EXPLANATORY MEMORANDUM TO

THE FEES AND CHARGES MEDICINES: THE MEDICINES FOR HUMAN USE AND MEDICAL DEVICES (FEES AMENDMENTS) REGULATIONS 2006

SI 2006 No. 494

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 SI amends relevant regulations which set out fees payable by the pharmaceutical industry in relation to services provided by MHRA for the regulation of medicines on the UK market. It increases the fees payable by amounts ranging from 4% to 42.8%. The overall effect of the increases is to increase fees by 17%. The fees are targeted to ensure that actual costs for specific services are met through the fees charged in line with treasury guidance on fees and charges.

3. Matters of special interest to the JCSI

3.1 The MHRA does not receive any central funding for this area of its work. It is fully funded by fees paid by the industry.

3.2 The fee increase is above the rate of inflation for several reasons:

- the MHRA did not impose any increase in fees for the 2005/2006 financial year;
- there were significant unexpected costs in year that mean that full cost recovery of fees in 2005/2006 cannot be achieved;
- further unplanned costs have added to the MHRA cost base for 2006/2007 year (such as increased employers' pensions contributions, rent review, enhanced regulatory processes required under European legislation and increased emphasis on public health and patient safety monitoring (for example, patient reporting through the yellow card scheme)).

3.3 The fee increases in this instrument are made in order to ensure that the fees charged for each area of activity properly reflect the cost of that activity. The Agency has a large number of different fees specific to different areas of work. Some fees are one-off capital fees (e.g. for a new licence application), some are charged for each time an activity takes place (e.g. fees for inspections), and others are annual fees that are intended to cover the costs of things like ongoing drug safety monitoring, and enforcement activity. The individual fee levels vary greatly (from £53 for an export certificate, up to £80,000 for a licence application for a major new product). A rigorous costing exercise revealed greater discrepancies between costs and fees in some areas compared with others. The increases vary from 4% to 42.8%, the latter relating

to most fees for inspections of premises. Main application fees are increased by 10%, variations by around 14% and annual fees by 17%.

3.4 The Agency assesses its fees and costs each year, whilst there are likely to be future increases in fees in line with costs, we are taking measures to deliver efficiencies and do not expect to need to make increases at this level in future years.

4. Legislative background

4.1 This SI was made under powers in section 2(2) of the European Communities Act 1972, section 56(1) and (2) of the Finance Act 1973, and section 1(1) and (2) of the Medicines Act 1971. It amends: the Medicines (Products for Human Use – Fees) Regulations 1995 (SI 1995 No 1116 as amended); the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 (SI 1995 No 449 as amended); and the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (SI 1994 No105 as amended).

5. Extent

5.1 This SI applies to all of the United Kingdom.

6. European Convention on Human Rights

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

7. Policy background

7.1 The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health. It acts on behalf of Ministers comprising the Licensing Authority (as described in the Medicines Act 1968), in the regulation of the parts of the pharmaceutical industry concerned with medicines for human use. It also ensures safety, quality and efficacy of medical devices. This SI only affects the medicines regulation part of the Agency's work.

7.2 The MHRA is a Government Trading Fund and, as such, is fully funded for its medicines regulatory work by fees paid by the industry in connection with the manufacture, sale and supply of medicines. 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.

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

7.4 The cost of compliance associated with this instrument is estimated to be around £8.1 million. In addition, the Agency is also proposing efficiency gains from within its current running costs. There is no associated recurring or non-recurring costs

for those affected. The total income estimated for MHRA in 2006/2007, taking into account the increased fees and anticipated volumes, is expected to be around £70 million.

7.5 All sectors of the pharmaceutical industry involved in the manufacture, sale and wholesale of medicinal products for humans use (around 3,000 organisations and companies in all) are affected. All of these companies and organisations have been consulted on the proposals to increase these fees. A full RIA has been prepared and is attached to the memorandum. Copies can also be obtained from Karen Salawu, Fees Policy Unit, Room 16-137 Market Towers, Tel: 020 7084 2216, e-mail: karen.salawu@mhra.gsi.gov.uk. The industry fully supports the MHRA's work in relation to medicines regulation but is concerned about the level of increase in the fees, particularly in relation to current service levels being experienced. The MHRA has met directly with, and discussed these issues with some of the main industry associations and is working closely with them to resolve the problems. It is taking a number of steps to improve service levels. These include organisational restructuring, additional recruitment, re-training of staff, voluntary schemes for extended working hours, and information system performance enhancements.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

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

FULL REGULATORY IMPACT ASSESSMENT

1. TITLE

THE MEDICINES FOR HUMAN USE AND MEDICAL DEVICES (FEES AND MISCELLANEOUS AMENDMENTS) REGULATIONS 2006

2. The Purpose and Intended Effect of the Measure

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

2.2 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.

