EXPLANATORY MEMORANDUM TO

THE MEDICINES FOR HUMAN USE AND MEDICAL DEVICES (FEES AMENDMENTS) (NO.2) REGULATIONS 2007

2007 No. 803

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health, and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 This instrument revokes and supersedes the Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2007 (SI 2007/610) ("the defective instrument"). For the reasons explained in its Explanatory Memorandum, the defective instrument was partially invalid. This instrument revokes the defective instrument, but otherwise contains identical provisions.

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

3.1 This instrument revokes and replaces the defective instrument. As explained in paragraph 3.2 of its Explanatory Memorandum, the defective instrument was partially invalid. In so far as the provisions of that instrument were made under section 1(1) and (2) of the Medicines Act 1971, the instrument should have be made jointly with, and signed by, the Department for Agriculture and Rural Development in Northern Ireland.

3.2 In so far as the defective instrument did not purport to be made under the Medicines Act 1971, it was properly made by the Secretary of State, acting alone, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 and, with the consent of the Treasury, section 56(1) and (2) of the Finance Act 1973. The Department's view is that in so far as the provisions of the defective instrument are made under those sections, it is valid. In the light of this partial validity, the Department did not consider it appropriate to withhold laying the defective instrument and substitute a new instrument with the same SI number (see paragraph 3.4.11 of Statutory Instrument Practice). This instrument therefore revokes and replaces the defective instrument. In accordance with paragraphs 3.4.11 to 14 of Statutory Instrument Practice, this instrument is being made available free of charge to all known recipients of the defective instrument.

3.3 This instrument was laid less than 21 days before it comes into force (1st April). The defective instrument was laid on 7th March, more than 21 days before its (valid) provisions came into force. Between making and laying, the Department identified the defect and set out in its Explanatory Memorandum the nature of that defect and its proposal to make this instrument. This instrument revokes the defective instrument and is signed by the Department for Agriculture and Rural Development, but otherwise

contains provisions identical to the defective instrument. The 21 day rule was breached in order to ensure that the relevant fee increases came into effect on 1st April 2007. If the instrument did not come into force on that date, the increases in periodic fees for authorisations and licences (see regulations 9 and 11, and the entries for Part III of Schedule 3 to the Medicines Fees Regulations in the Schedule to this instrument) would not have effect for the financial year 2007/8, as all periodic fees are payable as of 1st April in the year to which they relate. In addition, there would have been a delay in the increases for licence applications, inspections etc. The MHRA, which is financed by means of a Government trading fund and has a statutory obligation to break even, would have suffered a substantial financial loss as a result.

3.4 The Committees are also asked to note that those affected by the fee increases were made aware of the proposals by the MHRA's consultation, details of which were set out in the Explanatory Memorandum to the defective instrument. In addition, as the defective instrument was laid more than 21 days before coming into force and contained identical provisions to this instrument, users of the instrument and the Committees have in effect had an opportunity to consider those provisions before this instrument was laid.

4. Legislative Background

4.1 See the Explanatory Memorandum to the defective instrument.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

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

7. Policy background

7.1 See the Explanatory Memorandum to the defective instrument.

8. Impact

8.1 See the Explanatory Memorandum to the defective instrument. The Regulatory Impact Assessments for these proposals (one for medicines and one for devices) are unaffected by the revocation of the defective instrument, but have been attached to this Memorandum for convenience.

9. Contact

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

FULL REGULATORY IMPACT ASSESSMENT

1. TITLE

THE MEDICINES AND MEDICAL DEVICES (FEES AND MISCELLANEOUS AMENDMENTS) REGULATIONS 2007

2. The Purpose and Intended Effect of the Measure (on medicines regulation fees)

Background

2.1 The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health. It acts on behalf of the Ministers comprising the Licensing Authority (as described in the Medicines Act 1968 as amended [a]), in the regulation of the parts of the pharmaceutical industry concerned with medicines for human use.

2.2 This RIA relates only to the effects of the changes to fees relating to medicines regulation. There is a separate RIA relating to the effects of changes to fees relating to medical devices regulation also implemented by this SI.

