



To all licence holders, blood banks, blood establishments and representative associations

Our Ref: MLX 344

17 October 2007

**MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)  
REGULATORY FEES – PROPOSALS FOR 1 APRIL 2008**

**INTRODUCTION**

1. I am writing to consult you on proposals to change the levels of fees charged by the MHRA for the regulation of medicines, including herbal and homoeopathic medicines, and blood establishments and blood banks<sup>1</sup>. A separate consultation is being carried out in respect of medical devices regulatory fees (Reference RCX/004/002/036) which can also be found on our website [www.mhra.gov.uk](http://www.mhra.gov.uk). This consultation is being undertaken following the guidelines in the Cabinet Office Code of Practice on Consultations (<http://bre.berr.gov.uk/regulation/consultation/code>).

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<sup>1</sup>This consultation is in accordance with section 129(6) of the Medicines Act 1968 and will, subject to consultation, lead to the amendment of: The Medicines (Products for Human Use – Fees) Regulations 1995 (SI 1995 No.1116 as amended by SI 1996 No.683), SI 1998 No.574, SI 1999 No.566, SI 2000 No.592, SI 2000 No.3031, SI 2001 No.795, SI 2002, No.236, SI 2002 No.542, SI 2003 No.625, SI 2003 No.2321, SI 2004 No.666, SI 2004 No.1157, and SI 2005 No.1124, SI 2005 No.2979, SI 2006 No.494, SI 2006 No.2125 and SI 2007 No.803; also the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (SI 1994 No.105 as amended), SI 2005 No.2753, SI 2006 No.494 and SI 2007 No.803) The Medical Devices (Consultation Requirements) (Fees) Regulations 1995 (SI 1995 No.449 as amended by SI 1996 No.622, SI 1998 No.574 SI 1999 No.566, SI 2000 No.592, SI 2000 No.3031, SI 2001 No.795, SI 2002, No.236 SI 2002 No.542, SI 2003 No.625, SI 2003 No.2321, SI 2004 No.666, SI 2004, No.1157, SI 2005 No.1124, SI 2006 No.494 and SI 2007 No.803). The Blood Safety and Quality Regulations 2005 (SI 2005 No.50, SI 2005 No.2898 and SI 2007 No.604).

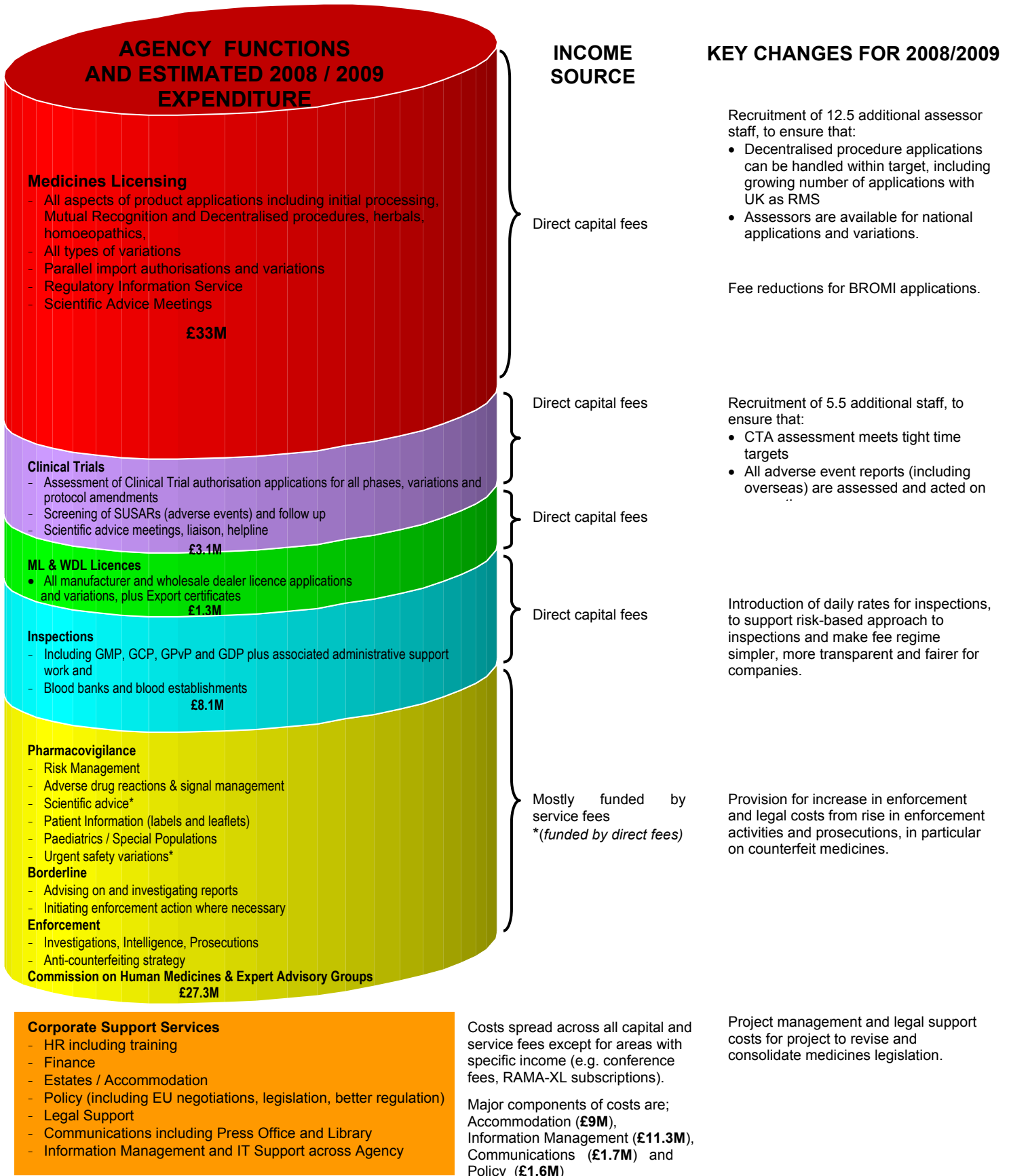
## SUMMARY

2. The key proposals in this consultation are as follows:
  - Fees for regulatory activities will be revised from 1 April 2008, in line with the normal annual assessment of regulatory costs.
  - There will be some specific targeted fee increases (for decentralised procedure applications, and for clinical trials authorisations) to ensure that these areas of work can be dealt with effectively and within targets.
  - Some fees will be reduced, as part of the BROMI initiative to simplify and reduce regulatory burdens.
  - Other than the specific targeted increases, fees will be increased to account for additional costs. The level of increase varies in different areas, but the average increase is 7.3 per cent. The increase applying to licence applications and variations is 5.6 per cent.
  - Following positive consultation responses last year, a simplified scheme of daily rates for inspections will be introduced, to support the Agency's move to risk-based inspection.
  - The fee incentive for electronic (eCTD) applications introduced last year will be maintained, meaning that companies who now move to adopt eCTD will see their licence application and variation fees increase by 0.7 per cent.

## BACKGROUND

3. The MHRA is required, as a Government Trading Fund, to recover the costs of its medicines regulatory functions through fee income. Fee levels are set in Regulations, and are revised on an annual basis, subject to consultation and Parliamentary approval.
4. There are a large number of separate fees, so that the fee charged accurately reflects the cost to the Agency of the associated work. But in the main they fall into two categories:
  - "capital" fees, for a particular event, for example a licence application, an inspection, or an application for an export certificate;
  - "periodic" or "service" fees, payable annually.
5. Capital fees are calculated to cover the cost of the relevant area of work, for example the full cost to the Agency of receiving, assessing and dealing with a licence application. Service fees are intended to cover the costs of those parts of the Agency's functions for which direct fees cannot be charged but which are nevertheless part of the Agency's overall regulatory responsibilities. These include, for instance, most pharmacovigilance activities and enforcement activities. Corporate costs that contribute to all the Agency's activities – for instance IT support and accommodation costs – are spread across both capital and service fees.
6. The following graphic sets this out in more detail, showing what the Agency spends in all areas of medicines regulation, what fee areas fund those costs, and a summary of what lies behind the main proposals for April 2008.

# MHRA ACTIVITIES AND FUNDING SOURCES FOR MEDICINES REGULATION



## MAIN PROPOSALS

7. Annex A sets out the full set of proposed fee changes for all types of fees. The main proposed changes are described below, with fuller details in Annex B.

