EXPLANATORY MEMORANDUM TO

THE MEDICINES (PRODUCTS FOR HUMAN USE – FEES) REGULATIONS 2008

2008 No. 552

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. Description

2.1 This instrument consolidates and amends the regulations 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 average of 7.3%, although the increase is targeted to cost. Some fees have gone up by more than 7.3%, some by less, some fees have not been increased and some have been reduced (for certain types of applications flowing from the Better Regulations of Medicines Initiative (BROMI) or submitted electronically and for clinical trial authorisations where the product which is being or was tested or used in a clinical trial which has been authorised by the licensing authority in accordance with Directive 2001/20/EC of the European parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.). The instrument also introduces a new means of calculating inspection fees based on the time spent in making the inspection rather than on the type of inspection carried out.. This new method replaces 35 different types of inspection fee.

This instrument introduces a new fee designed to cover costs associated with a new area of work which relates to an appeals process for applications for medicinal products (Persons Appointed). The provisions include a full refund if the decision by the Licensing Authority, at the end of the process, is in the applicant's favour.

This instrument also amends some of the original provisions for waiving certain fees in certain circumstances.

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 above the rate of inflation 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;
- to ensure that the MHRA can effectively carry out its responsibilities to safeguard public health.

3.3 Some individual fees are being reduced, as part of the Better Regulation of Medicines Initiative (BROMI). This is a joint initiative between the Agency and other stakeholders including industry, to seek opportunities to simplify and reduce regulatory burden whilst maintaining public health protection.

3.4 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 £63 for an export certificate for a medicinal product, up to £98,000 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 background

4.1 This instrument consolidates the Medicines (Products for Human Use–Fees) Regulations 1995 (SI 1995 No 1116 as amended); 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), and to introduce a new, simplified fee regime for inspections.

5. Extent

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

7.1 The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health. It carries out the functions of the Ministers (as described in section 1 of the Medicines Act 1968) who under section 6 of the Medicines Act 1968, constitute the Licensing Authority responsible for the grant, renewal, variation, suspension and revocation of licences and certificates and which, by regulation 2 of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 (S.I. 1994/3144) shall perform the functions of the competent authority of the United Kingdom under *inter alia* Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Commission Regulation (EC) No 1084/2003 concerning the examination of variations to the terms of a marketing authorisations for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State and Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.), in relation to the regulation of medicines for human use. This instrument affects the medicines functions of the Agency.

7.2 By virtue of the Government Trading Funds Act 1973, the MHRA has an obligation to at least break even taking one year with another and to set fee levels to achieve this.

7.3 The fees charged by the MHRA are monitored and reviewed annually to ensure, as far as possible, that the fees charged for a particular service, reflect the cost of the work undertaken. This is in line with Treasury guidance on Fees and Charges. This instrument amends the level of fees charged by MHRA in order to ensure that the full cost of the work undertaken is recovered.

7.4 The cost of compliance associated with this instrument is estimated to be around £6.9 million. In addition, the Agency is also proposing efficiency gains from within its current running costs. There are no associated recurring or non-recurring costs for those affected. The total income estimated for MHRA in 2008/2009, taking into account the increased fees and anticipated volumes, is expected to be around £73 million.

7.5 All sectors of the pharmaceutical industry involved in the manufacture, sale and wholesale of medicinal products for humans use (around 3,000 organisations and companies in all) are affected by these regulations. All of these companies and organisations have been consulted during a 12 week period on the proposals to increase these fees. The industry fully supports the MHRA's work in relation to medicines regulation but is concerned about the level of increase in the fees for medicines, particularly in relation to any impact on the NHS and to some service levels being experienced in the area of licensing for medicines. The MHRA has met directly with, and discussed these issues with some of the main industry associations and has worked closely with them to resolve the problems. Improvements have been achieved which will continue to be built on in 2008/2009.

8. Impact

8.1 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.

8.2 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.

9. Contact

9.1 Sue Jones at MHRA Tel: 020 7084 2652 or e-mail: sue.jones@mhra.gsi.gov.uk can answer any queries regarding this instrument.