2.3 The MHRA is a Government Trading Fund and, as such, is fully funded for its medicines regulatory function by fees in connection with the manufacture, sale and supply of medicines. The fees charged by the MHRA are monitored and reviewed annually to ensure, as far as possible, that the fees charged for a particular service reflect the cost of the work undertaken. This is in line with Treasury guidance on Fees and Charges. Under the terms of the Trading Funds Acts, the MHRA has a financial objective to at least break even taking one year with another and to set fee levels to achieve this, after taking account of HM Treasury's requirement to earn 3.5% return on capital employed in real terms.

Objectives

2.4 These 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. (This RIA only covers Medical devices in terms of drug/device combination products. A separate RIA has been prepared to illustrate the effect of the regulations on medical devices regulatory fees.) The proposal for 2007/2008 is to achieve full cost recovery of the work undertaken.

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

2.5 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;
- Targeting the additional income from fee increases to support performance improvement in those areas where the Agency and the industry wish to see improvement.

Rationale for Government intervention

2.6 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.

2.7 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.

2.8 It is therefore important that the MHRA is able to gain sufficient income from fees to resource these functions effectively. However, it is also recognised that the Agency must carry out its responsibilities efficiently and in accordance with the Government's principles on Better Regulation, so that regulation is proportionate, targeted and risk-based. The Agency also has a role in supporting innovation and enabling businesses to prosper, through handling routine regulatory processes promptly and efficiently. Unnecessary delay in regulatory activity can be

costly to companies in terms of delayed product launches, lost revenues from new or revised products, and planning blight from unpredictable timetables.

2.9 The rationale behind these fee proposals is therefore to ensure a fee regime that enables the Agency to fulfil its role in safeguarding public health; and also uses the resources from fee income to target improvement in key areas of the Agency's business.

3. Consultation

3.1 These proposals have been considered at length with Department of Health officials and with Treasury. Both have approved the proposals and are satisfied that the Agency is making every effort to match fees with costs and that these changes serve to ensure that this is the case.

3.2 A public consultation exercise was carried out with letters being issued to some 3,200 companies, individuals, industry associations and licence and Marketing Authorisation holders who were likely to be affected by the proposals or interested in them. The consultation document was placed on the Agency's website.

3.3 A total of 21 responses to the fees proposals for medicines (6 of which were content or had no comment to make) were received. Almost all responses were from industry associations. Whilst there was acknowledgement that there was a need for the Agency to be well-funded in order to deliver its responsibilities effectively, there were some concerns expressed about the levels of service currently being provided by the Agency and the need to improve further. Concern was expressed over the new proposed annual fees for Homoeopathic and Anthroposophic PLRs. The Agency will be offering the relevant companies assistance with time for paying the fees but a reduction in the fee could not be justified against the cost of reviewing these particular licences over the coming years. A comment was received in relation to the increase in the fees for scientific advice meetings. These had been introduced two or three years ago and we planned to monitor the costs of the meetings. They are not compulsory, but are at the request of the companies. The Agency has assessed the cost of a group of highly skilled staff attending each of these meetings for several hours at a time and taken into account the fact that they are taken away from assessment work to attend these meetings. The new rates are the true costs associated with these types of meetings. The incentive for companies to submit eCTD applications was welcomed but there was concern about acceptability of these same applications by other agencies. The Agency is leading a Europe-wide group to agree set requirements that will be acceptable to all. There was also support for the proposed daily rates for inspections fees structure for 2008/9 and willingness to be involved in discussions on this.

3.4 Industry responses have raised a number of issues which the Agency has considered carefully. In particular, the Agency accepts that it will be necessary to demonstrate further improvement in service levels experienced by companies in return for the proposed fee increases and will continue to work with the industry associations to achieve this. Discussions will also take place during 2007/2008 with industry to design the new structure for daily rates for inspection.

4. Options

4.1 Three options for the main proposals have been identified:

Option 1 - increase fees as proposed to cover costs.

Option 2 - make no changes.

Option 3 - increase fees by an inflationary figure across-the-board.