### Decentralised Procedure Applications

8. The Decentralised Procedure (DCP) is a new way for companies to apply for licences across different EU countries. Companies choose which national agency should be the lead agency for all of Europe, known as the Reference Member State (RMS).
9. The DCP has benefits for companies in offering a single coordinated process for gaining licences in different EU countries, and industry and regulators have a shared interest in ensuring that it works effectively. It is a growing area of activity, and it is important that EU agencies, including the MHRA, are able to respond to the workload demands in order to avoid delay in medicines getting licensed and marketed.
10. Experience in the MHRA has shown that the costs to us of being RMS is higher than originally estimated when DCP fees were first set. We want to be able to act as RMS and help ensure that companies are not delayed, but we need to be sure that we fully cover our costs if we are to do this. The proposal is therefore to add an additional amount (£4,333) to DCP application fees where UK is the RMS, which reflects the additional work that has to be undertaken within the Agency (see section 1 of Annex B for more detail).
11. The additional funding from this will pay for an additional 12.5 staff to work in the relevant assessment teams, and should help to ensure that we are able to act as RMS for more DCP applications and complete the work within target timescales. This should also benefit other areas of licensing work – for instance national applications, and variations – by ensuring that enough assessors are available to deal with both European and national work.
12. After a period of delays and backlogs in some areas of licensing work, we have been working intensively to improve performance. We set specific 2007/8 business plan targets to cut backlogs, and started to publish detailed performance figures on a monthly basis. We have made significant improvements over the last 12 months, particularly in making the time taken to complete work more predictable and in shortening times to complete the assessment process, but we need to maintain this improvement and see it through. The fee proposals set out in this document are designed to enable us to do this.
13. The most recent licensing performance data can be found on our website at [www.mhra.gov.uk/mhra/LicensingPerformanceMeasures](http://www.mhra.gov.uk/mhra/LicensingPerformanceMeasures)

### Clinical Trials Authorisations

14. One of the Agency's tasks is to assess and authorise applications for clinical trials. This is a key function for protecting the health of trial participants. However, it is also important that the Agency's authorisation processes do not unduly delay the start of clinical research that can develop beneficial new medicines. The MHRA has worked closely with partners such as the Department of Health and the UK Clinical Research Collaboration to help make the UK a good environment for carrying out clinical research.
15. The Agency has reviewed its resources in this area in the face of growing demands, and we have concluded that we need 5.5 additional staff to deal with the work effectively and without causing delay. This therefore requires targeted fee increases across the various clinical trials fees.

16. The task of assessing applications has grown hugely in recent years. Previously, clinical trials authorisations had a maximum limit of 60 pages for chemical products and 100 pages for biological products. These limits were removed by the Clinical Trials Directive, but our fees were set on the basis that this would in practice continue to be the size of applications received. However, applications now range in size, but generally exceed 400 – 500 pages and frequently reach 1,000 pages. We continue to work with applicants to encourage them to reduce and summarise their documentation, but we must fully assess all the information provided to us.
17. We are proud of the fact that we assess clinical trial applications within a tight timescale target that is faster than most other regulators, preventing the unnecessary delay that the clinical research community tells us is the most important factor for them. But we cannot continue to do this without diverting assessor staff from other areas of licensing. Other elements of the clinical trials unit's work – such as assessing adverse events – would also be affected, with unacceptable risks to health.
18. We recognise that the proposed increases may cause concern as to potential impact on clinical research in the UK. However, we believe that without additional resources we will no longer be able to deal with applications within our published targets. We are often told how expensive delay can be in a clinical trials programme costing many millions of pounds. Within the overall cost of a clinical trial, the regulatory fees are relatively small. We therefore believe that the proposed fee increases in this area represent the best course of action, in the interests not only of safeguarding health but also of supporting clinical research.

#### Fee reductions for BROMI applications

19. The Better Regulation of Medicines Initiative (BROMI) is one of the Agency's major contributions to better regulation and simplification. It has been recognised in the Government's Simplification Plan, is regularly cited by the industry as an example for other regulators to follow, and has recently been awarded an international prize for better regulation<sup>2</sup>.
20. The main benefit to companies from BROMI is that handling of certain regulatory applications is simpler and quicker, leading to potential savings that have been estimated by the industry as £53.6m. Since these simplified processes can also reduce the amount of work the Agency needs to do, we are proposing reductions in the relevant fees. These are:

Fee type	2008/9 fee without reduction	Proposed 2008/9 fee with reduction	% decrease
BROMI self-certification notification	188	176	6.4%
Type IA BROMI variation	296	188	36.5%
Type IB BROMI variation	778	296	62%
Article 61(3) notification (labels & leaflets)	524	188	64%

\* fees for eCTD – compliant will be lower still

#### Other Medicines Fees

21. Aside from the specific increases for decentralised procedure and clinical trials referred to above, regulatory fees for medicines are revised to reflect additional costs faced by the Agency in undertaking its work. The increases in specific areas vary according to the degree to which costs have increased, but the overall average increase is 7.3 per cent. The individual fee rates are set out in Annex A.
22. This level of increase reflects a number of specific additional costs associated with the Agency's regulatory work. These include:
- a) Pay costs for Agency staff, and in particular, specialist assessor staff. During the last

<sup>2</sup> The Red Tape Reduction Award – <http://www.administrative-burdens.com/>

financial year we filled 88 vacancies, three quarters of which were specialist posts. Despite this, we have also lost staff, meaning an actual increase of 20 and we are still short of experts in some key areas. For example, our average vacancy rate for medical specialists over the period of the last 12 months has been 5 – 6 posts at any one time. This has an effect on our ability to work to full capability. With medical salaries having increased in the NHS and elsewhere, we need to reflect those market pressures in the salaries needed to recruit and retain specialists.

These particular additional pay costs contribute to overall paybill pressures of roughly £4m across the Agency's medicines costs, representing 5.7% out of the overall 7.3% cited above.

- b) Enforcement costs, including legal costs. These are the costs of investigators and legal support associated with having a proactive enforcement and anti-counterfeiting programme, and are increasing in particular as a result of the growing task of tackling counterfeit medicines. In 2005/06, we completed 10 prosecution cases involving 13 defendants; in 2006/07 we completed 17 cases. Currently, we have 31 prosecution cases running involving a total of 61 defendants. Cases are increasing in number and complexity with a 25% increase in cases being referred for prosecution this year compared with last year.

This is essential work to protect the integrity of the supply of medicines in the UK, and to safeguard health. There is a clear benefit for the legitimate industry in prosecution of counterfeit medicines suppliers and others acting outside the law. The Agency recently welcomed the successful outcome of a major court case, which saw four defendants convicted of offences related to counterfeit medicines, with sentences of up to six years in prison. As UK medicines regulator we must respond to the growing demands in this area, and it does involve targeted extra expenditure.

The additional investment in this area amounts to £1m, representing 1.4% of the 7.3% cited above.

- c) Medicines legislation project. A small part of the fee increase (£120,000, representing 0.2% of the 7.3% increase cited above) has been calculated to fund a project to revise and consolidate the medicines legislation. This is a further move to support better regulation and simplification, and comes in response to industry requests (it was the ABPI's top priority simplification proposals in 2006). The aim of this project will be to rationalise the currently very fragmented regulations going back to 1968, and consolidate them as far as possible into an up to date and comprehensible package of legislation. The intention will be also to seek opportunities to simplify requirements where possible.

23. The allocation of the average 7.3% increase varies across different fee types according to the nature of the cost – for example, items b) and c) above are reflected in service fees. Licence application and variation fee increases are set at 5.6%.

#### Daily Rates for Inspections

24. Following positive responses to our proposals set out in last year's fee consultation, and further discussions with industry associations, we are proposing to implement a scheme of daily rates for inspections from 1 April 2008.
25. The details are in Annex B. As explained in last year's consultation, we see this as a significant step to support better regulation and risk-based inspections. We are about to publish a consultation document on our broader programme of introducing risk-based inspections (MLX 345) and this can be found on the MHRA website when published.

#### **OTHER PROPOSALS FOR CHANGE**

26. Other fee proposals are detailed in Annex B. These are:
- Introduction of a specific fee related to "Persons Appointed" hearings of appeals against decisions by the Commission on Human Medicines and others.

- Introduction of fees to accompany the new accreditation scheme for Phase I clinical trial units
- The removal of a number of fee waivers from the Regulations, some of which are now obsolete.

## BETTER REGULATION AND SIMPLIFICATION

27. Better regulation and simplification is an increasing focus of the Agency's work, to ensure that regulatory systems are proportionate, targeted and risk-based. The Agency's fee proposals this year have been designed to support this agenda in a number of areas, in particular:

- The daily rate for inspections, supporting the broader move to a risk-based inspection programme and reducing over 35 categories of inspection fee down to 3.
- Fee reductions to encourage uptake of BROMI applications, and to reflect the fact that agreed simplifications for certain areas of business can reduce burdens for both companies and the Agency whilst maintaining public health safeguards.
- The continuation of a reduced fee for eCTD applications, encouraging companies to adopt full electronic working following the international standard that will be the basis for all regulatory business in the future.
- The project to update and consolidate the legislation on which medicines regulation is based, to make it clearer and more accessible for companies and others.

28. In addition to this, following helpful discussions earlier in the year with industry on possible areas for simplification, we are working with company representatives to address some of the day-to-day practical issues associated with the payment of fees, including:

- Looking to standardise the MHRA invoices, credit notes and statements onto A4 size plain white paper in a clearer font to allow easier handling, scanning and copying in the recipient organisations.
- Taking steps to ensure that companies reference numbers particularly Purchase Order Numbers, are prominently quoted on our invoices.

29. Finally, we are also planning to develop a guidance note for fees aiming to help companies understand the fee structure and identify what fee they need to pay. We will complete this and make it available on our website during 2008.

## CONCLUSION

30. The fee proposals set out in this document are designed to ensure that:

- Resources are available – including additional recruitment of assessors – to manage regulatory applications effectively and promptly, continuing to focus on areas where timescales need further improvement.
- The Agency can respond effectively to the threat from counterfeit medicines.
- We can take forward programmes of better regulation and simplification, so that regulation achieves its goal of safeguarding health whilst avoiding unnecessary burdens.

