EXPLANATORY MEMORANDUM TO

THE MEDICINES (PRODUCTS FOR HUMAN USE) (AMENDMENTS TO FEES FOR VARIATIONS) REGULATIONS 2009

2009 No. 3222

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.

2. Purpose of the instrument

2.1 This instrument makes amendments to current legislation in respect of the fees payable for an application to vary the terms of a marketing authorisation for a medicinal product for human use. The amendments to fees reflect the new procedures and the new classification into different categories of variations to medicinal products set out in Commission Regulation (EC) No 1234/2008 which applies from 1 January 2010.

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

3.1 None

4. Legislative Context

4.1 This instrument amends the Medicines (Products for Human Use) (Fees) Regulations 2009 (S.I. 2009/389) (The Fees Regulations 2009). The Fees Regulations 2009 provide for the fees which are payable in connection with applications to the Medicines Healthcare products Regulatory Agency in respect of marketing authorizations, licences and certificates relating to medicines for human use, including applications for the variation to the terms of such authorizations, licences and certificates. Commission Regulation (EC) No 1234/2008 which comes into force on 1 January 2010 establishes new procedures for the examination of applications relating to variations to the terms of marketing authorisations and introduces categories of different types of variations and enables some variations to be grouped and Member States to enter into a work sharing procedure. The amendments provide for fees to be payable in respect of the classification into new categories of types of variations to medicinal products and fees to be payable in respect of those applications subject to the worksharing procedures.

5. Territorial Extent and Application

5.1 This instrument applies to the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- ***What is being done and why***

7.1 Commission Regulation (EC) No 1234/2008 ("the EC Regulation) comes into force on 1 January 2010. The EC Regulation sets out a new framework for examining the variation to the terms of a market authorisation in respect of authorisations granted in accordance with Commission Directive 2001/83/EC which lays down the principles and guidelines of good manufacturing practices in respect of medicinal products for human use. The EC Regulation applies directly only to variations to marketing authorisations granted in European procedures and not to those granted from 'purely National' procedures. The EC Regulation adjusts the current procedures for variations and enables variations to be classified in different categories depending on the level of risk to the public and the impact on the quality, safety and efficacy of the medicinal product. The EC Regulation also enables variations to be in certain circumstances to be grouped and enables Member States to enter into work sharing procedures.

7.2 The MHRA's usual policy is to amend the fees legislation once a year (with effect from 1 April each year). The MHRA have to depart from this policy and have to make amendments now because of the coming into force date of the EC Regulation. If the MHRA waited until April 2010 to make amendments it would mean there would be no legal basis to charge fees for variations to Marketing Authorisations between January and the end of March 2010 as the current EC legislation relating to variations is revoked on the coming into force of the new EC Regulation. The MHRA is carrying out a separate consultation on proposed changes to the fees legislation and proposed increases from October of this year.

7.3 At present the UK has two systems for managing variations – a legislated system for EU procedures for variations (under the existing EU Regulation 1084/2003) and a UK system provided for under the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 and underpinned by Guidance which reflects the European procedures where appropriate .

7.4 Various options were considered but in order to achieve simplification for the administrative procedure for applications for variations to the terms of marketing authorizations granted under the European procedures and the administrative procedures for national variations which are broadly similar it would be simplest for both companies and the Agency to have a single common system from 1 January 2010 rather than have two different systems running until the scope of the European Regulation is enlarged. This will bring the 'better regulation' benefits

embodied in the new Regulation to UK-only MA variations. It will provide benefits of:

- Administrative simplification – a single set of rules (classification and procedural) for all variations regardless of marketing authorisations procedure.
- Achieving 'better regulation' measures for variations, which the UK Government strongly supports in respect of authorisations granted under the European procedure and national procedure, and taking a lead in Europe.
- Simplification, lower administrative burden of processing variations, particularly relatively minor ones which are usually straightforward, but of which there are large volumes and cost effectiveness for industry.
- Being compliant with the new EU Variations Regulation 1234/2008.