4.2 Option 1 will ensure that the correct fee is charged to cover the cost of each area of work undertaken. Some fees are increasing, some are remaining the same. The new fees being introduced will ensure that adequate resources can be given to undertaking functions to protect public health. Overall, the increase 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 and thus better service can be provided.

4.3 Option 2 would freeze licensing costs at 2006/2007 levels (with some fee being frozen at 2004/2005 levels). This 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. If the Agency were not resourced adequately there could be a long-term risk to public health. 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.

4.4 Option 3 would not meet the need to fully resource the Agency to carry out its work. Inflation-level increases do not address real-life increases in the Agency's costs for example, pay awards, pensions contributions and accommodation costs. 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.

5. Costs and Benefits

Sectors and groups affected

5.1 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.

5.2 It is not possible to identify a "typical" business. Businesses will 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 costs from paying higher fees. There are no indirect costs, policy costs or administrative burden costs as a result of these proposals.

5.3 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 (none of which are eCTD compliant applications, will pay £268,899 in fees in 2007/2008 compared to £253,774 in 2006/2007. If he were able to make all of his applications eCTD compliant, his cost would be £262,567. 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 variations; and has an inspection in year, will pay around £141,138 in 2007/2008 compared to £133,007 in 2006/2007. If he were able to make fully compliant eCTD applications his costs would be £138,928.

Benefits

5.4 The benefits are to all sectors of the pharmaceutical industry (relating to human medicines), research facilities, NHS organisations and, more generally, to the public health. Stakeholders will continue to see benefit from improvements in service levels from the MHRA in terms of speed and predictability of processing of licence applications. 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.

5.5 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 1 is that fees are set in such a way that the resources can be concentrated on the areas where improvements are most needed and can most effectively be made.

Costs

5.6 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. 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 is 4.9 per cent, which – on the basis of activity remaining the same as this year – would amount to roughly £3.1m in total.

5.7 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 frozen at 2006/7 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 Agency is consulting on the introduction of daily inspection fee rates from April 2008, which would also benefit more compliant companies in that the fees per inspection would be set proportionate to the actual resources used.

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

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

Impact on drug prices

5.10 There is unlikely to be a significant impact on drug prices to the NHS through these proposals. The biggest impact is likely to come through the change in the way fees are charged for imports of unlicensed drugs and this has been estimated to add £0.04 to each pack or dosage regime if fully passed on to customers. Much of this business is destined for the private market rather than the NHS, although detailed information on purchasers of imported unlicensed medicines is not available.

6. Small Firms Impact Test

6.1 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.

6.2 Examples of the effects on small businesses of option 1 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 £141 in 2007/2008 which is £10 greater than in 2006/2007 and 2005/06. 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 £747 compared to £712 in 2006/2007. For this particular small business, increased costs will amount to £45 over the year if he has an inspection in the coming year - if he does not, his costs will increase by £10. 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; an inspection fee; and the assessment of a new label and leaflet. In 2007/2008 the company would pay £6,424 compared to £5,964 in 2006/2007.

- An application from a new wholesale dealer for a standard licence would remain the same in 2007/2008 as in 2006/2007. There is no increase in this fee.

6.3 Two small companies were approached for their views on the impact of these proposals. One company was only affected by the inspection fees and felt that the impact on them would be minimal. The other company felt that the increase would severely limit the growth potential for the business and its ability to invest in the product/facility to improve the standard of equipment. Costs incurred by the company to support the current licensing and inspection activities represent 3.4% of the company's total turnover and they felt the level of expenditure was far from sustainable for a small or medium enterprise (SME). They felt that the fee structure did not accommodate the needs of SMEs. There are provisions for staggered payments for SME's as well as some lower periodic fees reflecting lower turnover in licensed products. We are taking steps to ensure that this company receives all the information it needs to take advantage of these provisions (see also para 6.7 below).

6.4 The effect of Option 2 would be that small firms' costs in 2007/2008 would remain the same as in 2006/2007 but that levels of service would suffer further and increased delays in undertaking work would be likely to occur which could have a damaging effect on the livelihood of a small business.

