.

Rationale for Government intervention

1.6 The need for a statutory system for regulating medicines and other healthcare products is well accepted by all parties, and reflects the position followed in all developed countries. The rationale for

[1] *Relevant amendments have been made by the Veterinary Medicines Regulations 2006 (S.I 2006/2497). "The Ministers" are the Secretary of State for Health and the Northern Ireland Department of Heath, Social services and Public Safety.*

this is not only to protect the public from unsafe, ineffective or poor quality medicines (although this is the primary purpose of the regulatory system), but also to enable and support a successful industry sector able to develop and market products that can benefit health. In the absence of a regulatory system, the lack of public confidence – and the lack of a level playing field - would hamper companies' ability to do this. The fee proposals in these Regulations are designed so as to ensure that the MHRA can effectively carry out its responsibilities to safeguard health, through charging fees that provide the resources for its work.

1.7 It is difficult to quantify precisely the health or economic impact of the Agency having insufficient resources to carry out its work effectively, but examples that are relevant to the proposals being made are:

Health impact - 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 the protection of public health through medicines. This would undermine the core purpose of the regulatory system to protect public health, and lead to harm and unnecessary deaths.

Economic impact 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.

1.8 It is therefore important that the MHRA is able to gain sufficient income from fees to resource these 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. The Agency also has a role in supporting innovation and enabling businesses to prosper, through handling routine regulatory processes promptly and efficiently. Unnecessary delay in regulatory activity can be costly to companies in terms of delayed product launches, lost revenues from new or revised products, and planning blight from unpredictable timetables. Again, although it is difficult to quantify health or economic costs of failing to undertake regulatory work – for instance, failing to act quickly to recall a defective medicine, or failing to spot and act on a new safety signal – any estimates of the impact that may be offered by consultation recipients would be welcome.

1.9 The rationale behind these fee proposals is therefore to ensure a fee regime that enables the Agency to fulfil its role in safeguarding public health; and also uses the resources from fee income to target essential developments in the Agency's regulatory functions.

2. Consultation

2.1 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.

2.2 A 12 week public consultation on the proposals began on 16th October 2009 and ended on 8th January 2010. Over 2000 letters were posted alerting interested organisations to the consultation on the MHRA website. A total of 8 responses were received (6 from industry associations, and 2 from companies) all broadly supporting the proposals.

3. Options

3.1 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 less well resourced in real terms than currently.

Option 2: Increase fees as proposed to cover costs. Last year's fees consultation incorporated a 3 year outlook which had suggested that this year's fee increase for medicines would be in the region of 4-6%. The anticipated cost increase in 2010/11 could be in the region of 4-5% and this would therefore fall within the range previously communicated. However, the economic climate has changed since last

year's fees round and means that the fee increase in 2010/11 is reduced to 1% which will still recover full-costs.

Option 3: Increase fees by an inflationary figure (1.8% - CPI level at August 09) across-the-board. This option would mean that the Agency would be charging more for its fees than it considers it needs for 2010/2011.

4. Costs and Benefits

Sectors and groups affected

4.1 All sectors of the pharmaceutical industry, including herbal and homeopathic sectors involved in the manufacture, sale and wholesale of medicinal products for human use (around 3,000 organisations and companies in all). These Regulations also affect academia where medical research and clinical trials are carried out, and NHS organisations that manufacture products.

4.2 It is not possible to identify a "typical" business. Businesses range from small "one-man-band" wholesale dealers, NHS Trusts and hospitals, academic research establishments, up to multi-billion pound international manufacturing businesses. In all cases, the costs involved are simply the direct additional (or reduced in some cases) costs from paying higher fees. We are advised by the relevant industry associations that the costs associated with MHRA fees are a very small proportion of overall costs for the OTC industry – between 3% and 8% of total budgets. There are no indirect costs, policy costs or additional administrative burden costs as a result of these proposals. These proposals include a measure which will reduce administrative burden for one particular type of variation.

4.3 Some examples of potential costs are:

- A large innovative company that: makes 4 complex abridged applications (2 of which are fully eCTD compliant) and 2 eCTD compliant standard abridged applications; has an existing portfolio of 100 products, 50% of which are Prescription Only Medicine (POM), 40% Pharmacy sale and 10% GSL; makes 1 Type II complex, 3 Type II and 12 Type IA variations none of which are eCTD compliant applications, will pay £309,486 in fees in 2010/2011 compared to £307,084 in 2009/2010. This figure equates to less than a 1% increase across the board due to the changes in variation fees (the implementation of the new variation group fees implemented into UK legislation in January 2010). The sum payable in fees is likely to comprise a very small part of such a company's turnover –in the region of 1% - 6%.

- A generic company that: has a portfolio of 15 POM products, 50 Pharmacy sale products and 30 GSL products; makes 5 standard abridged applications; and has an inspection in year that takes 1 day, will pay around £107,749 in 2010/2011 compared to £106,682 in 2009/2010 (1% increase across the board for fees). This is likely to represent between 3% and 8% of total turnover.