7.5 The main changes made by EC Regulation No 1234/2008 to procedural work proposed are:

- The change from an approval based system for simple variations to a "do and tell" system. The MHRA already made provision for the introduction of this procedure when changes were last made to fees in April 2009 i.e. no fee would be payable from April 2009.

- Certain types of variations to be grouped so applicants/ companies will be able to apply for a group of variations in a single application. Whilst this will not reduce the workload for the Agency in assessing and approving these variations, it will reduce the burden on companies significantly, to be able to make a single application rather than complete an individual application for each variation.

- To avoid duplication of work, in respect of the evaluation of variations of several marketing authorisations, a work sharing procedure is introduced. This enables one authority, chosen amongst the competent authorities of the Member States and the European Medicines Agency, to examine the variations on behalf of the other concerned authorities.

7.6 The Fees Regulations 2009 are amended to reflect the fees payable in respect of these newly defined types of variations, the possible types of groups of variations and the work sharing procedures where the MHRA is the chosen authority.

- ***Consolidation***

7.7 It is proposed that the Fees Regulation 2009 will be revoked and re-enacted in consolidated form with these amendments and to include the annual increase in fees in April 2010.

8. Consultation outcome

8.1 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.

8.2 Only three responses were received: from the Association of the British Pharmaceutical Industry (ABPI), the Proprietary Association of Great Britain (PAGB) and the Independent Healthcare Advisory Services, and all supported the proposals. We also held a meeting with all of the various industry trade associations (six in total), at which there was also support.

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9. Guidance

9.1 Guidance and information regarding the process followed for applying for a variation to a Marketing Authorisation by the pharmaceutical industry can be found on the MHRA website at www.mhra.gov.uk. European guidance for European procedures is available and the UK system is underpinned by National Guidance which reflects the European procedures where appropriate. This guidance is essential to understanding how the instrument will operate, but is not itself subject to Parliamentary scrutiny, copies are to be sent to the libraries of both Houses and to the Merits Committee at the same time as the SI is laid.

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 mainly affect the private sector pharmaceutical industry.

11. Regulating small business

11.1 The legislation applies to small business. 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. The Agency will consider further assistance and continue to targets small businesses in all its consultation processes each year.

12. Monitoring & review

12.1 The changes will be monitored, any feedback from industry will be noted and a full review will take place on a yearly basis.

13. Contact

13.1 Tracy Murray at MHRA Tel: 020 7084 2329 or e-mail: tracy.murray@mhra.gsi.gov.uk can answer any queries regarding this instrument.

Summary: Intervention & Options

Department /Agency:	Title: **The UK proposals on the charging of fees in respect of the European Regulation (EC 1234/2008) on Variations to Medicines Marketing Authorisations**	
Medicines and Healthcare products Regulatory Agency (MHRA)		
Stage: Final	**Version:** 2	**Date: 14 October 2009**
Related Publications: Consultation letter – MLX361 can be found at : www.mhra.gov.uk/Publications/Consultations/index.htm		

Available to view or download at:

http://www.mhra.gov.uk

Contact for enquiries: Tracy Murray **Telephone: 020 7084 2329**

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

The MHRA is required to change some of its fees provisions in-year in order to implement a European Regulation by January 1 2010. If we do not make these changes from this date, we will be unable to charge fees for variations to marketing authorisations (MAs) as the current legislation will no longer be operable. Variation fees comprise a significant amount of the annual income for the Agency.

What are the policy objectives and the intended effects?

To deliver a policy of simplification for companies by reducing administrative burden and making applications for variations more cost effective, and for the agency by reducing some costs associated with processing invoices and applications

To produce a single set of rules (classification and procedural) for all variations regardless of MA authorisation procedure.

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

1. Implement changes with fixed fees for group only for variations to Mutual Recognition (MR) procedures from 1 January 2010 in line with the scope of the Regulation.

2. Implement changes with fixed fees for groups in full to all variations (MR and UK-only procedures) as from 1 January 2010.

3. Implement changes with cumulative fees for groups in full to all variations (MR and UK-only procedures) as from 1 January 2010.

