EXPLANATORY MEMORANDUM TO

THE MEDICINES (PRODUCTS FOR HUMAN USE-FEES) REGULATIONS

2009 No. 389

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. In addition, this instrument amends the Medicines (Homoeopathic Products for Human Use) Regulations 1994.

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

3.1 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.

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

- to reflect the correct cost of undertaking each area of work;
- 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.

3.3 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. The individual fee levels vary greatly from £66 for an export certificate for a medicinal product, up to £153,174 for a licence application for a major new medicinal product.

3.5 The Agency assesses its fees and costs each year. Where there are likely to be future increases in fees in line with costs, the Agency is taking measures to deliver efficiencies.

4. Legislative Context

4.1 This instrument revokes and re-enacts in consolidation form the Medicines (Products for Human Use–Fees) Regulations (S.I. 2008 No 552); and amends the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (S.I. 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 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

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 (S.I. 2008 no 552) 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 targeted increases in fees in some specific priority areas; and more generally applies fees changes with an overall average of 3%. Some fees have gone up by 5.7%, (all Marketing Applications and variations) some by less (Manufacturing and Wholesale Dealers Licences by 4%) The principle changes in the Regulations are:

- Two new Parallel import fees, Complex and Standard, for applications where there is no common origin between the imported and UK reference product. Current Parallel import applications will be renamed as Parallel import (Simple). This change is in light of the Kohlpharma Case which determined that competent authorities could not refuse a parallel import application solely on grounds that the Parallel import and the reference product authorised in the Member State of importation do not have a common origin. The absence of a common link requires the Agency to request further information, therefore could amount to a considerable amount of more work, (requesting more information and further assessment of data), therefore the rate(s) of fees need to reflect the work carried out in each case;

- A provision to transfer, without a fee, the older herbal Marketing Authorisations to more suitable traditional herbal registration(THR) scheme;

- A new banding for service fees for manufacturing and wholesale dealers who import unlicensed medicines calculated on the basis of the number of notifications submitted, and with new fee categories that will recover more of the cost of the work;

- An extension of the fee of £10,000 to all applications for Person Appointed hearings in order to fully cover the costs involved (with one exception, that relating to applications concerning blood) ;

- A new fee structure for Reclassification Variation Applications and for reclassification elements of a new MA application to reflect more accurately the work incurred by the Agency in reclassification for prescription only (POM) to pharmacy (P);

- A new fee for wholesale dealers licenses to include the first inspection fee. There will also be a provision, whereby if the application is withdrawn either at the time when the inspection is arranged, or within 15 days of the date of inspection, there will be a

refund of the charge equivalent to the inspection fee. This simplifies invoicing and ensures that the inspection fee is recovered;

This instrument also makes miscellaneous minor drafting amendments to clarify current anomalies in consolidation from last year.

- ***Consolidation***

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

8. Consultation outcome

8.1 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.

8.2 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. The consultation document was placed on the Agency's website.

8.3 A total of 11 responses to the fees proposals for medicines were received. Almost all responses were from industry associations. Whilst there was acknowledgement that there was a need for the Agency to be well-funded in order to deliver its responsibilities effectively, there were some concerns expressed over the levels of increases in some areas and about the levels of service currently being provided by the Agency and the need to improve further. The Agency accepts that it will be necessary to demonstrate further improvement in service levels experienced by companies in return for the proposed fee increases and will continue to work with the industry associations to achieve this.

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, 1 Nine Elms Lane London SW8 5NQ, 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, paragraph 1.4 (objectives) for further details.

13. Contact

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 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: 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 3% overall (which is less than current inflation) in order to cover estimated unavoidable increases in costs for the Medicines and Healthcare products Regulatory Agency (MHRA) from April 2009. 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. It will also implement further its Better Regulation initiatives by simplifying the fees structure to reflect a forthcoming change in EU regulation on variations. This simplification will produce significant savings to industry in the region of £2m through actual reduced fees and through simplified admin processes.

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

1. Do nothing.

2. Increase fee to ensure unavoidable costs can be met, targeting increases accordingly, and make simplification. This is our preferred option

3. Increase fees across the board by inflation – however, this would mean fees would be increased by a figure higher than we are proposing and would not reflect costs.