2.3 There was no fee increase for 2005/06, with fees frozen at 2004/05 levels.

Objectives

2.4 These Regulations amend existing legislation relating to the fees charged to the pharmaceutical industry in connection with the regulation of medicinal products for human use in the United Kingdom. The proposal for 2006/2007 is to achieve full cost recovery.

For some years, fee increases have been implemented across the board, with equal up rating for all fees to match the overall cost increases. This has led to a position where the fees charged no longer match the cost of the related activity. This creates inequity (with companies being cross-charged for services provided to others) and is a contravention of Treasury guidance on fees and charges. An objective of these proposals, therefore, is to target increases to ensure fee levels match costs.

Following a detailed costing assessment, proposed increases therefore vary above and below an overall average of 17%. The increase is greatest for inspection fees, where current fee levels significantly under-recover costs. These regulations also make a number of other

amendments which will help to ensure that the MHRA's fees reflect more accurately the cost of the work undertaken.

Rationale for Government intervention

2.5 If no change is made to the current fee levels, the MHRA will be unable to fulfil its obligations in relation to the protection of public health through medicines regulation. 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.

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 also carried out with consultation 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 also placed on the Agency's website.

3.3 A total of 65 responses (8 of which were content or had no comment to make) were received. Almost all responses were from pharmaceutical companies and industry associations. The main themes of the comments were:

- that the role of the MHRA, and the need for it to be well funded in order to deliver its responsibilities effectively, is accepted and supported;
- that fee increases of this level are not supported, unless significant improvements to service were delivered commensurate with the size of the increase;
- that current service performance is poorer than it should be, with delays in assessing licence applications and variations;
- that budgets for the industry are often already set by the time the consultation document is circulated and no plans were made for an increase of this level;
- the increase of 42.8% in fees for inspections will be particularly difficult for companies to bear.

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 improvement in service levels experienced by companies in return for the proposed fee increases. In further discussion with industry representatives, discussions have focussed on the benefits to be realised from the following initiatives:

- Full introduction – from April 2006 – of the Agency's new IT system, which will significantly improve the flow of information within the Agency and speed up processes. It will also offer major benefits for companies, especially if they take up electronic submission of applications through the new electronic portal
- The implementation – from April, and fully in place by the Summer – of a restructured organisation in the MHRA's key operational divisions, with teams of scientific assessors covering the full life cycle of products (i.e., both initial licences and follow-up variations) rather than the traditional licensing/ post-licensing split. The new structure will also include a "service desk", with dedicated support for companies to advise them on applications, track progress through the system, and manage two-way communications.
- Taking advantage of the above changes to improve speed of handling and quality of information. This will include improvements in the speed of decision making, but also improved information as to likely timescales in order to assist company planning.

4. Options

4.1 Three options for the main proposals have been identified:

Option 1 - increase fees as proposed to bring costs and fees in line.

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 industry by around 17% 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 licensing costs 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 considerably 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. 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 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

<u>Sectors and groups affected</u>

5.1 All sectors of the pharmaceutical industry 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 to multi-billion pound international manufacturing businesses. However, whatever the size of the business, costs relating to licensing fees will increase through the implementation of these Regulations. There are no other recurring or non-recurring costs associated with these Regulations.

5.3 Some examples of potential costs are:

- A large innovative company that: makes 4 complex abridged applications and 2 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, will pay £253,774 in fees in 2006/2007 compared to £223,254 in 2004/2005 and 05/06. 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 £133,007 in 2006/2007 compared to £115,223 in 2004/2005 and 2005/2006.

Benefits

5.4 The benefits are to the pharmaceutical industry (relating to human medicines) and to the public health. The industry will 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.

Costs

5.5 The total additional cost of compliance across the whole industry is estimated to be around £8.1m. This is dependant upon volumes of applications, but is based on best estimates.

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

6. Small Firms Impact Test

6.1 Some of the businesses affected by these proposed fee increases are small firms. The actual number of small firms affected is not known but it will be a significantly small proportion of the whole number of companies and organisations affected. 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 £131 in

2006/2007 which is £19 greater than in 2004/2005 and 05/06. If he also has an inspection during the coming year (these are carried out on a 5-year cycle for GSL wholesale dealers), it will cost £712 compared to £499 in 2004/2005 and 05/06. This fee in itself is less than half the cost of a standard inspection to a larger wholesaler's site. For this particular small business, increased costs will amount to £231 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; an inspection fee; and the assessment of a new label and leaflet. In 2004/2005 and 2005/2006 the company would pay £4,532 compared to £5,964 in 2006/2007.