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

On a yearly basis in line with the Agency's annual fees review (April each year).

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

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

Signed by the responsible Minister:

Mike O'Brien Date: ***29th October 2009***

Summary: Analysis & Evidence

Policy Option: 1	Description: Implement changes with fixed fees for group only for variations to Mutual Recognition (MR) procedures from 1 January 2010 in line with the scope of the Regulation

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups'
One-off Yrs **£0.5m**	Initial one off adjustment cost to new regulation. A second major cost, which has yet to be estimated, is that of major changes to Sentinel. 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.
Average Annual Cost (excluding one-off) **£ nil**	**Total Cost** (PV) **£ 0.5m**

Other **key non-monetised costs** by 'main affected groups' If we implement this option, MHRA will be operating at complex 'two tiered' system' where cost will be difficult to work out for companies and different methods of application would be needed for different types of variation (UK or EU). Would also be costly to operate for the MHRA.

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups'
One-off Yrs **£ NIL**	Benefits for companies through introduction of group applications for some cases and not for others will not provide maximum benefit to companies. The cost of maintaining two different systems concurrently on the IT system (Sentinel) will erode these.
Average Annual Benefit **£**	**Total Benefit** (PV) **£**

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

Key Assumptions/Sensitivities/Risks

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

What is the geographic coverage of the policy/option?	UK
On what date will the policy be implemented?	I January 2010
Which organisation(s) will enforce the policy?	MHRA
What is the total annual cost of enforcement for these organisations?	£ N/A
Does enforcement comply with Hampton principles?	Yes
Will implementation go beyond minimum EU requirements?	No
What is the value of the proposed offsetting measure per year?	£ N/A
What is the value of changes in greenhouse gas emissions?	£ N/A
Will the proposal have a significant impact on competition?	No

Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

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

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

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

Summary: Analysis & Evidence

Policy Option: 2	Description: Implement changes including fixed fees for groups in full to all variations (MR and UK-only procedures) as from 1 January 2010.

COSTS

ANNUAL COSTS	
One-off Yrs	Description and scale of **key monetised costs** by 'main affected groups' One off costs adjusting to the new process and new regulation
£ 0.5m	
Average Annual Cost (excluding one-off)	
£	**Total Cost** (PV) £ 0.5m

Other **key non-monetised costs** by 'main affected groups' - administrative simplification – a single set of rules for all variations regardless of MA authorisation procedures…- no other non-monetised costs identified

BENEFITS

ANNUAL BENEFITS	
One-off Yrs	Description and scale of **key monetised benefits** by 'main affected groups' Companies should see administrative costs and burden reduced by the introduction of the new procedures, particularly the ability to make a single application for a group of variations rather than have to complete a separate application for each change. The Agency will have some minimal savings and benefits in not having to raise invoices for every individual variation made and companies will save through not having to process individual invoices. However, the work associated with processing the variations, whether in a group or separately will be virtually the same for the Agency. Company fees will reflect the slight reduction in work for the MHRA in the fees for groups.
£	
Average Annual Benefit (excluding one-off)	
£ 3m	**Total Benefit** (PV) £ 3m

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

Companies will have a single system for MA variations applications regardless of whether they are EU or UK-only applications. Once rules are established and they have some experience of them, it should be simpler to operate.

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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) £ **2.5m**

What is the geographic coverage of the policy/option?	UK
On what date will the policy be implemented?	1 January 2010
Which organisation(s) will enforce the policy?	MHRA
What is the total annual cost of enforcement for these	£ 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	£ nil	Decrease	£ 1.2m	**Net**	**£** 1.2m

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

Summary: Analysis & Evidence

Policy Option: 3	Description: Implement changes including cumulative fees for groups in full to all variations (MR and UK-only procedures) as from 1 January 2010.