Summary: Intervention & Options

Department /Agency:	Title:	
MHRA	Impact Assessment of The Medicines (Products for Human Use - Fees) Regulations 2008	
Stage: Final	**Version:** 2	**Date:** 17 January 2008
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 Pharmaceutical industry, some NHS and other public bodies in relation to the regulation of medicines. Fees are being increased overall in order to cover estimated unavoidable increases in costs for the Medicines and Healthcare products Regulatory Agency (MHRA) from April 2008. The MHRA protects public health by ensuring that all medicines and medical devices on the market in the UK are safe, of good quality and (for medicines) efficacious. The proposals include those supporting Better Regulation.

What are the policy objectives and the intended effects?

The objectives are to ensure the MHRA can recover its costs in relation to this work and thus continue its role to protect public heath. It is also to implement further benefits of Better regulation initiatives by reducing some fees and simplifying others.

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

1 Do not increase fees but implement benefits from better regulation and simplification initiatives.

2. Increase fees to ensure only essential unavoidable costs can be met. Target increases/decreases as appropriate. This is our preferred option.

3.Increase fees across the board by inflation - but this would fail to reflect the actual costs associated with essential regulatory functions.

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: ***30th January 2008***

Summary: Analysis & Evidence

Policy Option: 1	Description: Do not increase fees but implement benefits of better regulation and simplification initiatives

COSTS

ANNUAL COSTS	
One-off (Transition) **Yrs**	Description and scale of **key monetised costs** by 'main affected groups' This figure represents the status quo. On 2007/2008 fee levels, the budgeted income for MHRA activity in medicines regulation is £66m. All holders of manufacturers' and wholesale dealers'licences and Marketing Authorisations are liable for fees.
£ NIL	
Average Annual Cost (excluding one-off)	
£ nil	**Total Cost** (PV) **£ nil**

Other **key non-monetised costs** by 'main affected groups' If we implement this option, the MHRA will suffer a shortfall in funding with no other means to make up the difference. Recruitment would have to be stalled and performance is likely to suffer. Efforts to tackle counterfeit medicines and other risks would be curtailed,with harm to public health and safety.

BENEFITS

ANNUAL BENEFITS	
One-off **Yrs**	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.
£ NIL	
Average Annual Benefit (excluding one-off)	
£ 320k	**Total Benefit** (PV) **£ 320k**

Other **key non-monetised benefits** by 'main affected groups' Lower costs for companies.The Agency would have to seek to make cuts. Its biggest cost is for staff costs and 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 2008	
Which organisation(s) will enforce the policy?				MHRA	
What is the total annual cost of enforcement for these organisations?				£ N/A	
Does enforcement comply with Hampton principles?				Yes	
Will implementation go beyond minimum EU requirements?				No	
What is the value of the proposed offsetting measure per year?				£ N/A	
What is the value of changes in greenhouse gas emissions?				£ N/A	
Will the proposal have a significant impact on competition?				No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large	
Are any of these organisations exempt?	No	No	N/A	N/A	

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

Increase of £ NIL Decrease of £ NIL **Net Impact** **£** NIL

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Summary: Analysis & Evidence

Policy Option: 2	Description: Increase fees to ensure unavoidable cost increases for 08/09 are covered. Implement Better regulation and simplification initiatives

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 are increased by more than the average, small number are reduced. Two new fees for new work introduced. 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) **£ 6.9m**
£ 6.9m	

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 reduced where changes to procedures under Better Regulation have produced savings. Savings in terms of reduced fees paid are estimated to total £320k in 08/09.
£ NIL	
Average Annual Benefit (excluding one-off)	**Total Benefit** (PV) **£ 320k**
£ 320k	

Other **key non-monetised benefits** by 'main affected groups' Some fees are simplified through replacing 40+ individual inspection fees with 2 daily rates. More transparent costing. Public health continues to be protected by a fully funded Agency

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 2008	
Which organisation(s) will enforce the policy?				MHRA	
What is the total annual cost of enforcement for these organisations?				£ N/A	
Does enforcement comply with Hampton principles?				Yes	
Will implementation go beyond minimum EU requirements?				No	
What is the value of the proposed offsetting measure per year?				£ N/A	
What is the value of changes in greenhouse gas emissions?				£ N/A	
Will the proposal have a significant impact on competition?				No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large	
Are any of these organisations exempt?	No	No	N/A	N/A	

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

Increase of £ nil Decrease of £ nil **Net Impact** **£** nil

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Summary: Analysis & Evidence

Policy Option: 3	Description: Increase fees by inflationary rate (2.75% GDP deflator for 2008/9) across the board.