## COMMENTS

31. Any comments on these proposals should be sent to Karen Salawu, 16th Floor, Market Towers by **9 January 2008** using the reply sheet provided at **Annex D**, or by e-mail to [karen.salawu@mhra.gsi.gov.uk](mailto:karen.salawu@mhra.gsi.gov.uk) using the subject reference of "Fees consultation MLX 344". We regret that we cannot take comments over the telephone but you may also send your comments by fax on the following telephone number – 020 7084 2121. **Copies of replies will be made available to the public on request unless you clearly state that you are replying "in confidence"**.

## IMPACT ASSESSMENT

32. In considering proposals for new regulations, the Government places great importance on giving due weight to the proposals' likely impact on business. To assess costs and benefits of all such proposals, an Impact Assessment (IA) is produced and made available to business on request – a draft IA is attached at **Annex C**. The IA covers the detail of the proposals above, and it will be revised following the end of the consultation period to reflect the response to the consultation.
33. In giving your views on the proposals described in this document, it would be particularly helpful if you could identify and quantify the effects these proposals are likely to have on your business. **We would particularly like to hear from smaller companies and will be contacting some smaller companies during the consultation process. If you would like to be included in this exercise, please let Karen Salawu know (contact details in para 31 above).**

Yours sincerely

Sue Jones  
Corporate Policy Unit

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	Current fee*	Proposed 1 April 2008	Proposed 1 April 2008 for fully compliant eCTD
	£	£	£
<b>LICENCE APPLICATIONS MARKETING AUTHORISATIONS</b>			
<b>MAJOR</b>			
<b>National Fee</b> (including Decentralised procedure where UK is CMS and Hybrid applications)	93,289	<b>98,491</b>	<b>93,907</b>
MAJOR (Reduced in exceptional circumstances <sup>1</sup> OR Orders under Section 104/105)	29,890	<b>31,576</b>	<b>30,101</b>
<b>OUTGOING MUTUAL RECOGNITION</b>			
- 1 <sup>ST</sup> WAVE	39,850	<b>42,090</b>	–
- 2 <sup>ND</sup> WAVE	26,176	<b>27,648</b>	–
INCOMING MUTUAL RECOGNITION and European reference products	64,995	<b>68,649</b>	<b>65,453</b>
<b>ABRIDGED COMPLEX</b>			
<b>National Fee</b> (including Decentralised procedure where UK is CMS and Hybrid applications)	25,780	<b>27,228</b>	<b>25,962</b>
<b>OUTGOING MUTUAL RECOGNITION</b>			
- 1 <sup>ST</sup> WAVE	10,256	<b>10,883</b>	–
- 2 <sup>ND</sup> WAVE	6,837	<b>7,221</b>	–
INCOMING MUTUAL RECOGNITION and European reference products	18,045	<b>19,059</b>	<b>18,172</b>
<b>ABRIDGED STANDARD</b>			
<b>National Fee</b> (including Decentralised procedure where UK is CMS and Hybrid applications)	9,453	<b>9,984</b>	<b>9,519</b>
<b>OUTGOING MUTUAL RECOGNITION</b>			
- 1 <sup>ST</sup> WAVE	4,102	<b>4,333</b>	–
- 2 <sup>ND</sup> WAVE	3,419	<b>3,611</b>	–
INCOMING MUTUAL RECOGNITION and European reference products	6,613	<b>6,985</b>	<b>6,660</b>
<b>ABRIDGED SIMPLE</b>			
<b>National Fee</b>	2,577	<b>2,722</b>	<b>2,596</b>
OUTGOING MUTUAL RECOGNITION	2,455	<b>2,593</b>	–
OUTGOING MUTUAL RECOGNITION (INFORMED CONSENT)	2,455	<b>2,593</b>	–
- 1 <sup>ST</sup> WAVE	2,455	<b>2,593</b>	–
- 2 <sup>ND</sup> WAVE	2,455	<b>2,593</b>	–
<i>Duplicates for all of the above <u>Outgoing Mutual Recognition applications</u> when undertaken at the same time as the lead application</i>	2,455	<b>2,593</b>	–
<b>DECENTRALISED PROCEDURE WHERE UK IS RMS</b>			
<b>MAJOR</b>	133,204	<b>144,914</b>	<b>138,145</b>
<b>ABRIDGED COMPLEX</b>	36,036	<b>42,444</b>	<b>40,461</b>
<b>ABRIDGED STANDARD</b>	13,554	<b>18,650</b>	<b>17,779</b>

\* Throughout this annex, "current fee" refers to the non-eCTD rate.

	Current fee*	Proposed 1 April 2008	Proposed 1 April 2008 for fully compliant eCTD
	£	£	£
<b>PARALLEL IMPORT</b>			
	1,718	1,815	–
<b>CHANGE OF OWNERSHIP (incl.THMPD registrations)</b>			
	424	448	–
<b>MANUFACTURERS' LICENCES (incl. THMPD and Homoeopathic Medicinal Products)</b>			
STANDARD	2,688	2,911	–
Non Orthodox Practitioner (NOP)	156	169	–
CHANGE OF OWNERSHIP	295	319	–
<b>WHOLESALE DEALERS' LICENCES (incl.THMPD and Homoeopathic Medicinal Products)</b>			
STANDARD	1,542	1,670	–
REDUCED RATE <sup>2</sup>	660	715	–
CHANGE OF OWNERSHIP	341	369	–
<b>EXPORT CERTIFICATES</b>			
Per set (1 original + 2 copies)	58	63	–
Per set (URGENT)	130	141	–
Extra Copies (3 <sup>rd</sup> copy +)	29	31	–
<b>CLINICAL TRIALS</b>			
<b>Accreditation of Phase 1 Units</b>	New	120	–
<b>Certificate of accreditation</b>	New	63	–
<b>Applications</b>	Phase I Trial	707	2,146
	Phase II or Phase III trial where product being tested is unknown	3,128	4,040
	Phase II or Phase III trial where product being tested is known	2,607	3,283
	Phase IV trial	163	252
	Additional protocols	105	252
	Cross-referrals	147	252

**Notes:**

- To which Section G of Part IV of the Annex to Council Directive 75/318/EEC refers.
- Special reduced rate to apply for wholesale dealers handling GSL products only and for registered retail pharmacies and small wholesale dealers where wholesaling of licensed products does not exceed 15% or £35,000 of total turnover in licensed products.

**APPEALS TO PERSONS APPOINTED (PA)**

	NEW FEE FROM 1 APRIL 2008
Application for a PA hearing	£10,000

**Notes:**

This fee will be payable on application for a Persons Appointed hearing. If the outcome of the hearing is positive for the company and the original advice is overturned, the fee will be refunded. If an application is made and subsequently withdrawn before a panel has been appointed to consider the case, a partial refund will be made (60%). If the application is withdrawn after the panel has been appointed, no refund will be applicable.

DRUG/DEVICE COMBINATION PRODUCTS	Current	Proposed 1 April 2008	Current	Proposed 1 April 2008
	£	£	£	£
In respect of a request by Notified Body to the MHRA to supply an additional assessment report.				
<b>DEVICE WHICH INCORPORATES:</b>				
A known medicinal substance from a source previously used in medicinal products or in medical devices in respect of which MHRA has previously been consulted.	4,141	4,374	819	865
A known medicinal substance from a new source.	9,653	10,197	2,291	2,420
A new active substance.	42,352	44,741	10,515	11,108

**Notes:**

1. Where a device incorporates two or more medicinal substances the fee will relate to one of the substances only - the one which commands the highest fee.
2. The same fee will apply regardless of the strength or concentration of the medicinal substance. But only one fee will apply to multiple applications made at the same time for a range of similar devices (e.g. a range of catheters made of the same material) incorporating the same medicinal substance at the same level.
3. The fee for an additional assessment report will apply when changes to the device require assessment under the terms of the Directive, and at any time after the initial assessment when further data is submitted to the MHRA for assessment.

SCIENTIFIC ADVICE MEETING	Current	Proposed 1 April 2008
	£	£
<b>PRE APPLICATION MEETINGS</b>		
Quality development only	2,108	2,227
Safety development only	2,108	2,227
Quality and safety development	2,934	3,099
Clinical development only	2,648	2,797
Quality and clinical development	3,474	3,669
Safety and clinical development	3,474	3,669
Quality, safety and clinical development	4,300	4,542
<b>DRUG / DEVICE MEETINGS</b>		
Quality development only	750	792
Safety development only	750	792
Quality and safety development	950	1,004
Clinical development only	950	1,004
Quality and clinical development	1,300	1,373
Safety and clinical development	1,300	1,373
Quality, safety and clinical development	1,650	1,743
<b>COMPANY DISCUSSION MEETINGS</b>	4,335	4,579
<b>PHARMAOVIGILANCE ADVICE MEETINGS</b>		
STANDARD meeting	2,934	3,099
MAJOR meeting	3,474	3,669
<b>POST-AUTHORISATION REGULATORY ADVICE MEETINGS</b>		
<b>ADVERTISING ADVICE</b>	2,108	2,227
<b>ADVICE ON LABELS AND LEAFLETS</b>	2,108	2,227
<b>RECLASSIFICATION ADVICE MEETINGS</b>		
P to GSL switch	-	2,797
POM to P switch	-	3,669