COSTS

ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups' Initial one off adjustment cost to new Regulation
One-off	**Yrs**	
£ 0.5m		
Average Annual Cost (excluding one-off)		
£		**Total Cost** (PV) **£ 0.5m**

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

BENEFITS

ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups' As the fees are cumulative; there will not be the reduction in the amount of fees paid for groups (as would be a benefit in Option 2). However, the reduction in administrative burden may be higher for companies as they will need to calculate each fee manually but other costs for companies would be the as for option 2.
One-off	**Yrs**	
£		
Average Annual Benefit (excluding one-off)		
£		**Total Benefit** (PV) **£ 3m**

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

Key Assumptions/Sensitivities/Risks

Requirements of the Trading Fund Order to break even taking one year with another;. Treasury guidance on ensuring fees match costs; Responsibility to protect public health, Implementing Better Regulation benefits.

Price Base Year	Time Period Years	**Net Benefit Range** (NPV) **£**	**NET BENEFIT** (NPV Best estimate) **£ 2.5m**

What is the geographic coverage of the policy/option?	UK
On what date will the policy be implemented?	1 January 2010
Which organisation(s) will enforce the policy?	MHRA
What is the total annual cost of enforcement for these	£ 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	£ nil	Decrease	£ nil	**Net** **£** nil

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

Evidence Base (for summary sheets)

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

1.2 The MHRA is a Government Trading Fund and, as such, is fully funded for its medicines regulatory function by fees in connection with the manufacture, sale and supply of medicines. The fees charged by the MHRA are monitored and reviewed annually to ensure, as far as possible, that the fees charged for a particular service reflect the cost of the work undertaken. This is in line with Treasury guidance on Fees and Charges.

1.3 Medicines can only be placed on the UK market if they have a Marketing Authorisation (MA). Because companies sometimes need to change things about the product, they apply to make variations to their individual MAs. These variations could be simple ones such as changes of address, but can also be very technical for a change in the use of the product for example, which would require technical assessment before it was granted by the Licensing Authority (MHRA). Currently, companies must apply for each change separately, and the Agency processes, assesses and invoices separately for each of these variations.

1.4 EC Regulation 1234/2008, which was published in November 2008 and comes into force in January 2010, outlines new procedures and changes to classification systems for various types of variations approved through the mutual recognition or centralised approval systems. Eventually (but possibly not until 2012) the new Regulation will apply to variations to all authorisations regardless of approval procedure and therefore including UK-only licences. It introduces new 'better regulation' concepts for handling variations including grouping of related changes into a single submission and new systems for handling minor (Type IA) changes. It also has a section on urgent safety restrictions in case of serious concerns based on pharmacovigilance, pre-clinical safety or quality, where the product information needs to be changed. A new 'worksharing' procedure allows one competent authority to examine variations to several marketing authorisations on behalf of the other Member States and the European Medicines Agency. MHRA representatives have been closely involved in the development of the new Regulation and the associated Guidance.

1.5 These changes are being introduced by EC Regulation 1234/2008 must be implemented by 1 January 2010.

Objectives

1.6 The simplest option is to change the MA variations systems as a whole (i.e. for EU and national applications) so that they match, thus simplifying procedures for the industry. It will provide benefits of:

- Administrative simplification – a single set of rules (classification and procedural) for all variations regardless of MA authorisation procedure.
- Regulatory/legislative simplification – drafting the new legislation should be more straightforward with reference to only one set of rules and no need to refer to local guidance which has no legislative basis.
- Achieving further 'better regulation' benefits for all MA variations and taking a lead in Europe.
- Simplification, lower administrative burden and cost effectiveness for industry.
- Being complient with the new EU Variations Regulation 1234/2008.

These proposed Regulations will consolidate existing legislation and guidance for MA variations fees charged by the MHRA in connection with the regulation of medicinal products for human use in the United Kingdom incorporating changes proposed for 1 January 2010.

1.7 The Agency also intends that, through the implementation of these 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 MA 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;
- Supporting "Better Regulation" activities, including simplified regulatory processes, and revised and consolidated legislation.