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

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

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

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

Signed by the responsible Minister:

Dawn Primarolo .....Date: ***26th January 2009***

Summary: Analysis & Evidence

Policy Option: 1	Description: Do nothing

COSTS

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

Description and scale of **key monetised costs** by 'main affected groups' This figure represents the status quo. On 2009/20010 fee levels, the budgeted income for MHRA activity in medicines regulation is £76.3m. All holders of manufacturers', wholesale dealers' licences, marketing authorisations and herbal and homoeopathic registrations are liable for fees.

Total Cost (PV)	**£ nil**

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

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£ NIL	
Average Annual Benefit (excluding one-off)	
£ 2.2m	

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

Total Benefit (PV)	**£ 2.25m**

Other **key non-monetised benefits** by 'main affected groups' Costs for companies would remain the same as for 2008/2009 but they would not benefit from a significant Better Regulation initiative. MHRA may have to cut costs and as staff costs are a major cost, a freeze on recruitment for vacancies might be considered. But this is likely to result in areas of the Agency being undermanned. Performance would be affected and public health protection may suffer as a result.

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

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

What is the geographic coverage of the policy/option?			UK	
On what date will the policy be implemented?			1 April 2009	
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 2009/10 are covered. Implement Better Regulation and

COSTS

ANNUAL COSTS	
One-off (Transition) **Yrs**	Description and scale of **key monetised costs** by 'main affected groups' Increased costs are targeted to specific fees at different levels to balance out cost recovery. Some specific fees will be removed to reflect a less onerous method of processing varations which will come into force in Autumn 2009. Other fees will be increased between 4% and 6% with a small number of annual fees increased by 8%. All holders of manufacturers' and wholesale dealers'licences and Marketing Authorisations are liable for fees.
£ . NIL	
Average Annual Cost (excluding one-off)	**Total Cost** (PV) **£ 2.2M**
£ 2.2M	

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

BENEFITS

ANNUAL BENEFITS	
One-off **Yrs**	Description and scale of **key monetised benefits** by 'main affected groups' Some fees are removed where changes to procedures under Better Regulation will produce savings. Savings in terms of reduced fees paid are estimated to total £1.9m.
£ NIL	
Average Annual Benefit (excluding one-off)	**Total Benefit** (PV) **£ 2.9m**
£ 2.9m	

Other **key non-monetised benefits** by 'main affected groups' Some fees removed along with a high number of low-value financial transactions will create savings for both industry and MHRA. Removal of need to submit high number of specific applications for variations will save industry time and money. MHRA can continue to meet all obligations to protect public health.

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 2009	
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 (RPI fig Aug 2009/10) across the board.

COSTS

ANNUAL COSTS	
One-off (Transition) **Yrs**	Description and scale of **key monetised costs** by 'main affected groups' All holders of manufacturers' and wholesale dealers'licences and Marketing Authorisations are liable for fees. Costs would be raised by 4.8% (RPI fig Aug 08)across the board for every individual fee.
£ NIL	
Average Annual Cost (excluding one-off)	
£ 3.4m	**Total Cost** (PV) **£ 3.4m**

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	
One-off **Yrs**	Description and scale of **key monetised benefits** by 'main affected groups' All companies' costs would be increased by a greater amount than required for MHRA to operate.
£ 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 2009	
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

1.3 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.

1.4 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 2009. (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 2009/2010 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 - Being unable to tackle counterfeit medicines effectively would expose medicines users to health risks in two ways:

- toxic or impure ingredients in the counterfeited medicines
- lack of, or insufficient active ingredient in the medicine

Most counterfeit products seized by MHRA contain no or insufficient active ingredient, risking adverse health impact. Counterfeit medicines discovered in the last year have included antipsychotic drugs, cancer drugs and blood thinning drugs – if products of this kind were able to circulate freely and be supplied to patients in large numbers, serious health effects and deaths would be likely.

Economic impact – Unnecessary delay in MHRA approvals can have an impact on pharmaceutical companies through lost earnings. For example, for a branded medicine earning £19m annual revenue in the UK, a delay of two weeks might reduce profits by an estimated £36,000 for that one product (this is a crude estimate). The consultation exercise seeks more detailed estimates by individual companies.