COSTS

ANNUAL COSTS

One-off (Transition) **Yrs**

£ NIL

Average Annual Cost (excluding one-off)

£ 2m

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 2.75% across the board for every individual fee.

Total Cost (PV) **£ 2m**

Other **key non-monetised costs** by 'main affected groups' The Agency would not be fully funded for the year, costs and fees would not be matched correctly contrary to the Treasury guidance and Trading Fund Order. Lack of funds could mean lack of resources to fully undertake responsibilities of the Agency, including protecting health and prompt handling of regulatory applications.

BENEFITS

ANNUAL BENEFITS

One-off **Yrs**

£ NIL

Average Annual Benefit (excluding one-off)

£ 320k

Description and scale of **key monetised benefits** by 'main affected groups' Lower costs for some companies using BROMI procedures.

Total Benefit (PV) **£ 320k**

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 2008	
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**

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.]

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 [a]), in the regulation of the parts of the pharmaceutical industry concerned with medicines for human use.

[a] *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.*

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 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 2008. (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 2008/2009 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 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.

Much of the additional £1m costs from anti-counterfeiting work is in investigating and bringing prosecutions in order to provide effective deterrence and prevent counterfeit suppliers from gaining penetration in the UK supply chain. Given the risk of harm to health, as well as the risk of loss of public confidence in the integrity of the medicines they receive, we believe this is essential action for us to take, and that the benefits justify these additional costs. The consultation exercise sought quantitative estimates of the harm in both health and economic terms from the risk of counterfeits but no specific comments were received.

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 sought more detailed estimates by individual companies but none were received.

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 22 responses to the fees proposals for medicines (3 of which were content or had no comment to make) 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 but implement the fee reductions arising from Better regulation initiatives introduced last year. 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 significantly less well resourced in real terms than currently.

Option 2 -. increase fees as proposed to cover costs and introduce reductions in fees for the Better Regulation benefits.

Option 3 - increase fees by an inflationary figure (2.75% - GDP deflator measure for 2008/9) across-the-board. As a measure of basic inflationary costs, this can be seen as a "do nothing" option

3.2 Option 1 would freeze most licensing costs at 2007/2008 levels (meaning no cost to the industry) but also implement some reductions in a number of fees (mostly relating to variations applications) which have come about through implementing some procedural changes through the Better Regulation initiative (estimated savings of £320k). This lack of full funding 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 not be able to resource its work on responding to the growing threat from counterfeit medicines, thus 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 reducing. Two new fees being introduced will ensure that adequate resources can be given to undertaking functions to protect public health – one of these is in relation to an accreditation scheme for phase I Clinical trial Units and the other in relation to ensuring adequate funding is in place to provide an appeal mechanism for licensing issues. Overall, the increase, the specified reductions 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 not meet the need to fully resource the Agency to carry out its work. An increase linked to the GDP deflator level of inflation does not reflect actual costs arising from essential regulatory functions. This would have a significant impact both on the Agency's ability to deal promptly with applications from companies, and on wider public health protection functions such as monitoring and responding to safety concerns about drugs in use. Neither would it adequately target fees to the actual costs incurred and would mean that the Agency's costs and fees were out of line. This would create inequity for companies and other bodies (including NHS bodies) paying fees, as there would be cross-subsidy between different activities. This is a concern which industry has expressed in the past, and cross-subsidy also contravenes the Agency's duties under the Trading Fund Act.

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. NHS and other organisations that store or manufacture blood products would also be affected.

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. There are no indirect costs, policy costs or administrative burden costs as a result of these proposals.

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 IB variations (all of the latter would be BROMI notifications) none of which are eCTD compliant applications, will pay £290,002 in fees in 2008/2009 compared to £268,899 in 2007/2008. If he were able to make all of his applications eCTD compliant, his cost would be £286,828. The sum payable in fees is likely to comprise a very small part of such a company's turnover.