Benefits

4.4 The benefits are to all sectors of the pharmaceutical industry (relating to human medicines), research facilities, NHS organisations and more generally to the public health. Stakeholders will continue to see benefit from improvements in service levels from the MHRA in terms of speed and predictability of processing of licence applications. Increases in fee for 2009/2010 enabled the Agency to improve its service levels considerably and it will be able to build on that more stable platform for the coming years. The public health will benefit from these measures by ensuring that the MHRA is adequately resourced for the work it undertakes in ensuring the safety, quality and efficacy of the medicines used by patients in the UK and the safety and suitability of blood establishments.

Better Regulation benefits

4.5 The Agency has already removed some MA variation fees (for the "do and tell" applications in anticipation of the Directive being implemented. The cost of the remaining work associated with these particular variations is recovered through the annual fee in anticipation of this EU procedure. The new procedure is a "do and tell" approach, which can be done annually rather than companies having to apply for each change individually, and having to wait for action by the Agency before they can benefit

from the change. – the full benefits of this are estimated to be in the region of £2m, calculated at £1m reduction in actual fees and £1m in reduced administrative costs in relation to making individual applications and processing individual invoices for each change. This benefit was introduced in April 2009.

5. Small Firms Impact Test

5.1 Some of the businesses affected by these proposed fee increases are small firms. The overall effect of the proposed fee increase will vary depending on what types of licences companies have and how active their business is.

5.2 Examples of the effects on small businesses of option 2 might be:

- An application from a new wholesale dealer for a standard licence would cost £1,754 in 2009/2010 compared to £1,737 in 2009/2010.

- Small manufacturers will also benefit from the grouping of certain variation fees.

5.3 A number of small businesses will again be contacted during the consultation process.

5.4 The effect of Option 1 would be that small firms' costs in 2010/2011 would remain more or less the same as in 2008/2009.

5.5 The effect of Option 3 would be to increase costs for smaller companies by 1.8% compared to 2009/2010**.** Using the specific examples above, the increases in fees for the example shown would amount to £31.27. These would all be a higher cost than in Option 2.

5.6 It is recognised that although regulatory fees represent a relatively small element in the annual outgoings of a small pharmaceutical business, it is likely to represent a greater proportion of their outgoings than for larger businesses. The smallest of the businesses in the pharmaceutical industry do not tend to be developmental companies and so costs associated with applications for new products rarely arise.

5.7 The MHRA operates a number of provisions to assist smaller companies, for example:

- reduced fees for certain smaller companies;
- lower periodic fees for products with low turnover;
- extended terms of payment of a number of capital fees.

5.8 The Agency will consider further assistance it is able to offer. However, reducing fees below costs incurred would lead to cross-subsidisation from fees paid by other companies, so it is not possible to offer general fee reductions for smaller companies.

6. Competition Assessment

6.1 The proposed fee increases will affect a number of different markets within the pharmaceutical industry and the NHS. No organisation may operate in the pharmaceutical market in the UK (whether in manufacturing, distribution or sales) without being subject to the regulatory system operated by the MHRA. Regulatory fees are a permanent feature of the market, and we do not anticipate that the increases are likely to have any significant impacts for competition in any of the affected markets.

6.2 Fees expenditure represents a relatively small proportion of the annual outgoings of most of the affected firms (between 1% and 8% for all but the smaller companies), and this will continue to be the case following implementation of the proposed increases. The current fees structure provides for reductions in the case of certain smaller companies and lower periodic fees for products with low turnover. There is also provision for paying by instalments. This helps to mitigate potentially disproportionate effects on smaller participants in the affected markets and any potential barriers to entry. 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.

6.3 The consultation will seek comments on whether these proposals would be likely to have any impact on barriers to market entry or the structure of competition.

7. Equality Impact Assessment:

7.1 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.

8. Legal Aid, Sustainable Developments, Carbon assessment, other environmental issues

8.1 There are no impacts on environmental, sustainable development or carbon offsetting from these proposals. There are no implications for Legal Aid from these proposals.

8. Enforcement, Sanctions, and Monitoring

8.1 The new proposals will be enforced by the Finance Division of the Agency which is responsible for raising invoices and collecting revenue for the Agency. There are certain sanctions where some fees are paid late and an additional charge is incurred. The Agency also has the power to suspend certain licences where fees have not been paid although safety and protection of public health would be a test that would be applied before taking this route. Work will not usually be started on applications which have not been accompanied by a payment. The measure of whether the policy meets its objectives will be apparent through the year through monitoring the budgets and also through auditing final accounts.

9. Implementation and delivery plan

9.1 The new fees will apply to all applications received 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.

10. Post-implementation review

10.1 The new fees and the anticipated income through estimated volumes have been matched with the Agency's budget plan for 2010/2011.

10.2 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. In addition, the Agency is continuing to seek efficiencies from within its working practices, both to speed up the processes and also to provide a better standard of service from within current resources.

11. Summary and Recommendations

11.1 Option 2 best achieves the objective of ensuring that costs to the pharmaceutical industry reflect the actual cost of the work undertaken by the MHRA in connection with medicines regulation. It will allow the MHRA to undertake its responsibilities for protecting public health. It will support the Agency's ability to respond to public health threats as well as deliver prompt handling of regulatory business. In order to ensure that over the coming year the Agency can meet its responsibilities towards its various stakeholders, the fee proposals as set out in Option 2 represent the most effective option.

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