6.5 The effect of Option 3 would be to increase costs for smaller companies by, say, 3.2% compared to 2006/2007. Using the specific examples above, the increases in fees for the three examples shown would amount to £26.97, £190.84, and £49.34 respectively. In the third example, this would be a higher cost than in Option 1.

6.6 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.

6.7 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.

6.8 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.

7. Competition Assessment

7.1 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. Regulatory fees for this work also apply in all other EU member states.

7.2 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.

8. Equality Impact Assessment:

8.1 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.

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 1st April 2007. 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 2007/2008.

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 seeking 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 1 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 priority of addressing performance improvement in areas where response times are slow. In order to ensure

that over the coming year there are sustained improvements in the product licensing processes, the fee proposals as set out in Option 1 represent the most effective option.

Summary costs and benefits Table

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: economic, environmental, social, policy and administrative
1	- MHRA fully funded to enable it to fulfil current functions and new requirements without loss of quality - companies receiving prompt and effective service with improved speed of decision making - protection of public health by ensuring swift action is taken in response to defective medicines and adverse reactions, etc.	- Total cost to industry, roughly £3.1m
2	No additional cost to industry from MHRA fees	- delays for companies in having medicines authorised, with consequent costs of lost potential earnings - MHRA inadequately funded and not able to fulfil public health responsibilities - Delays in getting urgent medicines on to the market - Failure to meet terms of Trading Fund Order
3	Some resources for Agency to meet additional regulatory requirements, though not sufficient to maintain current levels of service	- Total cost to industry, roughly £2m - Possibility of cross-subsidisation of fees contrary to Treasury guidelines - No incentive for eCTD, reducing the potential to improve efficiency of processes - Inability of Agency to recruit essential staff, hampering ability to lift performance levels in key areas

13. Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that benefits justify the costs.

Signed by the responsible Minister ..Hunt.....

Date ..28th February 2007.....

14. Contact point

Any enquiries about these Regulations should be made, in writing to:

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FULL REGULATORY IMPACT ASSESSMENT

1. TITLE

THE MEDICINES FOR HUMAN USE AND MEDICAL DEVICES (FEES AMENDMENTS) REGULATIONS 2007

2. The Purpose and Intended Effect of the Measure (on medical devices regulatory fees)

Objectives

2.1 These Regulations amend existing legislation relating to the fees charged to the medical device industry and notified bodies in connection with MHRA's regulatory activities with regard to medical devices in the United Kingdom. The proposal for 2007/2008 is to achieve full cost recovery. Following a rigorous costing exercise, the proposal is to increase individual fees by differential amounts according to how closely current fee levels match the actual cost of the related activity. Proposed fees therefore vary, with some (ie registration) remaining the same. The overall effect is an increase in fees of 20%. There is a separate RIA relating to the effects of the changes proposed by these regulations in relation to medicines regulation.

Background

2.2 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 Competent Authority for Medical Devices.

2.3 The MHRA is required to recover its costs for its routine regulatory activities with regard to Medical Devices. The fees charged by the MHRA are monitored and reviewed 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. There has been no increase in fees since 1997.

2.4 The regulations will also cover increase in fees for which MHRA charges for its regulatory activities with regard to human medicines. This RIA only covers medical devices. A separate RIA has been prepared to illustrate the effect of the regulations on medicines fees.

Rationale for Government Intervention

2.5 The fees, which have been in place since 1995, are charged for regulatory activities that MHRA undertake as required by the three main European Medical Devices Directives:

90/385/EEC Active Implantable Medical Devices Directives
93/42/EEC Medical Devices Directive
98/79/EC In Vitro Diagnostic Medical Devices Directive

These and relevant amendments have been transposed and consolidated into the Medical Devices Regulations 2002 and amendments.

2.6 These fees have remained at the same level since 1997. 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 ongoing performance of UK Notified Bodies or in meeting the statutory target of 60 days for the review of clinical investigations. As well as the potential impact on public health, medical devices companies and notified bodies would suffer from a lower level of service from the Agency in dealing with their business.

3. Consultations

3.1 These proposals have been considered at length with Department of Health officials and with Treasury. Both have approved the proposals and are satisfied that the Agency is making every effort to match fees with costs and that these changes serve to ensure that this is the case.