1.8 The MHRA had already implemented some Better Regulation approaches within its MA variations procedures but these proposals take those initiatives further and deliver more benefits to companies. The Variations Directive has been anticipated in the Department of Health's Simplification Plan for year 3 including the following benefits to:

"i) industry through streamlined processes and time to market (which may mean a small admin burden savings but a big overall benefit to the industry);
ii) the regulator through greater efficiency and being able to focus resources on higher priority work; and
iii) the public and patients who can obtain remedies on the shelves in a more timely way. "

This initiative is expected to bring about administrative savings to industry and the MHRA. The estimated admin burdens savings for this coupled with the **£10m** reassessment of the review of variations regulation means an overall saving of **£1.2m**.

1.9 By implementing the Directive across all MA variations now, rather than waiting perhaps another 1.5 – 2 years to make the changes for UK-only variations, the UK will be ahead of the rest of Europe in "Delivering Simplification In Europe" which is the rationale behind the Directive.

Rationale for Government intervention

1.10 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 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.

1.11 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 - The implementation of this proposal will improve efficiency of the process, allowing MA variation applications to be determined earlier, streamline applications to the benefit to the industry and Agency and also indirectly allow the public to have earlier access to new medicines.

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.

1.12 It is therefore important that, in making the changes to the MA variations procedures, the MHRA is able to ensure that the fees they charge reflect the amount of work associated with these applications. 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 changes.

1.13 The rationale behind these proposals is therefore to ensure compliance with the new EU regulation whilst balancing the fee regime that enables the Agency to fulfil its role in safeguarding public health.

2. Consultation

2.1 These proposals have been considered with Department of Health officials and with Treasury. Both have approved the proposals and are satisfied that the Agency is making every effort to achieve:

- Administrative simplification – a single set of rules (classification and procedural) for all variations regardless of MA authorisation procedure.
- Regulatory/legislative simplification – drafting the new legislation should be more straightforward with reference to only one set of rules and no need to refer to local guidance with no legislative basis.
- Further 'better regulation' benefits for all MA variations and taking a lead in Europe.
- Simplification, lower administrative burden and cost effectiveness for industry.
- Compliance with the new EU Variations Regulation 1234/2008.
- Fees matched with costs.

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 Three responses were received all in support of these proposals. We intend to respond to individuals on any points they have raised.
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3. Options

3.1 Three options for the main proposals have been identified:

3.2 Option 1 - **Implement changes with fixed fees for group only for variations to Mutual Recognition (MR) procedures from 1 January 2010 in line with the scope of the Regulation**
Would bring complexity to the whole process of variation applications and the fees associated with them. Companies would have a very complex set of fees to work out, and different applications and fees would be needed depending on which process the company chose (EU or UK). This would place considerable admin burden not only on industry but also on the Agency who would need to assess each application to ensure that (a) the correct fee has been paid and (b) the correct process is being followed. This would be unnecessarily complicated.

3.3 Option 2 - **Implement changes with fixed fees for groups in full to all variations (MR and UK-only procedures) as from 1 January 2010.**
The new process for making changes to MAs 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 with savings for the Agency mostly in the finance/invoicing area. Overall, the specified removal of certain variation fees and the new fees for group applications 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,.

3.4 Option 3 – **Implement changes with cumulative fees for groups in full to all variations (MR and UK-only procedures) as from 1 January 2010.**
Although the benefits of this option would be similar to Option2, companies would pay slightly higher fees for group applications than under option 2. They would not, therefore, fully benefit from the changes.

4. Costs and Benefits

<u>Sectors and groups affected</u>

4.1 All manufacturing sectors of the mainstream pharmaceutical industry, involved in the marketing of medicinal products for human use.

4.2 It is not possible to identify a "typical" business. Businesses range from small medicines MA holders, up to multi-billion pound international manufacturing businesses. In all cases, additional costs are only likely to be related to learning new procedures.

<u>Benefits</u>

4.3 The benefits are to the same sectors of the pharmaceutical industry as mentioned in paragraph 4.1 above. All concerned will benefit from the new procedures, particularly those who make group applications for MA variations but also those who simply make very minor changes to their MAs during the year. The benefits are mostly related to the reduction in administrative burden of following the new

procedures but significant savings in fees have also already been implemented for minor administrative variations.

