EXPLANATORY MEMORANDUM TO

THE MEDICINES FOR HUMAN USE (FEES AMENDMENTS) (No. 2) REGULATIONS 2005

2005 No. 2979

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 amends the Medicines for Human Use (Fees) Regulations 1995. The Medicines for Human Use (Fees) Regulations 1995 make provision for the fees payable in connection with the regulation of medicinal products for human use in the United Kingdom. These Regulations are amended to introduce fees to cover new work resulting from the implementation of Directive 2004/24/EC, which introduces a new licensing scheme for traditional herbal medicinal products, and amendments to the existing licensing scheme by Directive 2004/27/EC.

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

3.1. This instrument corrects errors in the Medicines for Human Use (Clinical Trials Fees Amendments) Regulations 2004 (S.I. 2004/1157)) which inserted regulations 13A and 14A in the Medicines (Products for Human Use - Fees) Regulations 1995. The Medicines for Human Use (Clinical Trials Fees Amendments) Regulations 2004 were reported in the Twentieth Report of the Joint Committee on Statutory Instruments – session 2003-2004.

3.2. The fees for inspections of manufacturers of medicinal products have been increased to cover the issue of a certificate of good manufacturing practice at the end of an inspection (a new requirement introduced by Directive 2004/27/EC). All routine inspection fees have been increased by £53. In broad terms the percentage increase over the range of these inspections is from less than 1% to 31%. This is a one off increase in these fees to cover this new work.

4. Legislative Background

4.1. This instrument amends the Medicines for Human Use (Fees) Regulations 1995. The Medicines for Human Use (Fees) Regulations 1995 make provision for the fees payable under the Medicines Act 1971, and other fees payable in respect of Community obligations, in respect of the regulation of medicinal products for human use.

4.2. The changes are being made to introduce charges for new work resulting from the implementation of Directive 2004/24/EC and Directive 2004/27/EC. This instrument is linked to the following legislation implementing these Directives:

- The Medicines for Human Use (Manufacturers, Wholesale Dealers and Miscellaneous Amendments) Regulations 2005
- The Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005
- The Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2005
- Medicines for Human Use (Advertising) Amendment Regulations 2005.

5. Extent

5.1. This instrument applies to all of the United Kingdom.

6. European convention on Human Rights

No statement required.

7. Policy Background

7.1. The 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.

7.2. The MHRA is a Government Trading Fund and, as such, is 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. MHRA also has to comply with a Treasury minute dated 9 February 2004 which requires the MHRA, for the 5 year period from 1 April 2003 to 31 March 2008, to achieve a return, averaged over the period as a whole, of at least 3.5% in the form of a surplus on ordinary activities before interest (payable and receivable) and dividends expressed as a percentage of average capital employed.

7.4. In order to ensure that the fees charged for a particular service reflect, as far as possible, the cost of the work undertaken by MHRA this instrument introduces new fees for areas of work not previously charged for.

7.5. The following summarises the main legislative changes to the Medicines for Human Use (Fees) Regulations 1995 brought about by the implementation of Directive 2004/24/EC.

Directive 2004/24/EC introduces a new simplified registration procedure for the marketing of certain traditional herbal medicinal products for human use. The regulations introduce fees for the registration of products; variations; periodic fees; fees for manufacturers' licences and inspection fees relating to manufactures of registered herbals products; fees for wholesale dealers' licences and inspection fees relating to wholesalers of registered herbal products.

7.6. The following summarises the main legislative changes to the Medicines for Human Use (Fees) Regulations 1995 brought about by the implementation of Directives 2004/27/EC.

The regulations introduce a fee for new types of marketing authorization application; in particular, generic applications where the reference product is authorized elsewhere in Europe and decentralised procedure applications where an application for a marketing authorization is submitted in more than one Member State at the same time.

The regulations also introduce a new fee for the inspections of API manufacturers *[API manufacturer means a person, other than the holder of a manufacturer's licence, engaged in the manufacture or assembly of active substances used as starting materials in the manufacture of medicinal products]* and a fee for the issue of certified copies of certificates of good manufacturing practice.

Importers of products from countries outside of the EU will from 30th October hold manufacturer's licences rather than wholesale dealer's licences. The application, variation, periodic and inspection fees for these importers are amended accordingly so that there will be no increased cost to Industry from the change of licence type.