- An application from a new wholesale dealer for a standard licence would increase from £1,402 in 2004/2005 and 05/06 to £2,002 in 2006/2007, an increase of £600.

A specific impact test was undertaken with one small manufacturer. The company's assessment was that:

- Although the additional cost of an inspection is spread over a 2 year period, it represents a greater percentage of the turnover for small businesses in comparison to large businesses
- The proposed increase in fees will have a greater impact on small businesses than on large businesses
- The increase in fee discriminates against small business
- Small businesses would benefit from more flexibility in the payment of fees
- Additional services to small companies e.g. a point of contact within the Agency to provide advice, would be seen as providing more value for money

6.3 The effect of Option 2 would be that small firms' costs in 2006/2007 would remain the same as in 2004/2005.

6.4 The effect of Option 3 would be to increase costs for smaller companies by, say, 4% compared to 2004/2005. Using the specific examples above, the increases in fees for the three examples shown would amount to £24.44, £4,181, and £28.04 respectively.

6.5 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.

6.6 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.

The Agency will consider further assistance it is able to offer, for example, a point of advice for smaller companies. 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 in the UK, other EU Member States, and other countries across the world who seek to market medicines for humans in the UK. Generally, no firm 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 (although companies from any European Member State may apply to the European Medicines Agency (EMA) for a Central Marketing Authorisation that will permit them to market their product in any member state including the UK without having to apply directly to each country). The UK regulatory system is subject to European medicines regulatory legislation.

7.2 Regulatory fees are a permanent feature of the market, both in the UK and other countries, and we do not anticipate that the increases are likely to have any significant impacts for competition in any of the affected markets. Companies have different routes by which they can choose to market a product in a particular member state – these choices will remain. Companies applying for wholesale dealer's or Manufacturer's licences to operate in the UK can only apply to the MHRA. Apart from companies that apply for an EU-wide central Marketing Authorisation from the EMA, any company wishing to apply to market a product in the UK, either through reference to a Marketing Authorisation (MA) already obtained in another EU Member State, or using the UK to obtain its first MA, will pay a fee to the MHRA for the service. That fee is set to reflect the cost of the work undertaken in order to determine the application. The Fees in the UK are generally higher than in other member states because of inequities in the extent to which the service is funded in each country. The UK is one of the only EU member States that seeks to recover all of its costs (including associated overheads, accommodation, etc) through fees charged to the industry. Other Member States are generally centrally funded by their Governments for certain elements of their costs.

7.3 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 for small companies. 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. Enforcement, Sanctions, and Monitoring

8.1 The new proposals will be enforced by the Finance Division of the Agency who is responsible for raising invoices and collecting revenue for the Agency. There are certain sanctions where some fees are paid late and an additional charge is incurred. Work will not usually be started on applications which have not been accompanied by a payment. The measure of whether the policy meets its objectives will be apparent through the year through monitoring the budgets and also through auditing final accounts.

9. Implementation and delivery plan

9.1 The new fees will apply to all applications received on or after the 1st April 2006. The new fees will be advertised on the MHRA's website and all those affected are already aware through the consultation exercise.

10. Post-implementation review

10.1 The new fees and the anticipated income through estimated volumes have been matched with the Agency's budget plan for 2006/2007. Individual fee levels that have been set will be reviewed against emerging time recording data from a new system implemented at the Agency around 12 months ago.

10.2 MHRA fee levels are subject to continuous rigorous monitoring and review with a view to making annual amendments (where necessary) to ensure that, as far as possible, the cost of the work undertaken by the MHRA is reflected in the fees charged to industry.

10.3 MHRA will work directly with industry representatives on ensuring the delivery of benefits from the initiatives set out in paragraph 3.4; and on setting and monitoring benchmarks for improving service levels during 2006/07, so that there is demonstrated service improvement as a result of the fee increases.

11. Summary and Recommendations

11.1 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, coping with the additional requirements and costs that it is subject to for the coming year without loss of quality of service. And it will allow fee-paying companies to receive an effective and prompt service, with improved levels of service in terms of speed on decision making.

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 £8.1m
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 or exported to third world countries - Delays in handling FOI enquiries and other policy/Parliamentary work - possibility of cross-subsidisation of fees contrary to Treasury guidelines - 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	- 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

Signed: Jane Kennedy

Date: 26th February 2006

Minister of State, Department of Health.

13. Contact point

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

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