- 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; and has an inspection in year that takes 1 day, will pay around £147,331 in 2008/2009 compared to £141,138 in 2007/2008. If he were able to make fully compliant eCTD applications his costs would be £145,006.

- An NHS hospital blood bank requiring to pay annual haemovigilance fee, an annual compliance fee and has a I.5 day inspection in year would have paid £4,103 in 2007/2008 but for the same services in 2008/2009 would pay £4,796 – a difference of £693
- Hospital blood bank inspections are targeted according to assessed risk and will generally take place every few years. The same hospital blood bank, if there were no inspection in year, would pay £1,118 in 2008/09 instead of £1,032 in 2007/8 – an increase of £86.

Benefits

4.4 The benefits are to all sectors of the pharmaceutical industry (relating to human medicines), research facilities, NHS organisations, blood establishments 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. 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 fee reductions for certain types of applications flowing from the BROMI initiative. The main benefit to companies from BROMI is in helping them to get products to market more quickly and with greater certainty – the full benefits of this were estimated in last year's Simplification Plan as saving the industry as much as £75m. But we have said that when we could be reasonably confident that changed processes led to lower costs within the Agency, we would consider reflecting that in fees. Proposed changes will result in estimated savings in fees of around £320k. Further administrative savings within companies may also be added.

4.9 Daily rate fees for inspections. Another initiative under the Better Regulation banner is the introduction of daily rates for inspections. Currently, there are around 35 different inspection fees for different types of inspection, all based loosely on the average time spent on site by the inspector. The new daily rates – of which there are two representing the different skills and thus grades of staff needed for two different types of inspection – replace the existing 35. The costing will be more transparent for companies and companies that are fully compliant are likely to be inspected less and thus costs will reduce. Conversely, companies who are less compliant are likely to receive more frequent inspections.

Costs

4.10 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 average increase for fees other than those (DCP and clinical trials authorisations) with specific targeted increases, is 7.3 per cent. On the basis of activity remaining the same as this year, this would amount to roughly £6.9m in total.

4.11 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 2008/2009 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.

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

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

Downstream cost impact

4.14 Those affected operate in different market sectors, with different impact on purchasers. The estimated impact on the medicines sector is in total £5.9m under option 2 or £1.8m 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 £160 in 2008/2009 which is £19 greater than in 2007/2008. 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 £896 compared to £747 in 2007/2008. For this particular small business, increased costs will amount to £168 over the year if he has an inspection in the coming year - if he does not, his costs will increase by £19. 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; a one day inspection fee; and the assessment of a new label and leaflet. In 2008/2009 the company would pay £5,376 compared to £6,424 in 2007/2008.

- An application from a new wholesale dealer for a standard licence would cost £1,670 in 2008/2009 compared to £1,542 in 2007/2008.

- Small manufacturers will also benefit from the new lower fees for BROMI notifications for variations and some label and leaflet changes.

5.3 Several small businesses were contacted during the consultation process. Two responded: One, a generic manufacturer said that the impact of the increases would cost in the region of £56k. As a result they may have to rearrange or cancel some of their planned submissions. They felt that MHRA increases were out of proportion with inflation and other European Regulatory Authorities. The other was a distributor of generic products to wholesalers and multiple retail pharmacies. They felt that the would be very little impact on them as a result of the proposed increases and felt that the benefits of complying with MHRA Regulations was ensuring that high standard are maintained.

5.4 The effect of Option 1 would be that small firms' costs in 2008/2009 would remain more or less the same as in 2007/2008 with the exception of some savings if they used the BROMI notifications systems for any applications.

5.5 The effect of Option 3 would be to increase costs for smaller companies by, say, 3.9% compared to 2007/2008. Using the specific examples above, the increases in fees for the three examples shown would amount to £25, £251, and £60 respectively. In the second example, this would 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, 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 sought comments on whether these proposals would be likely to have any impact on barriers to market entry or the structure of competition but no responses were received.

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 who 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. 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 2008. 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 2008/2009.

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

Annexes