		Current £	Proposed 1 April 2008 £
<b>LICENCE RENEWAL APPLICATIONS</b>			
<b>MANUFACTURERS' LICENCES</b>	NOP	152	165
<b>OUTGOING MUTUAL RECOGNITION</b>	FIRST RENEWAL OF A MAJOR APPLICATION <sup>1</sup>	9,281	9,803
	ALL OTHERS <sup>2</sup>	722	756

		Current £	Proposed 1 April 2008 £	Proposed 1 April 2008 for fully compliant eCTD £
<b>RECLASSIFICATION</b>				
COMPLEX <sup>3</sup> – Additional for MA or PI application with reclassification element		8,206	8,666	8,264
- Reclassification variation application		8,206	8,666	8,264
STANDARD <sup>4</sup> – Additional fee for MA or PI application with reclassification element		4,104	4,336	4,134
- Reclassification variation application		4,104	4,336	4,134
Reclassification variation application (MA) (analogous product) <sup>4</sup>		738	778	744
Reclassification variation application (PI) (analogous product)		178	188	180
<b>ASSESSMENT OF LABELS &amp; LEAFLETS</b>				
	SINGLE OR FIRST APPLICATION <sup>5</sup>	496	524	–
BROMI	Article 61(3) Notification <sup>6</sup>	NEW	188	–
<b>PARALLEL IMPORTS</b>		315	332	–

**Notes:**

1. If a number of such renewal applications are made at the same time and in relation to products with the same active ingredient, dosage form, indications, Periodic Safety Update Report (PSUR) and renewal date, the full fee is charged for the first application, but a fee of £756 will be payable in respect of each of the other applications.
2. If a number of such renewal applications are made at the same time and in relation to products with the same active ingredient, dosage form, indications, PSUR and renewal date, the full fee is charged for the first application, but a 50% "discount" applies to each other application.
3. A reclassification application is complex where it requires consideration by a medicines advisory committee; the 50% reduction for standard applications applies where the Agency are of the view that no such consideration is required.
4. If multiple MA applications with reclassification elements are made at the same time and in relation to products with the same active ingredient, the full additional fee is charged for one application but only £778 (£744 for eCTD application) for each other application.  
If multiple reclassification variations applications are made at the same time and in relation to products with the same active ingredient, the full fee is charged for the one application but in relation to each other application the fee is only £778 (£744 for eCTD), in the case of other complex/standard applications, or £389 in the case of other applications where there is analogous product already with the same legal status.
5. For all label and leaflet applications, a bulk "discount" applies where a number of simultaneous applications are made for identical changes covering a range of strengths of the same dosage form. The first application is charged at the full rate shown and second and subsequent applications are charged at 50%.
6. See Annex B for explanation re BROMI.

LICENCE VARIATIONS APPLICATIONS		Current	Proposed 1 April 2008	Proposed 1 April 2008 for fully compliant eCTD
		£	£	£
<b>MARKETING AUTHORISATION</b>				
<b>BROMI Self- certification<sup>1</sup></b>	National	178	176	170
<b>Type IA</b>	National/CMS	178	188	180
<b>Type IA</b>	RMS	276	292	278
<b>Type IB</b>	National/CMS	280	296	280
<b>Type IA BROMI<sup>1</sup></b>	National	280	188	180
<b>Type IB</b>	RMS	552	583	556
<b>Type II</b>	National/CMS	738	778	744
<b>Type IB BROMI<sup>1</sup></b>	National	738	296	280
<b>Type II</b>	RMS	894	944	900
<b>Type II Complex</b>	National/CMS	8,354	8,824	8,412
<b>Type II Complex</b>	RMS	14,484	15,298	14,586
<b>Extended Type II Complex</b>	National/CMS	25,780	27,228	25,962
<b>Extended Type II Complex</b>	RMS	36,036	38,062	36,290
<b>PL(PI)</b>				
STANDARD		342	360	–
ADMINISTRATIVE		166	176	–
<b>MANUFACTURERS' LICENCES (incl. THMPD)</b>				
STANDARD		440	476	–
ADMINISTRATIVE		220	238	–
NOP		220	238	–
<b>WHOLESALE DEALERS' LICENCES (incl. THMPD)</b>				
STANDARD		416	450	–
ADMINISTRATIVE		220	238	–
<b>CLINICAL TRIAL AUTHORISATIONS</b>				
AMENDMENTS TO:	ONE PART OF DOSSIER	115	252	–
	TWO PARTS OF DOSSIER	231	505	–
	THREE PARTS OF DOSSIER	346	757	–
<b>TRADITIONAL HERBAL REGISTRATION SCHEME</b>				
TECHNICAL:				
Standard		234	247	–
Complex		618	654	–
New excipient		6,998	7,394	–
ADMINISTRATIVE		148	156	–

**Notes:**

1. For BROMI explanation – see Annex B
2. For all variation applications a bulk “discount” applies where a number of simultaneous applications are made for identical variations. In general, the first of those applications is charged at the full rate shown above and second and subsequent applications are charged at 50%. But, where the first application is a Type II Complex or an extended Type II complex, the second and subsequent applications are charged at the rate for Type II.
3. MA variations fees above apply to Reduced Major applications except where they seek to extend the range of the drug's use outside a limited use area within 5 years of the date of grant of the MA. In this case, in addition to the variation fee applicable, there will be a further fee equal to the difference between the fee paid at the time of the new application and the fee applicable to a full Major Application.

## INSPECTION FEES

From 1 April 2008 fees for inspections will be charged at a daily rate as follows:

Type of inspection	Daily rate from 1 April 2008 £
All GMP, GCP and Pharmacovigilance inspections including: <ul style="list-style-type: none"> <li>- intermediate biological sites</li> <li>- manufacturers of active pharmaceutical ingredients (API)</li> <li>- sterile, non-sterile and assembly sites</li> <li>- non-routine inspections</li> <li>- pharmacovigilance inspection</li> <li>- clinical trials</li> <li>- contract laboratories</li> <li>- homoeopathic manufacturers</li> <li>- blood banks</li> <li>- blood establishments</li> </ul>	2,452
<b>GDP (wholesale dealers including homoeopathic wholesalers):</b>	
Full day rate	1,792
Reduced rate ( <i>see notes below</i> )	896

### Notes:

- There is a minimum fee of one day (with the exception of the GDP inspections).
- The inspection daily rate is calculated against a standard 7 hour working day (excluding lunch breaks). Therefore the number of days spent on site for fees purposes will be calculated by dividing the number of hours on site by 7. Additional part days of less than 3.5 hours will be charged at half the daily rate and part days in excess of 3.5 hours will be charged at the full daily rate.
- The daily rate fee includes pre-inspection preparation, travelling time, reporting of inspections and resolving issues. It also incorporates activities such as evaluation of compliance assessment report and other support functions and directly related overheads.
- A reduced rate fee for a wholesale dealer inspection will be payable by wholesale dealers who handle GSL products only and for registered retail pharmacies and small wholesale dealers where wholesaling of licensed products does not exceed 15% or £35,000 of total turnover **ONLY** where an inspector spends less than 3.5 hours on site.
- For inspections where two (or more) fully qualified inspectors undertake the inspection, the time on site for fees purposes will be the aggregated time for both inspectors.
- For inspections attended by two or more inspectors, one or more of who is in training, only the cost of one inspector will be charged – the status of the inspectors should be made clear to the company at the start of the inspection.

**OTHER FEES FOR TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMP) (not included elsewhere\*):**

**CHANGES PROPOSED FOR 1 APRIL 2008**

	Current £	Proposed 1 April 2008 £
<b>TRADITIONAL HERBAL REGISTRATION SCHEME</b>		
<b>STANDARD</b>		
- 3 or fewer existing herbal active ingredient	2,360	2,493
- more than 3 existing herbal active ingredients	3,540	3,740
<b>REDUCED</b>		
<b>Category I</b>		
- 3 or fewer existing herbal active ingredients	525	555
- more than 3 existing herbal active ingredients	787	831
<b>Category II</b>		
- 3 or fewer existing herbal active ingredients	787	831
- more than 3 existing herbal active ingredients	1,180	1,247
<b>COMPLEX</b>		
- single new herbal active ingredient	4,720	4,986
- 2 or more new herbal active ingredients	7,081	7,480
<b>SUPPLEMENTARY FEES:</b>		
<b>Ancillary vitamins / minerals:</b>		
Existing Sources plus CEP	1,049	1,108
New sources (non-CEP)	2,098	2,216
<b>New excipients</b>	6,999	7,394
<b>New sources TSE risk excipients (non-CEP)</b>	622	657
<b>Sterile products</b>	2,098	2,216
<b>Inspection of Manufacturers</b>		
Full day	1,364	1,496
Half day	839	920
<b>Inspection of Wholesale Dealers</b>		
Full day	1,154	1,266
Half day	629	690
<b>Inspection of non-orthodox practitioners</b>		
	252	273

\*For further fees relating to THMPD, see sections relating to Manufacturers' licences and Wholesale dealers' licences, variations, change of ownership and periodic fees.

**OTHER FEES FOR HOMEOPATHIC MEDICINAL PRODUCTS (not included elsewhere\*):**

**HOMOEOPATHIC NATIONAL RULES SCHEME AND REVIEW OF PRODUCT LICENCES OF RIGHT (PLRS)<sup>3</sup> - FEES**

The U.K. introduced a new National Rules Scheme for homeopathic medicinal products under Article 16.2 of Directive 2001/83, which started on 1 September 2006. Products are required to meet particular standards on safety, quality and patient information.