1.8 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. The Agency, as a Trading Fund (TF), would be unable to sustain its financial position. Staff numbers would have to be cut to be able to break even taking one year with another as required by the TF Order. If the MHRA is not adequately resourced for the work it undertakes there could be a risk to human health in the long term. This could occur through delays in assessing the safety, quality and efficacy of a critical medicine which could delay the product getting to the market and thus lives could be lost. There could be delays in handling reports of defective medicines or adverse reaction alerts which, if the information is not disseminated quickly enough, could allow medicines known to present risk of harm to patients to continue to be used. This would undermine the core purpose of the regulatory system to protect public health, and lead to harm and unnecessary deaths.

1.9 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.

1.10 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 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. The consultation document was placed on the Agency's website.

2.3 A total of 11 responses to the fees proposals for medicines were received. Almost all responses were from industry associations. Whilst there was acknowledgement that there was a need for the Agency to be well-funded in order to deliver its responsibilities effectively, there were some concerns expressed over the levels of increases in some areas and about the levels of service currently being provided by the Agency and the need to improve further.

2.4 Industry responses have raised a number of issues which the Agency has considered carefully. In particular, the Agency accepts that it will be necessary to demonstrate further improvement in service levels experienced by companies in return for the proposed fee increases and will continue to work with the industry associations to achieve this. We intend to respond to individuals on the points they have raised.

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, make adjustments to some fees to ensure costs are covered and implement Better Regulation benefits.

Option 3 - increase fees by an inflationary figure (**4.8**% - RPI level at August 08) across-the-board.

3.2 Option 1 would freeze most licensing costs at 2008/2009 levels (meaning no additional cost to the industry). This would result in a lack of full funding which 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 contrary to the requirements of the Agency's Trading Fund status. The Agency would have difficulty in resourcing its work generally, potentially placing the public at risk of harm. There would also be a direct impact on companies in terms of the speed and efficiency with which work – such as licence applications, or variations – were dealt with. This in turn has a direct effect on the costs and earnings of pharmaceutical companies.

3.3 Option 2 will ensure that the correct fee is charged to cover the cost of each area of work undertaken. Some fees are increasing, some are being removed altogether. Efficiency gains are being implemented through this proposed increase – the increase proposed will net less income than the Agency estimates its costs will increase but the shortfall will be met by efficiency gains. Other main changes include introducing additional categories of existing applications where the current fee does not cover the cost of the work undertaken. For example, reclassification of products from prescription only supply (POM) to pharmacy sales (P) cost more to process than a change from P to General sales List (GSL) over the counter drugs. Making drugs more accessible to the public is a key Government aim and we need to be fully funded to enable us to work to meet this. Another area where a differential fee is being introduced is in response to a recent European Court of Justice (ECJ) case, Kohlpharma, which involves importing products from other EU member states. The ruling means that applications for this type of importation must now be accepted, but there is far more work associated with ensuring the safety of the products than for other imports (Parallel Imports) and the Agency needs to be able to cover this cost if they allow these applications.

3.4 Certain variation application fees are proposed to be removed in anticipation of a new EU Directive on variations being implemented next autumn (2009). The new process for making administrative changes to licences will be much less onerous on companies resulting in savings for them in terms of not having to make individual applications for minor amendments each time they arise but operating a "do and tell" process. In addition, both companies and the Agency will gain from there not

being individual financial transactions taking place for each of these variations. Overall, the increase, the specified removal of certain variation fees and the new fees will ensure continuing targeting of costs and that the Agency is remunerated adequately for the work it undertakes. It will also help to ensure adequate resources for essential public health protection, and for improving response times in some areas of licensing work.

3.4 Option 3 would mean that the Agency would be charging more for its fees than it considers it needs for 2009/2010. An increase linked to the level of inflation as at August 2008 (4.8%) does not reflect actual costs arising from essential regulatory functions.

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 £307,084 in fees in 2009/2010 compared to £288,706 in 2008/2009. 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; makes 16 Type IB (BROMI) variations; 50 Type 1A variations; and has an inspection in year that takes 1 day, will pay around £159,631 in 2009/2010 compared to £154,006 in 2008/2009. 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 2008/2009 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.

4.5 A key concern of pharmaceutical companies is that they receive a prompt and efficient response from the MHRA when they submit applications or variations for the licences that they hold. The Agency recognises that the business costs to companies from slower than expected processing of applications (for example delayed product launches) can greatly outweigh the costs from the fees themselves. The intention of Option 2 is that fees are set in such a way that the resources can be deployed to ensure efficient and prompt handling of such work.