3.2 Preliminary consultation took place on an informal basis with affected small businesses prior to the final public consultation and the results can be found in section 6 below.

3.3 A public consultation exercise was also carried out with 79 consultation letters being issued to notified bodies, medical device companies, and industry associations who were likely to be affected by the proposals or interested in them. The consultation document was also placed on the Agency's website.

3.4 Four replies were received; three of which, including those from the key trade association and one of the notified bodies, were content or had no comment to make. One comment was received from a manufacturer who was opposed to the cost increases.

3.5 Copies of the replies are published on our website (www.mhra.gov.uk) and made available on request.

4. Options

4.1 Three options for the main proposals have been identified:

Option 1 - increase fees as proposed to cover costs.

Option 2 - make no changes.

Option 3 - increase fees by an inflationary figure across-the-board.

4.2 Option 1 will increase costs in relation to fees, to all parts of the sector by around £50,000 overall. The new fees being introduced will ensure that adequate resources can be given to issues affecting public health. Overall the increase and the new fees will target costs better and ensure that the Agency is remunerated adequately for the work it undertakes. It will also help to ensure adequate resources and thus better service can be provided.

4.3 Option 2 would freeze costs at existing levels. This would hamper the Agency's ability to maintain its operation, particularly as these fees have not been increased since 1997. It would create a position where costs would be running at a level considerably above income and would result in a deficit. If the Agency were not resourced adequately there could be a long-term risk to public health as the Agency would have to cut staff numbers to reduce its costs and some work would not be undertaken. There would also be a direct impact on companies in terms of the speed and efficiency with which work were dealt with.

4.4 Option 3 would not meet the need to fully resource the Agency to carry out its work. It would not adequately target fees to the actual costs incurred and would mean that the Agency's costs and fees were out of line. If we say an inflationary figure of 3.2% was added, this would increase costs in relation to fees to all parts of the sector by around £8000 overall; making the costs and fees out of line by about £42000.

5. Costs and Benefits

Identify the benefits

5.1 The benefits are to the medical devices industry, notified bodies and to the public health. The industry and notified bodies will benefit from the maintenance of a high level of service from the MHRA. The public health will benefit from these measures by ensuring that the MHRA is adequately resourced for the relevant work it undertakes in ensuring the safety, quality and performance of medical devices.

Business sectors affected

5.2 UK Notified and Conformity Assessment Bodies (7 in total) and sectors of the medical device industry involved in carrying out clinical investigations for regulatory purposes in the UK.

Compliance costs for a "typical" business

5.3 It is not possible to identify a "typical" business. Businesses will range from a small "one-man-band" manufacturer such as a dental laboratory to multi-million pound international manufacturing businesses. Due to the fact that registration costs are being maintained at the same level (£70) it is unlikely that small businesses will be affected unless they are intending to carry out a clinical investigation (An increase in £800 for a high risk product; £500 for a low risk). The additional costs for Notified Bodies, estimated at £20,000, will be split between the 7 UK Notified Bodies, which in turn is likely to be passed on to their clients which total in the thousands. There is unlikely to be any activity with regard to Conformity Assessment Bodies but the fees have been updated just in case.

5.4 Some examples of potential costs are:

- A large innovative company that makes 3 high risk and 2 low risk clinical investigation applications will pay £16800 in fees in 2007/2008 compared to £13400 in 2006/2007. The sum payable in fees is likely to comprise only a very small part of the development costs of such products.

- A small start up company that makes 1 low risk clinical investigation application will pay £2700 in 2007/2008 compared to £2200 in 2006/2007. The sum payable in fees is likely to comprise only a minor part of the development costs of the product.

- A typical Notified Body with around 400 clients designated under 1 directive that is subject to a surveillance and witnessed audit and makes 1 extension to scope application during the year will pay about £12400 in 2007/2008 compared to £9500 in 2006/2007 (Excluding travel and subsistence).