**HOMOEOPATHIC NATIONAL RULES SCHEME**

	Current	Proposed	Current	Proposed
	£	£	£	£
	5 or fewer stocks		More than 5 stocks	
<b>STANDARD</b>	1,060	<b>1,120</b>	1,278	<b>1,350</b>
<b>REDUCED:</b>				
Stock already assessed	788	<b>832</b>	988	<b>1,044</b>
Formulation	788	<b>832</b>	988	<b>1,044</b>
Both stock and formulation already assessed	503	<b>531</b>	713	<b>753</b>
<b>SUPPLEMENTARY FEES</b>	<b>Current</b>		<b>Proposed</b>	
	£		£	
New method of sterilisation (non-pharmacopoeial)	2,098		<b>2,216</b>	
New excipients	6,998		<b>7,393</b>	
New sources TSE risk actives/excipients (non-CEP)	618		<b>653</b>	

<b>SIMPLIFIED HOMOEOPATHIC REGISTRATION SCHEME</b>	<b>Current</b>		<b>Proposed 1 April 2008</b>	
	£		£	
	5 or fewer stock	More than 5 stock	5 or fewer stock	More than 5 stock
<b>STANDARD</b>	770	1,007	<b>813</b>	<b>1,064</b>
<b>REDUCED:</b>				
Stock already assessed	466	686	<b>492</b>	<b>725</b>
Formulation already assessed	466	686	<b>492</b>	<b>725</b>
Both stock and formulation already assessed	155	383	<b>164</b>	<b>405</b>

<sup>3</sup> 'Product Licences of Right (PLRs) are licences that were issued to all products on the market at the time that the Medicines Act 1968 was implemented (in 1971). Homeopathic products covered by PLRs may have indications'

**SIMPLIFIED HOMOEOPATHIC REGISTRATION SCHEME  
MUTUAL RECOGNITION PROCEDURES**

Current	Proposed	Current	Proposed
Mutual recognition OUTGOING			
5 or fewer stocks		More than 5 stocks	
£279	<b>£295</b>	£365	<b>£386</b>
Mutual recognition INCOMING			
5 or fewer stocks		More than 5 stocks	
£488	<b>£516</b>	£622	<b>£657</b>

**HOMOEOPATHIC VARIATIONS**

<b>Homoeopathic Simplified Scheme</b>	New technical	237	<b>250</b>	
<b>Homoeopathic National Rules Scheme</b>	Other	120	<b>127</b>	
	New technical	237	<b>250</b>	
	Indication	367	<b>388</b>	
	Other	120	<b>127</b>	

**Note:**

For variations to homoeopathic medicinal products authorised under the National Rules Scheme, a bulk "discount" applies where a number of simultaneous applications are made for identical variations. In general, the first of those applications is charged at the full rate shown above and the second and subsequent applications, up to 30 variations, are charged at 50%. Subsequent simultaneous applications for identical variations are charged at 25% of the full rate shown.

\* Fees relating to Homoeopathic Manufacturers' licences and Wholesale Dealers' licences applications and annual periodic fees - see tables elsewhere.

**PROPOSED PERIODIC FEES FROM 1 APRIL 2008 - PER LICENCE PER PERIOD**

<b>TYPE OF LICENCE</b>	<b>Current</b> £	<b>Proposed</b> <b>1 April 2008</b> £
New Active Substance <sup>1</sup>	18,573	<b>21,108</b>
Derivatives with a different Route of Administration <sup>1</sup> Or Complex Abridged <sup>2</sup>	7,648	<b>8,692</b>
Other derivatives <sup>1</sup>	5,163	<b>5,868</b>

<b>Legal Status/Sale Category</b>	<b>FEE TYPE</b> – see note 3	<b>Current</b> £	<b>Proposed</b> <b>1 April 2008</b> £
<b>POM</b>	Standard fee	1,913	<b>2,174</b>
	Reduced rate fee	955	<b>1,085</b>
	'Maintenance' fee	310	<b>352</b>
<b>P</b>	Standard fee	837	<b>951</b>
	Reduced rate fee	419	<b>476</b>
	'Maintenance' fee	155	<b>176</b>
<b>GSL</b>	Standard fee	346	<b>393</b>
	Reduced rate fee	172	<b>195</b>
	'Maintenance' fee	75	<b>85</b>
<b>NONE<sup>4</sup></b>	Standard fee	425	<b>483</b>
	Reduced rate fee	210	<b>239</b>
	'Maintenance' fee	89	<b>101</b>

<b>TYPE OF LICENCE</b>	<b>Current</b> £	<b>Proposed</b> <b>1 April 2008</b> £
<b>Herbal</b>	95	<b>108</b>
<b>Homoeopathic + Anthroposophic PLR's (per PLR)</b>	68	<b>77</b>
<b>Simplified Homoeopathic Registration</b>	19	<b>22</b>
<b>National Rules Homoeopathic Authorisation</b>	68	<b>77</b>
<b>Manufacturer's Licence</b>	383	<b>435<sup>A</sup></b>
<b>Wholesale Dealer's Licence</b>	235	<b>267</b>
<b>Wholesale Dealer's Licence (reduced rate or GSL)</b>	141	<b>160</b>
<b>Clinical Trials Authorisations</b>	252	<b>326</b>
<b>THMPD Registration</b>	80	<b>91</b>

<sup>A</sup> See also table below for additional fees for importers of unlicensed medicines

**NOTES:**

1. Payable for first five complete fee periods following the year of grant. Includes Reduced Major Drugs with turnover greater than £200,000 - otherwise treat as POM.
2. Payable for first three complete fee periods following the year of grant.
3. The standard fee for 2007/2008 is payable when the turnover of the drug in the calendar year 2006 exceeded £35,000. If the turnover was £35,000 or less, the reduced fee is payable unless the maintenance fee is applicable. A maintenance fee is payable where the licence holder declares that he does not intend to manufacture or import the product during the licence fee period (1 April 2008 - 31 March 2009) and, either he has not manufactured or imported the product in the previous fee period, or, the turnover during that period (1 April 2007 - 31 March 2008) did not exceed £1,000).
4. To cover products licensed under Section 104 or 105 (of the Medicines Act 1968) Order.

## FEES FOR SAFETY AND QUALITY VETTING OF UNLICENSED IMPORTED MEDICINES

Number of products imported in previous year	Number of notifications estimated for coming year	Current fee Additional sum to be paid with annual periodic fee for Manufacturers Licence holders £	Proposed 1 April 2008 Additional sum to be paid with annual periodic fee for Manufacturers Licence holders £
1 – 4	<b>0 – 100</b>	100	<b>114</b>
5 – 20	<b>101 – 1,000</b>	500	<b>568</b>
21 – 99	<b>1,001 – 10,000</b>	5,000	<b>5,682</b>
100 – 499	<b>10,001 – 25,000</b>	17,000	<b>19,312</b>
500 and over	<b>25,001 – 50,000</b>	37,000	<b>42,032</b>
	<b>50,001 – 100,000</b>	75,000	<b>85,200</b>
	<b>100,001 – 150,000</b>	125,000	<b>142,059</b>
	<b>150,001 – 200,000</b>	175,000	<b>198,800</b>
	<b>200,001 and over</b>	250,000	<b>284,000</b>

## FEES FOR BLOOD BANKS AND OTHER BLOOD ESTABLISHMENTS

INSTITUTIONS AND SERVICES PROVIDED	Current Fee £	Proposed April 2008 £
<b>Blood establishments</b>		
Application for authorisation	2,688	2,927
Substantial change to authorisation	449	493
Periodic fee	387	440
<b>DAILY RATE FOR ALL INSPECTIONS *to replace inspection fees below</b>		<b>2,452*</b>
Regular inspection – major site	13,153	–
Regular inspection – standard site	8,402	–
Regular inspection – minor site	4,120	–
Non-regular inspection – inspector on site >2 hours, but NMT 1 day	2,353	–
Non-regular inspection – inspector on site >1 day, but <3 days	6,143	–
Non-regular inspection – inspector on site 3 days or more	11,449	–
Annual haemovigilance fee (in respect of cost to MHRA of the operation of a system for receiving and assessing reports of serious adverse events and reactions)	432	468
<b>Hospital blood banks and facilities 1<sup>1</sup></b>		
<b>DAILY RATE FOR ALL INSPECTIONS* to replace inspection fees below –</b>		<b>2,452*</b>
Non-regular inspection – inspector on site >2 hours, but not more than 1 day	1,126	–
Non-regular inspection – inspector on site >1 day, but <3 days	3,071	–
Non-regular inspection – inspector on site 3 days or more	5,724	–
Annual haemovigilance fee (in respect of cost to MHRA of the operation of a system for receiving and assessing reports of serious adverse events and reactions) <sup>2</sup>	432	468
Annual compliance fee (in respect of the receipt and assessment of annual compliance reports submitted by hospital blood banks to MHRA) <sup>3</sup>	600	650
<b>Contract laboratories (that test blood or blood components on behalf of blood establishments or hospital blood banks)</b>		
Inspection – laboratory carrying out 1 type of analytical work	2,996	<b>Daily rate 2,452*</b>
Inspection – laboratory carrying out 2 types of analytical work	4,494	“
Inspection – laboratory carrying out 3 types of analytical work	5,992	“

### Notes:

<sup>1</sup> “Facility” is defined in SI 2006/2013 as: “a hospital, any other facility or service owned or managed by a health service body, a care home, an independent clinic, a manufacturer, or a biomedical research institute.”