4.6 Better Regulation benefits

We are proposing to remove some variation fees altogether and the cost of the remaining work associated with these variations will be recovered through the annual fee. The proposal is that we remove fees for administrative variations for marketing authorisations in anticipation of a new EU procedure for these types of application being implemented in autumn of 2009. The new procedure will be 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 a high volume, low value area of financial transactions and savings in time and effort will also be felt in the Agency's finance department. However, there will still be some administrative work for the Agency in updating the records when the notifications are received and this is reflected in a proportion of the total cost of these variations being transferred to the periodic fees. This saving will be reflected in the Simplification Plan.

Costs

4.7 Regulatory activity in this sector is in large part demand-led, in that companies choose whether to submit applications for new licences or variations to existing ones. In some areas, such as inspections, the Agency – following legal requirements and guidance – determines the degree of regulatory activity, although as noted below, companies have a degree of control in this area too as inspections become more risk-based. It is therefore not possible to give a reliable indication of total additional costs from these proposals. The Agency's estimate of the overall increase in income from fees is 3 per cent. The increases are being targeted and changes made to increase specific areas (mainly between 4% and 6%) are outweighed by the removal of the specific fees for certain variations. On the basis of activity remaining the same as this year, this would amount to roughly £2.2m in total. The Agency will be making efficiency gains enabling it to achieve its regulatory requirements and business plans within this resource provision.

4.8 For individual companies, as set out in the case studies above, the costs will vary according to the business they are in and the activities they choose to undertake. The proposals in these Regulations also allow companies to have a greater degree of control and choice as to the regulatory fees they face, in particular:

- By choosing to adopt the eCTD standard of electronic working (which is accepted as the future standard for all regulatory business across Europe and beyond), companies can ensure that their product licence application and variation fees remain below other 2009/2010 fee levels;
- The risk-based approach to inspection means that more compliant companies can expect to have fewer inspections than those who give cause for concern. This in itself would lead to lower fees as a result of less frequent inspections. In addition, the daily inspection fee rates now proposed would also benefit more compliant companies in that the fees per inspection would be set proportionate to the actual resources used.
- By taking up the opportunity to use new simplified processes developed under the BROMI initiative, companies can benefit from lower fee levels as well as a reduction in administration and other benefits.

4.9 In these areas, therefore, the degree of additional costs faced by companies from fee increases is in companies' own hands.

4.10 There are no associated policy costs or administration costs from these proposals.

Downstream cost impact

4.11 Those affected operate in different market sectors, with different impact on purchasers. The estimated impact on the medicines sector is in total £2.2m under option 2 or £3.4m under option 3. The Agency does not record the different medicines market sectors (i.e. retail over-the-counter, branded prescription, and generic prescription) in which the products it regulates are sold. The downstream impact of these additional costs on prices and purchasers will be mainly on general consumers (in the over-the-counter market), and the NHS drugs bill. Costs are more likely to passed on to the NHS drugs

bill in the case of generic prescription medicines than in the case of branded prescription medicines because of the nature of the market and price regulation.

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:

- A small wholesale dealer dealing in General Sales List (GSL) product only (probably the smallest business within the whole sector) will pay an annual periodic fee of £166 in 2009/2010 which is £6 greater than in 2008/2009. If he also has an inspection during the coming year (these are generally carried out on a 5-year cycle for GSL wholesale dealers), it will cost £932 compared to £896 in 2008/2009. For this particular small business, increased costs will amount to £42 over the year if he has an inspection in the coming year - if he does not, his costs will increase by £6. If he applied to the Agency's Finance Department, he would have the option to spread the cost of the inspection over two years by paying 50% of the fee on receipt of the invoice and the remaining 50% 12 months later. This applies to all examples.

- A small manufacturer holding five marketing authorisations for General Sales List products, may need to take into account annual periodic fees; 5 Type 1A variations; a one day inspection fee; and the assessment of a new label and leaflet. In 2009/2010 the company would pay £5,689 compared to £6,316 in 2008/2009.

- An application from a new wholesale dealer for a standard licence would cost £1,737 in 2009/2010 compared to £1,670 in 2008/2009.

- Small manufacturers will also benefit from the removal 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 2009/2010 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 4.7% compared to 2008/2009**.** Using the specific examples above, the increases in fees for the three examples shown would amount to £42, £1,237, and £78 respectively. 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 2009. 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 2009/2010.

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 provide incentives, and target resources, in a way that supports 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