8. Impact

8.1. A full Regulatory Impact Assessment has been prepared and is attached to this memorandum.

8.2. There are no identifiable costs to the public or to the Exchequer.

9. Contact

Lavinia O'Brien at Medicines and Healthcare products Regulatory Agency (MHRA) Tel: 020 7084 2884 or e-mail lavinia.obrien@mhra.gsi.gov.uk can answer your queries regarding the instrument.

REGULATORY IMPACT ASSESSMENT

1. TITLE

THE MEDICINES FOR HUMAN USE (FEES AMENDMENTS)(NO. 2) REGULATIONS 2005

2. The Purpose and Intended Effect of the Measure

The issue

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.

The MHRA is a Government Trading Fund and the medicines regulation part of the Agency is fully funded by fees paid by the industry 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.

Following a review of European Medicines regulation (known as the "2001 Review"), and the recent EU Directive on Traditional Herbal Medicinal Products, Member States are required to transpose the provisions into national law by 30 October 2005. The EU Directives will result in new and different types of work having to be undertaken by MHRA. New fees for each of these new areas of work need to be introduced in order to comply with Treasury guidance on fees and charges. Separate consultations have been undertaken in relation to the implementation of all these provisions.

The objective

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. They will ensure that the MHRA is funded for the work carried out as a result of the new obligations and that public health is protected adequately. The changes are:

- New fees for new European medicines laws implementation:
  - Decentralised procedures where the UK is the Reference Member State;
  - Decentralised procedures where the UK is the Concerned Member State;
  - Hybrid applications ;

- Abridged applications making reference to original MAs granted in other Member States but not authorised in UK;
Manufactures of Active Pharmaceutical Ingredients (API);
- new fees for inspections of sites producing Active Pharmaceutical Ingredients (API);
Certificates of Good Manufacturing Practice (GMPs):
- an increase of £53 in the cost of a GMP inspection to cover the routine issue of a GMP certificate (a new requirement).

- Traditional Herbal Medicinal Products Directive:
  - capital fees for the registration of products;
  - capital fees for variations;
  - periodic fees;
  - capital fees for manufacturers' licences and inspection fees relating to manufactures of registered herbals products.

- Manufacturer's Licence (Import) for both licensed and unlicensed medicines.
  - to move to a new system of Manufacturers licences for importation.

3. Risk Assessment

If the MHRA is not adequately resourced for the work undertaken 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 cost lives. Inadequate resourcing could also put consumer choice and industry prosperity at risk if it led to difficulties in companies registering products under the new regulatory scheme for herbal medicines.

4. Options

Two options were identified:

Option 1 - to make no changes

Options 2 - to make changes in following areas to reflect the new work carried out by the Agency:

To introduce new fees for new work arising from European Directives in relation to medicines licensing including the recent EU Directive on Traditional Herbal Medicinal Products. Failure to comply with European Directives could result in litigation being taken against the UK.

5. Issues of equity or fairness

The MHRA is not looking to increase revenue by any increases though these proposals. It is looking to ensure that it covers the cost of new work undertaken by the Agency. The fees will be charged directly to the companies who seek and receive the service being provided. There is no element of cross-subsidisation involved. The fees are proposed at levels that are consistent with existing fees for other similar work already undertaken by the MHRA. The level of fees will be monitored to ensure they are set at the right level and proposals will be made to adjust them at a later date if not.

6. Benefits

Identify the benefits

The benefits are to mainstream pharmaceutical industry relating to human medicines, to the herbal sector and to the public health. The industry will benefit from a good level of service from the MHRA if it is well-funded. The public health will benefit from these measures by ensuring that all medicines on the UK market, including herbal medicines, are safe and of good quality and that mainstream medicines are efficacious.

Quantify and value

Option 2 is the option chosen. Treasury requirements are that as a Trading Fund the MHRA must charge for the work it does. In order to do this changes to the regulations are proposed as above. The UK must also comply with European Directives and could face litigation if it fails to do so.

7. Compliance Costs for Business, Charities and Voluntary Organisations

Business sectors affected

All sectors of the pharmaceutical industry involved in the manufacture and sale of medicinal products for human use (around 3,000 organisations and companies in all) including herbal products.

Compliance costs for a "typical" business

It is not possible to identify a "typical" business.

- New fees for new European medicines laws implementation – Businesses affected by the fees associated with these changes are mostly mainstream pharmaceutical companies, both from the innovative and generic sectors of the industry and they can be from any Member State in the EU – not just UK companies. The changes in European licensing opens the market for new different types of applications for marketing authorisations providing more opportunities for companies. The fees proposed for these new applications are based on existing capital and inspection fees relating to applications for marketing authorisations. Costs will vary depending on what applications companies make.