<sup>2</sup> SI 2006/2013 exempts from payment of the annual haemovigilance fee a facility that has entered into an arrangement with a hospital blood bank for that hospital blood bank to report serious adverse events or reactions on the facility’s behalf.

<sup>3</sup> The annual compliance fee is only payable by hospital blood banks, not by facilities. It is charged in addition to any inspection fee that may be payable.

### \*Notes re Daily Rate inspection fees:

- There is a minimum fee of one day.

*continued ...*

*/continued ...*

- The inspection daily rate is calculated against a standard 7 hour working day (excluding lunch breaks). Therefore the number of days spent on site for fees purposes will be calculated by dividing the number of hours on site by 7. Additional part days of less than 3.5 hours will be charged at half the daily rate and part days in excess of 3.5 hours will be charged at the full daily rate.
- The daily rate fee includes pre-inspection preparation, travelling time, reporting of inspections and resolving issues. It also incorporates activities such as evaluation of compliance assessment report and other support functions and directly related overheads.
- For inspections where two (or more) fully qualified inspectors undertake the inspection, the time on site for fees purposes will be the aggregated time for both inspectors.
- For inspections attended by two or more inspectors, one or more of who is in training, only the cost of one inspector will be charged – the status of the inspectors should be made clear to the company at the start of the inspection.

## DETAIL OF FEE PROPOSALS FOR APRIL 2008

**1. Capital fees for new MA applications in European decentralised procedures where the UK is RMS**

1.1 This proposal is for ensuring cost recovery for the assessment and determination work carried out in the Licensing Division on applications for Marketing Authorisations where the UK has been nominated by the applicant as the Reference Member State (RMS) in the Decentralised Procedure (DCP) as described under Article 28(1) of the Directive. With 18 months' experience in the operation of DCP, it has become apparent that the DCP procedure involves considerably greater work by an RMS than was anticipated when the original DCP scale of fees was formulated. The original and 2007/8 fees for this type of work are approximately the sum of a National-only licence fee and an Outgoing Mutual Recognition fee. That was anticipated to be the equivalent amount of work we would do in the new Decentralised Procedure. However that basis for the fee was established before we had any real practical experience of how the new procedure would operate.

1.2 The proposed new basis for these DCP RMS application fees should be based on the combined fees for:

- + a National application,
- + an Outgoing Mutual Recognition application of the same complexity,
- + a further Standard Outgoing Mutual Recognition fee.

The reason for a standard single rate of increase for all three categories of application is because the costs do not increase because of the complexity of the application, the additional work is the same for all three types of application.

New fees for these applications are therefore proposed to be changed as follows:

<b>Decentralised procedure where UK is RMS</b>	<b>Current fee</b> £	<b>Proposed 1 April 2008</b> £	<b>1 April 2008 fully eCTD compliant</b> £
Major	133,204	<b>144,914</b>	<b>138,145</b>
Abridged complex	36,036	<b>42,444</b>	<b>40,461</b>
Abridged standard	13,554	<b>18,650</b>	<b>17,779</b>

**2. Proposals for increase in Fees for Clinical Trials Authorisations**

2.1 The fees for Clinical Trial Authorisation applications (CTAs) were initially set before the implementation of the Clinical Trials Directive. They were based on assumptions of the time required to process the different types of application, plus an overhead to cover the associated activities of the Clinical Trials Unit staff. After experience of three years working with these assumptions they have been re-visited in the light of the costs of resourcing these activities.

2.2 The fees for all initial CTA applications have now been reviewed to more accurately reflect the time required to assess them. In particular fees for Phase 1 CTAs (and especially First in Human) appear to be significantly under-recovering the cost of the work when compared to the resource required to process them. A key driver for additional resources is the size of the CTA applications compared with the applications made under the previous CTX/DDX exemption legislation and which formed the basis for the original assumptions. Previously, the supporting data dossier for CTX applications was restricted in size to around 60 pages for chemical based applications and 100 pages for biological applications and both

contained largely summary information. The implementation of the Directive resulted in the abolition of these restrictions and CTA applications now range in size, but regularly exceed 400 – 500 pages and frequently reach 1000 pages. This has an obvious time impact in terms of assessment of the data with additional costs for employing the staff to process these CTA applications. These additional costs are now reflected in the proposed fees in order to fully recover the costs of resourcing the Clinical Trials Unit.

## **BROMI Fee Reductions**

### **3. Changes to labels and leaflets under Article 61(3)**

- 3.1 The Agency is working with industry and other stakeholders to pursue a programme of reforms under the Government's "Better Regulation" initiative, to ensure that regulatory systems are proportionate, targeted and risk-based. This initiative has already led to new arrangements for self-certification of changes to leaflets and labels under article 61(3) of Council Directive 2001/83/EC for over-the-counter and prescription medicines in certain circumstances, backed up by an industry Code of Practice.
- 3.2. The self certification procedure operates for those changes to packaging which meet the criteria published on the MHRA website. These notifications are validated and acknowledged within 14 days of receipt with all updated packaging entered onto the Sentinel system. Applicants implement the change on receipt of acknowledgement. The notification scheme is supported by a regular audit and feedback mechanism operated by the Patient Information Quality Unit.
- 3.3 In establishing the scheme it had been explained to industry that fees would not be reduced in the initial phase. The primary benefit is reduced delay and greater certainty in planning, with consequent cost savings for companies. However, once such schemes are established and it can be shown that there are reduced costs to the Agency, then it is right that fee levels should be reassessed. Since these notifications follow the same workflow as a Type IA variation and include a validation step, it is proposed that they are charged the same fee as Type IA notifications.

### **4. National BROMI variation applications**

- 4.1 In addition to self certification of some changes to leaflets and labels the Agency has introduced procedures for expedited processing for certain national variation applications.
- 4.2 For UK National Variations Procedures MHRA follows the principles of the European Variations Regulation for Mutual Recognition (Commission Regulation 1084/2003/EC) and CMD(h) best practice guidance.
- 4.3. The Regulation provides two procedures for dealing with minor changes to licences. Minor changes that meet certain conditions and only require specified supporting documents are Type IA notifications processed within a 14-day timescale and involving a scientific validation only. Minor changes that are supported by specified data for assessment are termed Type IB notifications and follow a 30-Day assessment procedure. There are 46 changes that may be considered either Type IA or Type IB notifications; these are set out in an annex to the regulation and in guidance together with conditions necessary for following either a Type IA or Type IB procedure. Major changes to licences are known as Type II variations; these require professional assessment and usually follow a 90 day timetable. Regulation 1084/2003/EC although followed in principle is not applicable to nationally authorised products and the UK may adopt its own procedures for licence variations at the current time. The applicability of the variations regulations to national authorisations is currently being considered as part of the review of the EU Variations Regulations.
- 4.4 In the light of experience gained by both the MHRA and Industry over the last three years since the introduction of the current legislation, national procedures for minor notifications have been reviewed and the MHRA is now offering further simplified procedures for national variations.

4.5 In summary the following three tier model will be introduced:

- (i) A self certification procedure of some Type IA Notifications. These notifications will not be validated or assessed but will be acknowledged on receipt. The company can implement the change on submission of the notification (Self-Certification BROMI).
- (ii) A Scientific validation procedure for some current Type IB changes. Applicants will be notified of the validity of applications within 14 days of receipt. This is similar to the current Type IA procedure (Type IA BROMI).
- (iii) A 30-day assessment procedure for some specified changes that are considered Type II variations under current regulations but are considered minor in nature and require very little assessment (Type IB BROMI).

4.6 The fees will be reduced for expedited processing under BROMI commensurate with the amount of work involved. Therefore Type IB BROMI applications will be charged the same fee as an existing Type IB notification and Type IA BROMI applications will be charged the same as a Type IA application. Self –Certification BROMI applications will be charged at a fee equivalent to 93% of the existing Type IA fee.

4.7 Section 30 of the Medicines Act 1968 does not specify categories of variations and therefore the definitions as to which licence changes will fall into the categories of Self-Certification BROMI, Type IA BROMI and Type IB BROMI are given in a UK guidance document.

**Table: Summary of Fee Changes to be introduced under BROMI**

Fee type	2008/9 Fee without reduction*	Proposed 2008/9 fee with reduction*	% decrease
BROMI self-certification notification	188 (180)	176 (170)	6.4%
Type IA BROMI variation	296 (280)	188 (180)	36.5%
Type IB BROMI variation	778 (744)	296 (280)	62%
Article 61(3) notification (labels & leaflets)	524	188	64%

\*fee in brackets is for fully compliant eCTD applications

## 5. Daily Fees for Inspections

5.1 In our fees consultation letter last year (MLX 335), we asked for views on the proposal to introduce new daily rates for inspection fees from April 2008. The proposal was generally welcomed, subject to the practical detail of the scheme.

5.2 The proposal is to introduce a single daily rate fee for GMP, GCP and Pharmacovigilance (Pv) inspections and a different single daily rate fee for GDP inspections to wholesalers to replace the current 35 or more different inspection rates. These rates are proposed to be set at £2,452 and £1,792 respectively and reflect the different types of skills required for the different type of inspection. The daily rate fee includes pre-inspection preparation, travelling time, travel and subsistence costs (except for overseas visits), reporting of inspections and resolving issues. The intention of introducing the fee is that it should be cost-neutral, recovering the same aggregate income as would have been the case for the wide range of specific inspection fees.

