EXPLANATORY MEMORANDUM TO

THE MEDICINES (PRODUCTS FOR HUMAN USE) (FEES) REGULATIONS 2012

2012 No. 504

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. Purpose of the instrument

2.1 This instrument revokes and re-enacts in consolidated form the legislation setting out the fees payable by the pharmaceutical industry in relation to services provided and regulatory functions carried out by the MHRA in relation to medicines for human use. It will help clarify the provisions decrease the fees in specific priority areas by an overall reduction of 7% and simplify the scheme by reducing the range of bands at which certain fees are payable.

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

3.1 The fees in this instrument represent a general overall reduction of 7% in the amount charged.

4. Legislative Context

4.1 This instrument revokes and re-enacts in consolidated form the Medicines (Products for Human Use) (Fees) Regulations 2010 (S.I. 2010 No. 551); and regulations 12 to 18 of, and Schedules 2, 2A and 3 to the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (S.I. 1994 No. 105 as amended). This instrument also amends the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004 No.1031 as amended). The instrument is made to clarify the provisions, implement a decrease in fees payable in some specific areas and to simplify the scheme by reducing the range and number of bands at which certain fees are payable.

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

Background to the administration of fees for medicinal products

7.1 The Medicine and Healthcare products Regulatory Agency is a Government Agency responsible for, amongst other things, the regulation of medicines. The MHRA does not receive any central funding for carrying out this function and its work in this area is fully funded by fees paid by the pharmaceutical industry. The MHRA operates as a Government Trading Fund and must therefore ensure that its income is sufficient, taking one year with another, to meet its expenditure.

7.2 The fee increase is set at different rates in order to:

- reflect the correct cost of undertaking each area of work;
- reflect Treasury guidance on fees and charges which advises that actual costs should be taken into account;
- cover essential unavoidable costs for the Agency in carrying out its regulatory functions (such as accommodation costs, increasing utilities costs, retention and recruitment of staff in assessing applications);
- further improve efficiency and promptness in handling of applications; and
- to ensure that the MHRA can effectively carry out its responsibilities to safeguard public health.

7.3 The MHRA 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 variations to existing licences), and others are annual fees that are intended to cover the costs of activities such as ongoing drug safety, monitoring and enforcement. The individual fee levels vary greatly from £67 for a certified copy of a certificate of good manufacturing practice, to £139,235 for a licence application for a major new medicinal product.

7.4 The MHRA reviews its fees and costs each year to ensure that charges reflect an efficient use of its resources and operational expenditure.

What is being done and why

7.5 This instrument revokes and re-enacts in consolidated form the Medicines (Product for Human Use) (Fees) Regulations 2010 which set out fees payable by the pharmaceutical industry in relation to services provided and regulatory functions carried out by the MHRA in relation to medicines for human use. It applies targeted decreases in fees in some specific priority areas and more generally, an overall average decrease of 7% across all fees. These measures are necessary to ensure that the fees imposed on the industry are simpler and a better reflection of the costs to the MHRA in carrying out their regulatory functions while maintaining fee income at levels consistent with Government guidelines. The principle changes in the Regulations are that:

- there is a 10% reduction in fees for applications made under decentralised procedures where the UK is the Reference Member State in order to reflect efficiencies achieved by the MHRA;
- the fee structure for some types fees payable for marketing authorisations, licenses, registrations and certificates is simplified so that there is no price differential between applications made electronically and others;
- periodic fees for parallel import (PI) licence holders are simplified to reduce administrative burdens and provide greater clarity for the licensee;

- a single fee rate will apply for herbal, homoeopathic and traditional herbal medicinal product licenses;
- the Regulations are amended to enable applicants to pay fees in advance of any application or the fee becoming due in order to improve the quality service;
- the provisions for fees that are currently incorporated in the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (S.I. 1994 No. 105) are being consolidated in this instrument as a part of a wider exercise intended to consolidate medicines legislation.

Consolidation

7.6 No consolidation, other than what has already been consolidated is anticipated.

8. Consultation outcome

8.1 A 6 week public consultation exercise was carried out (with Ministerial agreement) with emails being issued to industry associations and Marketing Authorisation holders who were likely to be affected by the proposals, or interested in them. Two meetings were held with industry associations to explain the changes and the consultation document was placed on the MHRA website. The consultation closed on 31 January 2012.

8.2 A total of 8 responses to the fees proposals for medicines were received. All responses were supportive of the proposals. The respondents were positive and welcomed:

- the consultation process, the opportunity provided for early discussions on the proposals and the transparency of the fee setting process;
- the proposed simplification and measures to reduce administrative burden particularly on SMEs;
- the proposed reduction in the fees charged for the decentralised procedure applications where the UK is the reference Member State;
- the proposed removal of a number of fees as that would assist in reducing cost and time to industry; and
- the proposed freeze in some fees.

8.3 These proposals have also been considered by officials at the Department of Health and Her Majesty's Treasury. Both departments have approved the proposals and are satisfied that the MHRA is making every effort to match fees with costs and that changes in this instrument serve to ensure that this is the case.

9. Guidance

9.1 Guidance and information regarding fees payable by the pharmaceutical industry can be found on the MHRA website at www.mhra.gov.uk.

10. Impact

10.1 An Impact Assessment has been prepared and is attached to the memorandum. Copies can also be obtained from karen.salawu@mhra.gsi.gov.uk.

10.2 The impact on the public sector is minimal. The changes to fees mainly affect the private sector pharmaceutical industry. However, some NHS bodies, and academic research bodies will be affected by the decreases in some fees.

11. Regulating small business

11.1 The legislation applies to small business. 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 MHRA operates a number of provisions to assist smaller companies, such as reduced fees for certain small companies, lower periodic fees for products with low turnover, and extended terms of payment of a number of capital fees.

11.2 The Agency will consider further assistance and targets small businesses in it consultation process each year. However, reduced 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.

12. Monitoring & review

12.1 The fees charged by the MHRA are reviewed annually.

13. Contact

13.1 Karen Salawu at MHRA Tel: 020 3080 6216 e-mail: karen.salawu@mhra.gsi.gov.uk regarding any queries related to this instrument.