- Traditional Herbal Medicinal Products Directive:
  A full Regulatory Impact Assessment will accompany the legislation transposing Directive 2004/24/EC into UK law. An up-dated partial Regulatory Impact Assessment on the Directive accompanied the MHRA consultation document in the Summer of 2005. Additional costs to companies will vary widely, depending on many different factors relating to the nature of the product and the circumstances of the individual company. The MHRA's understanding from talking to individual companies is that a significant proportion are likely to spread planned registration applications over some years as they gain experience of the scheme and progressively assess the commercial value of the registrations achieved. A company that sought registrations for 10 single herb tinctures would pay capital registration fees of £7,500 for these products. A company that sought registration for 20 typical products classified as standard of which 5 contained more than three ingredients and 5 contained ancillary vitamins and minerals would pay registration fees of £55,625. For many companies MHRA's fees are likely to represent a relatively small proportion of the overall costs to companies; of greater overall significance for many companies will be the cost of demonstrating that the product meets the requirements of the Directive. However, the fee levels in aggregate will be more significant for those companies that manufacture a significant number of complex products or products containing ingredients that have not previously been assessed. These products will require more assessment time and hence incur higher fee levels.

- Manufacturer's Licence (Import) for both licensed and unlicensed medicines.
  The changes are cost neutral. There will be no charge to change for the current Wholesale Dealers licence to a Manufacturers Licence and fees from 30 October 2005 will remain the same for these licence holders.

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

A small business impact test has not specifically been undertaken although all affected businesses will be consulted on these measures. A significant number of the herbal sector companies will consist of micro, small or medium sized enterprises and regulatory impact assessments have been undertaken under the herbal consultations.

Certain provisions are already present in legislation to assist smaller companies both through reduced fees for certain smaller companies, lower periodic fees for products with low turnover and for extended terms of payment of a number of capital fees. 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. Deferment of capital fees for small companies is being extended to include fees relating to the new herbal medicine scheme.

9. Other Costs

There are no other costs occurring as a result of these Regulations.

10. Results of Consultations

The consultation period ended on 29 August 2005. A total of 44 replies were received, mostly from the herbal sector. In general terms, the responses supported the main thrust of the proposals. The following specific points were made:

- The Industry Associations were keen that the fees were set at the appropriate level to ensure that the Agency is adequately resourced for the assessment work undertaken.
- There were a number of comments opposing the full National level of fee proposed for de-centralised procedure when UK is the Concerned Member State (CMS).
- The general opinion was that although the Agency kept the proposed fees low for Traditional Herbal Medicinal Products there would still be a significant increase in running costs, in particular, for small and medium sized enterprises (SMEs). Most UK companies producing herbal remedies fall into these categories, many are very small and it was feared that the fees would impact disproportionately on these businesses. There was a common concern that this might lead to a reduction in the number of businesses and a fall in the range of products available to UK consumers.

We have considered all of the points made in response to the consultation but do not propose to make any changes the proposals which were set out in the consultation document. On the points made:

- We are in discussion with the industry associations about levels of service.
- The increase in fees is necessary for the de-centralised procedure when UK is the CMS as the timescale for is so tight it means that an application will have to be assessed without the benefit of the reference members state report. The fee reflects the increased assessment activities.
- Much of the UK herbal medicine industry has never been systematically regulated before so any fee imposed would be likely to be perceived as burdensome. The rate set for the herbal fees are based on Agency experience of homoeopathic products and "simple abridged" marketing authorisations, and the costs involved. As far as possible we have assessed the amount of work involved and set the fees at the minimum anticipated to cover the Agency's costs. The RIA accompanying the regulations transposing the herbal Directive sets out in some depth the help that the MHRA has given the herbal sector in adjusting to the new arrangements.

A full summary of the responses, and our comments in reply, will be placed on the MHRA website.

11. Competition Assessment

The proposed fee increases will affect a number of different markets within the pharmaceutical industry. However, we do not anticipate that the increases are likely to have any significant impacts for competition in any of the affected markets.

12. Race and Rural impact assessment

These regulations have no affect on race or rural issues.

13. Summary and Recommendations

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.

14. Enforcement, Sanctions, Monitoring and Review

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. A new electronic time recording system was introduced across the medicines staff in the MHRA in December 2004 and the results of this will inform future proposals for fees changes.

15. Declaration:

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

Signed: Jane Kennedy

Date: 24th October 2005

Minister of State, Department of Health.

16. Contact point

Any enquiries about these Regulations should be made, in writing or by e mail to:

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