5.3 Other points of note in relation to the new fee regime are:

- For GMP, GCP and GPvP inspections, there is a minimum fee of one day;
- The inspection daily rate is calculated against a standard 7 hour working day (excluding lunch breaks). For multi-day inspections, the number of days spent on site for fees purposes will be calculated by dividing the number of hours on site by 7.

Additional part days of less than 3.5 hours will be charged at half the daily rate and part days in excess of 3.5 hours will be charged at the full daily rate;

- For GDP inspections, a minimum fee of one day will be charged with the exception of wholesale dealers who handle GSL products only and for registered retail pharmacies and small wholesale dealers where wholesaling of licensed products does not exceed 15% or £35,000 of total turnover. The reduced rate of £896 is payable **ONLY** where an inspector spends less than 3.5 hours on site. If the time spent is greater, then the daily rate applies.
- For inspections where two (or more) fully qualified inspectors undertake the inspection, the time on site for fees purposes will be the aggregated time for both/all inspectors.
- For inspections attended by two(or more) inspectors, any of whom are in training, only the cost of the fully qualified inspector(s) will be charged – the status of the inspectors should be made clear to companies at the start of the inspection.

5.4 The benefits of this change include transparency and simplicity, but – most crucially – it would represent a fairer reflection of the actual costs incurred, and would support the better regulation principles of targeted and risk-based inspection. Taken together with the move to a risk-based programme of inspections, the effect will be that companies that are more compliant with requirements would benefit from less frequent inspections, and shorter inspections, and that (in addition to the business benefit of less time devoted to inspection) their inspection fees would also adjust accordingly.

5.5 The opposite would of course also be true, that less compliant companies might find more frequent inspections and proportionately higher fees to be the result. Another potential downside for companies will be that they will be less able than now to budget with certainty as to what their annual inspection fee costs will be, but the current length of inspections should provide an indicator.

## **6. Introduction of a Fee for Applications for Persons Appointed Hearings**

6.1 Persons Appointed hearings were introduced when the new committee arrangements were put in place in October 2005. In accordance with Schedule 2 to the Medicines for Human Use (Marketing Authorisation, etc.) Regulations 1994, a company has a right to a hearing before a Persons Appointed (PA) if it wishes to challenge a regulatory decision by the Licensing Authority. Experience is indicating that requests for these hearings are happening at a rate higher than was envisaged when the new committee arrangements were introduced, resulting in a new resource demand on the Agency, since these cases had previously been extremely infrequent.

6.2 It is a statutory responsibility and we have to be able to resource this work. It is therefore proposed that a fee is introduced for those applying for a Persons Appointed (PA) hearing. We estimate that the cost of each hearing will be in the region of £10,000. There is a significant amount of work involved in setting up a PA hearing, and in paying for a panel of appropriately skilled and experienced members to consider the appeals. The costs relate to MHRA staff time, other expert support, potential venue costs and fees and expenses for panel members. We therefore propose to charge a one-off fee of £10,000 for applications for an appeal to a Persons Appointed panel. We propose to include a provision whereby the fee would be refunded if the outcome resulted in the Licensing Authority making a subsequent decision in the company's favour, and for a proportion of the fee (60%) to be refunded if the application is withdrawn before the panel sits to hear the application.

6.3 The alternative option for recovering the cost of this work would be to spread the estimated annual cost across the fees for all new and complex MA applications. But this approach would not be equitable, given that the costs relate to a small number of companies who choose to undertake an appeal. In addition, any estimated costs estimated in advance might be too high or too low since the actual number of cases in any year will vary. The specific fee is therefore considered the best option.

## 7. Accreditation of Phase 1 Clinical Trial Units

- 7.1 The Expert Scientific Group which investigated the circumstances of clinical trial TGN 1412 that resulted in serious adverse reactions in six of the trial subjects made recommendations for procedural changes for the first in human studies. One of these proposals was the establishment of an accreditation scheme for units conducting Phase 1 clinical trials of higher risk agents. In response to this recommendation, MHRA will, from 1 April 2008, introduce a voluntary accreditation scheme for Phase 1 clinical trial units.
- 7.2 Inspections of Phase 1 clinical trial sites will continue as part of the routine statutory GCP inspection programme and inspection fees will be charged according to the daily rate. In addition Phase 1 units will be invited to participate in an accreditation scheme.
- 7.3 The operation of this scheme is the subject of a separate consultation.
- 7.4 Participants in the accreditation scheme will be asked to cover the additional costs of administering the scheme, namely:
- i) The creation and maintenance of a spreadsheet containing the details of the accredited units which will be published on the MHRA website.
  - ii) A certificate of accreditation following completion of each satisfactory inspection.
- 7.5 Units who volunteer to participate in the scheme will be charged an initial application fee of £120 to cover the cost of the administration of the database. This will be a single one-off payment. The fee for the accreditation certificate is proposed to be set at £63. An accreditation certificate will be issued following each completed satisfactory inspection.
- 7.6 Any additional inspection activity associated with the accreditation scheme will not need specific fees, but will instead be charged in accordance with the daily rate. This will mean that additional inspection time on site will mean a slightly higher fee for those units conducting the first in human studies of higher risk agents.

## 8. Fee waivers

- 8.1 Following the implementation of the new medicines legislation (Directive 2001/83/EC as amended), the Agency has reviewed the waivers, reduction or refund of capital fees set out in Schedule 5 to the Fees Regulations. In a number of instances, a waiver is no longer considered appropriate and their removal is proposed as described below.

### ***- Scientific advice for applications with a reclassification element***

- 8.2 The Agency proposes to remove the waiver which applies to applications for marketing authorisations including a reclassification element or reclassification variation applications (paragraph 1 of schedule 5). Encouragement of applications to reclassify medicines remains an important part of Agency strategy with regard to widening access to medicines and increasing patient choice. There has been a shift in recent years from changing the legal status of products indicated for minor ailments and self-limiting conditions to switching medicines for the treatment of more chronic diseases in the pharmacy setting. The nature of such applications is naturally more complex. Fees are not currently levied for scientific advice on reclassification applications but remuneration for such meetings would improve the Agency's ability to programme and resource such meetings, particularly for complex applications. Furthermore, the new European medicines legislation has provided an additional incentive for industry to reclassify medicines in the form of one year's data exclusivity for changes in classification arising from significant pre-clinical tests or clinical trials. Two new categories of scientific advice meetings are proposed for applications with a reclassification element, one for discussion of POM to P switches (£3669) and the other for P to GSL switches (£2797).

***- Changes to safety information at the request of the Licensing Authority or in response to a USR***

- 8.3 The Agency proposes that the fee waiver for variation applications as a consequence of new information having a bearing on the safe use of the product should be removed (paragraph 2 [1] of schedule 5). There should be no waiver for Type II variations requested by the LA or following Urgent Safety Restrictions (USRs) whether requested by the MAH or requested or imposed by the LA. (Note that there is currently no charge for the 24 hour USR procedure and we propose that this continues to be the case).
- 8.4 MAH have a responsibility to monitor the safety of their products and to take appropriate action to minimise risk. If the waiver is applied as currently it has the potential to penalise MAH who keep abreast of new safety information and apply to update their SPCs before being asked by the MHRA. New information bearing on safety will always be shared between MAH and licensing authority before the decision is made to update the SPC. It is therefore difficult to differentiate those variations which are at the specific written request from the LA from other safety variations following assessment of new safety data. Charging fees for safety variations will allow them to be implemented in a speedy manner that will benefit public health.

***- Changes to labelling and patient information leaflets at the request of the Licensing Authority in light of new information having a bearing on the safe use of the medicine.***

- 8.5 Paragraph 2 [2] of schedule 5 provides for the fee to be waived when amendments are made to the labelling and/or patient information leaflets for a product, specifically at the request of the licensing authority as a result of new information concerning the safe use of the medicine coming to light. It is proposed that this waiver is also removed for the same reasons as above and to ensure that such changes are processed in a consistent way by the Agency.

***- Variations relating to BSE and TSE guidance***

- 8.6 Paragraph 2A of Schedule 5 provides for a discretionary waiver of variation fees to MAs where the variation is to demonstrate compliance with the European “Note for Guidance on Minimising the risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal products”. There is no longer a need for this waiver and we therefore propose it is removed.

***- Withdrawal of applications***

- 8.7 Paragraphs 3 to 4A of Schedule 5 of the regulations provides for waivers of proportions of capital fees relating to the point at which applications are withdrawn by a company. It provides for 90% of the initial capital fee to be refunded if the application to be withdrawn has been received by the MHRA but no medical, scientific or pharmaceutical assessment has taken place. The regulations currently provide for a maximum limit of £1,500 in these circumstances to cover the administrative costs. However, we propose to remove the maximum limit imposed from 1 April 2008.

***- Inspections***

- 8.8 Paragraph 5 of Schedule 5 currently makes a provision for just one inspection fee to be charged if an inspection of a site takes place for two distinct purposes – e.g. where a wholesale dealer’s inspection takes place at the same time on the same site as a manufacturers’ inspection. This will no longer be relevant if the new daily rate for inspections is introduced and we therefore propose to remove this provision.