Total compliance costs

5.5 The total cost of MHRA's chargeable regulatory activity with regard to medical devices is estimated to be around £295,000 which represents the total estimated income in 2007/2008 from fees raised. This will be an additional cost of about £50000 to the Medical Device sector. It is not possible to predict the total income with any certainty as in any one year; the income will depend on the volume of registrations and clinical investigations received.

Other Economic, Social and Environmental Impacts

5.6 These regulations have no other affect on economic, social or environmental issues.

6. Consultation With Small Business : Small Firms' Impact Test

6.1 A small business impact test was undertaken.

6.2 The registration fee is the one that is likely to affect small businesses the most but this fee has been kept the same. The only fee increases which could impact to a limited amount is the increase in clinical investigation fees; however out of about the 50 applications received each year only a very small number are from small businesses. Four small businesses who had recently submitted clinical investigation applications provided information to us. Two replied stating that the increase would not affect their activities and that the proposed fee increases were reasonable. Two replied that it would have an affect on how many studies they would conduct and that an increase in regulatory fees reduces the resources they have for R & D. However these latter comments do not tie in with the fact that the increase of a few hundred pounds in the regulatory fees are a fairly insignificant cost in the design of a medical device (eg costs of undertaking the study, pre-clinical testing, initial design etc).

6.3 The smaller notified bodies have a correspondingly shorter and lower frequency of, audit and the fees for the smallest notified body are likely to be £4,400 in 2007/2008 compared to £3,300 in 2006/2007 (excluding travel and subsistence). The four smallest notified bodies (out of 7) were consulted. One thought the proposed increases were fair based on no increases for 10 years; another made the comment that the increase would not affect them greatly (they were however surprised at the amount of increase, had not realised that our fees had been static for so long, and asked if they could be phased in over 2-3 years); another was not particularly

concerned , but the cost would be a factor in future commercial decisions and finally one stated that they had not done any work in the last year (if this was the case then there would be no audit and therefore no fee). The proposed increase in fees are to be mainly spread between the Notified Bodies clients which is likely to result in a small increase (one Notified Body estimated this to be about a £5 increase on their annual fee charged to clients).

7. Competition Assessment

7.1 We do not anticipate that the proposed increases are likely to have any significant impacts for competition in any of the affected markets. MHRA fees expenditure represents a relatively small proportion of the annual outgoings of all the affected firms, and this will continue to be the case following implementation of the proposed increases. 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.

8. Equality Impact Assessment:

8.1 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.

9. Enforcement, Sanctions, Monitoring and Review

9.1 MHRA fee levels are under ongoing further 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. An ongoing exercise to monitor time being spent on specific activities is underway and a new electronic time recording system is to be shortly introduced. The results of this will inform future proposals for fees changes.

10. Implementation and delivery plan

10.1 The new fees will apply to all applications received on or after the 1st April 2007. The new fees will be advertised on the MHRA's website and all those affected will be made aware through the consultation exercise.

11. Summary and Recommendations

11.1 Option 1 best achieves the objective of ensuring that costs to the medical devices sector reflect the actual cost of the work undertaken by the MHRA in connection with its chargeable medical device regulatory activity. It will allow the MHRA to undertake its responsibilities for protecting public health with fees reflecting the cost of the service provided.

Summary costs and benefits Table

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: economic, environmental, social, policy and administrative
1	- MHRA fully funded to enable it to fulfil current functions without loss of quality - companies receiving prompt and effective service - protection of public health by ensuring proper and timely review of clinical investigation reviews and Notified Body activity.	- Total additional cost to medical devices sector is estimated to be about £50,000.
2	No additional cost to industry from MHRA fees	- MHRA inadequately funded and not able to fulfil public health responsibilities - MHRA being unable to meet its statutory deadlines - Fees charged for a particular service do not reflect the cost of the work undertaken which is contrary to Treasury guidelines
3	Some resources for Agency to meet regulatory requirements, though not sufficient to maintain current levels of service	- Total additional cost to medical devices sector is estimated to be about £8,000 but consequences are as Option 2 above but to a slightly lesser degree.

12. Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that benefits justify the costs.

Signed by the responsible Minister ..Hunt.....

Date...28th February 2007.....

13. Contact point

Any enquiries about these Regulations should be made, in writing to:

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