4.4 A key concern of pharmaceutical companies is that they receive a prompt and efficient response from the MHRA when they submit applications for variations for the MAs 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 companies can gain the maximum benefit from the implementation of the new procedures across the board for MA variations, and that the MHRA can still cover the costs of undertaking the work associated with these applications.

4.5 Better Regulation benefits

The Agency has already removed some MA variation fees (for the "do and tell" applications in anticipation of the Directive being implemented. The cost of the remaining work associated with these particular variations is recovered through the annual fee in anticipation of this EU procedure. The new procedure is a "do and tell" approach, which can be done annually rather than companies having to apply for each change individually, and having to wait for action by the Agency before they can benefit from the change. – the full benefits of this are estimated to be in the region of £2m, calculated at £1m reduction in actual fees and £1m in reduced administrative costs in relation to making individual applications and processing individual invoices for each change. This benefit was introduced in April 2009.

4.6 One of the main savings to industry beng implemented through these regulations will be for companies taking advantage of the new MA variation applications that can be made for a group of changes in a single application. The time saved by companies in preparing just one application rather than a single one for each change will be significant. A minor cost saving through fees for group applications will also be made but this is less significant.

Costs

4.7 Regulatory activity in this sector is in large part demand-led, in that companies choose whether to submit applications for variations to existing MAs. It is therefore not possible to give a reliable indication of costs from these proposals. The Agency estimates there will be minor additional costs to companies in having to learn the new procedures, but the fees are set so as to recover the cost of the work the Agency will still require to undertake to process the variations. It is estimated that there will be only minor savings to the Agency in terms of workload from the new procedures and so the fees are set at a level which should be cost-neutral to the industry. A small reduction in anticipated costs to the Agency has been estimated and the fees set for the group applications reflect this

4. 8 For individual companies, 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 variation fees remain below other 2009/2010 fee levels;
- By taking up the opportunity to use new simplified processes, companies can benefit from lower fee levels as well as a reduction in administration and other benefits.

4. 9 In these areas, therefore, there should be little or no additional costs faced by companies from these proposals.

4.10 There are no significant associated policy costs or administration costs from these proposals Apart from companies having to familiarise themselves with a new procedure.

5. Small Firms Impact Test

5.1 Some of the businesses affected by these proposed changes are small firms. The overall effect of the proposals will vary depending on what sort of changes a company might have to make to an MA. All active companies will benefit from the new procedures.

5.2 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.

5.3 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.

5.4 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 changes will affect only companies within the pharmaceutical industry that hold marketing Authorisations. 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 these changes are likely to have any significant impacts for competition in any of 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 MA variation applications received on or after the 1st January 2010. The new fees will be advertised on the MHRA's website and all those affected will be made aware through the consultation exercise.

10. Post-implementation review

10.1 The new fees and the anticipated income through estimated volumes have been matched with the Agency's budget plan for 2009/2010.

10.2 All of the MHRA fees 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. Risks

11.1 The Agency will face potentially lower income from fees, but this loss of income should reflect the lower costs to deliver the service which is passed on as benefits to the industry. The analysis has also shown a 3% loss of income from variations as around 10% of applications can be grouped. Variations are 10% of the Agency's fees income, which indicates this loss of income is not sufficient to pose a threat to the delivery of the service.

11.2 In addition, as with any new process there is the risk of errors in the initial period learning to use the new process. This may result in the calculations of fees being incorrect and having to be re-invoiced counter to the aim of this proposal. However it is assumed this learning period will be quick and those errors will be small.

11.3 Potentially there is a risk that companies will not group their applications. This should not pose a risk to the Agency as it will still charge fees that cover its costs, however as companies can make a saving in both administration time and lower fees; it is expected to be used.

11.4 Option 1 could act as a barrier to market for some companies as the process would be complex, and this could result in the Agency losing valuable trade. The preferred option avoids this risk.

12. Summary and Recommendations

12.1 Option 2 best achieves the objective of ensuring that companies get the most benefit in terms of Better 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 proposals as set out in Option 2 represent the most effective option.

Specific Impact Tests: Checklist

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