8.9 Paragraph 5A provides for a waiver of a fee for a “non-routine” inspection that takes less than two hours. This provision will also become redundant with the new daily rates for inspections.

**- Parallel imports**

8.10 There is provision in paragraph 6(a) of Schedule 5 for a waiver relating to “where the licence relates to a medicinal product in respect of which a separate marketing authorisation has been granted pursuant to the provisions of the 2001 Directive in more than one member state, those marketing authorisations are indicated on the parallel import licence as having been validly granted in those member states and the holder of that licence applies for the grant of a separate parallel import licence in respect of each marketing authorisation which has been granted and so indicated”. This waiver is considered to be no longer relevant and is being removed.

## **9. Paediatric Use Regulation**

9.1 On 1 May 2005 the MHRA introduced fee waivers for the granting of, and variation to, marketing authorisations for certain categories of products with paediatric indications. The fee waivers, which are included in Paragraph 2C of Schedule 5 of the 1995 Fee Regulations (SI 1995 No.1116), were introduced as an incentive for industry pending agreement at EU level of the Paediatric Use Regulation.

9.2 The UK strongly supported the introduction of the Paediatric Use Regulation and it was agreed by Member States on 12<sup>th</sup> December 2006. It provides various incentives to MA holders to conduct research into the paediatric use of medicines in the EU, and now that the Regulation is in place, we propose to remove the existing UK fee waivers for national assessment, variation work and provision of scientific advice.

9.3 There are additional elements of the Regulation that may require us to revise our fees, but we propose to absorb the costs of this additional work during 08/09 and collect appropriate data to support any proposals to revise fees in the future. In particular, we will monitor the resources needed to conduct the scientific ‘compliance check’, which is needed to ensure that MA applications covered by SPC or patent (and thus subject to the obligations in the Regulation) include either a Paediatric Investigation Plan (PIP) waiver or deferral, or evidence that the trials were conducted in accordance with the agreed PIP.

## Summary: Intervention & Options

Department /Agency:

Medicines and Healthcare  
products Regulatory  
Agency (MHRA)

Title:

Impact Assessment of The Medicines for Human Use  
and Medical Devices (Fees Amendments) Regulations  
2008

Stage: Consultation

Version: 1

Date: 5 October 2007

Related Publications:

Available to view or download at:

<http://www>.

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 health. 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 consultation 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:



Date: 8/10/07

## Summary: Analysis & Evidence

<b>Policy Option: 1</b>	<b>Description: Do not increase fees but implement benefits of better regulation and simplification initiatives</b>
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<b>COSTS</b>	<b>ANNUAL COSTS</b>	Description and scale of <b>key monetised costs</b> 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.
	<b>One-off</b> (Transition) <span style="float: right;"><b>Yrs</b></span>	
	£ NIL	
	<b>Average Annual Cost</b> (excluding one-off)	
£ nil	<b>Total Cost (PV)</b>	£ nil
Other <b>key non-monetised costs</b> 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.		

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>	Description and scale of <b>key monetised benefits</b> 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.
	<b>One-off</b> <span style="float: right;"><b>Yrs</b></span>	
	£ NIL	
	<b>Average Annual Benefit</b> (excluding one-off)	
£ 320k	<b>Total Benefit (PV)</b>	£ 320k
Other <b>key non-monetised benefits</b> 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		

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	<b>Net Benefit Range</b> (NPV) £	<b>NET BENEFIT</b> (NPV Best estimate) £
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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)	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; text-align: center;">Micro</td> <td style="width: 25%; text-align: center;">Small</td> <td style="width: 25%; text-align: center;">Medium</td> <td style="width: 25%; text-align: center;">Large</td> </tr> </table>	Micro	Small	Medium	Large
Micro	Small	Medium	Large		
Are any of these organisations exempt?	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; text-align: center;">No</td> <td style="width: 25%; text-align: center;">No</td> <td style="width: 25%; text-align: center;">N/A</td> <td style="width: 25%; text-align: center;">N/A</td> </tr> </table>	No	No	N/A	N/A
No	No	N/A	N/A		

<b>Impact on Admin Burdens Baseline</b> (2005 Prices)		(Increase - Decrease)
Increase of £ NIL	Decrease £ NIL	<b>Net Impact</b> £ NIL

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

## Summary: Analysis & Evidence

<b>Policy Option: 2</b>	<b>Description: Increase fees to ensure unavoidable cost increases for 08/09 are covered. Implement Better regulation and simplification initiatives</b>
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<b>COSTS</b>	<b>ANNUAL COSTS</b>	Description and scale of <b>key monetised costs</b> 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.	
	<b>One-off</b> (Transition) <b>Yrs</b>		
	<b>£ . NIL</b>		
	<b>Average Annual Cost</b> (excluding one-off)		
	<b>£ 6.9m</b>	<b>Total Cost (PV)</b>	<b>£ 6.9m</b>
Other <b>key non-monetised costs</b> by 'main affected groups' None			

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>	Description and scale of <b>key monetised benefits</b> 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.	
	<b>One-off</b> <b>Yrs</b>		
	<b>£ NIL</b>		
	<b>Average Annual Benefit</b> (excluding one-off)		
	<b>£ 320k</b>	<b>Total Benefit (PV)</b>	<b>£ 320k</b>
Other <b>key non-monetised benefits</b> 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	<b>Net Benefit Range</b> (NPV) £	<b>NET BENEFIT</b> (NPV Best estimate) £
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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

<b>Impact on Admin Burdens Baseline</b> (2005 Prices)		(Increase - Decrease)	
Increase of	£ nil	Decrease	£ nil
		<b>Net Impact</b>	£ 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.**

<b>COSTS</b>	<b>ANNUAL COSTS</b>		Description and scale of <b>key monetised costs</b> 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.	
	<b>One-off</b> (Transition)	<b>Yrs</b>		
	<b>Average Annual Cost</b> (excluding one-off)			
	<b>£ NIL</b>			
	<b>£ 2m</b>		<b>Total Cost (PV)</b>	<b>£ 2m</b>
Other <b>key non-monetised costs</b> 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				

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>		Description and scale of <b>key monetised benefits</b> by 'main affected groups' Lower costs for some companies using BROMI procedures.	
	<b>One-off</b>	<b>Yrs</b>		
	<b>Average Annual Benefit</b> (excluding one-off)			
	<b>£ NIL</b>			
	<b>£ 320k</b>		<b>Total Benefit (PV)</b>	<b>£ 320k</b>
Other <b>key non-monetised benefits</b> 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	<b>Net Benefit Range</b> (NPV) £	<b>NET BENEFIT</b> (NPV Best estimate) £
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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

<b>Impact on Admin Burdens Baseline</b> (2005 Prices)				(Increase - Decrease)
Increase of	£ nil	Decrease	£ nil	<b>Net Impact</b> £ 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 <sup>a</sup>), in the regulation of the parts of the pharmaceutical industry concerned with medicines for human use.

<sup>a</sup> *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 Health, 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 amend existing legislation relating to the fees charged by the MHRA in connection with the regulation of medicinal products for human use and medical devices in the United Kingdom. (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.) These proposed Regulations also amend existing legislation in connection with the regulation of blood banks and other blood establishments. 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. Any quantitative estimates that can be offered by consultation respondents of the harm in both health and economic terms from the risk of counterfeits would be very welcome.

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. Any more detailed estimates by individual companies will be welcome for inclusion in the final Impact Assessment).

- 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 the approval of HM Treasury, and of Department of Health Ministers, who are responsible for the work of the MHRA. Informal consultations have taken place with representatives of the affected industries as the proposals were developed.
- 2.2 A public consultation, particularly targeted at all those affected by these proposals, will take place between November 2007 and January 2008. [The remainder of this part of the RIA will be completed when consultation has been undertaken]

## **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 1.5 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 blood bank and blood establishment costs total £47,000 under option 2, or £16,000 under option 3. The majority of these costs will fall to the NHS. 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 (ie 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 be 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. [During the consultation process we will be discussing the effects of these proposals with one or two small companies and will complete this section in more detail].

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 Specific impact tests will be undertaken with one or two small companies and the results added here after consultation.

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 Any comments from consultation recipients would be welcome 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.

## **9. Enforcement, Sanctions, and Monitoring**

9.1 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.

## **10. Implementation and delivery plan**

10.1 The new fees will apply to all applications received on or after the 1 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.

## **11. Post-implementation review**

11.1 The new fees and the anticipated income through estimated volumes have been matched with the Agency's budget plan for 2008/2009.

11.2 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.

## **12. Summary and Recommendations**

12.1 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	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
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

**RESPONSE TO CONSULTATION LETTER MLX  
MHRA FEES FOR 2008/2009**

***Please complete the proforma below and return to: Mrs K Salawu, MHRA Fees Policy Unit, 16th Floor, Market Towers, 1 Nine Elms Lane, London SW8 5NQ by 9 January 2008***

*Please note that unless your response is specifically marked as "In Confidence", it will be made publicly available on request.*

Name: .....

Company/ Organisation Name: .....

Industry Sector\*.....

*\*for example, wholesaler, blood establishment, generic medicines manufacturer, etc. Please also specify which trade association your company/ organisation belongs to, if any. This information is not compulsory, but it will help us to categorise consultation comments more effectively.*

We have the following comments to make on the proposals for fees for 2008/2009:  
*Comments (Please use additional sheets as required):*