EXPLANATORY MEMORANDUM TO THE

MEDICINES FOR HUMAN USE (FEES AMENDMENTS) REGULATIONS 2005

2005 No. 1124

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.

2. Description

2.1. The instrument amends 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. For 2005/2006 there will be no overall increase in the current fee levels but the Regulations make four other amendments.

2.2. The changes are:

- To increase selected fees to cover new work for assessing user testing of Patient Information Leaflets from 1 July 2005;
- To restrict a waiver for fees for repeat inspections from 1 May 2005
- To introduce new waivers to support the paediatric strategy from 1 May 2005
- To re-categorise the fee for clinical trials with products which have a clinical trial authorisation elsewhere in the EU from 1 May 2005.

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

3.1. None

4. Legislative Background

4.1. This instrument amends the Medicines (Products for Human Use-Fees) Regulations 1995. The changes are being made to introduce charges for new work, to cover the cost of existing work more accurately and to introduce a waiver of fees to support Government policy on licensing of paediatric medicines.

5. Extent

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

6. European Convention on Human Rights

6.1 Not applicable.

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. It also ensures safety, quality and efficacy of medical devices. The Regulations referred to in this explanatory memorandum only affect the medicines regulation part of the Agency's work.

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 MHRA monitor and review the level fees annually. This is in line with Treasury guidance on Fees and Charges. This instrument introduces new fees for areas of work not previously charged for and adjusts existing fee levels so that they reflect the cost of work undertaken.

7.5. MHRA is required to consult the pharmaceutical industry and other interested parties before making any amendments to the fees structure. Around 1,700 copies of the consultation letter were issued on 20 December 2004 to licence holders, industry associations and other interested parties. The consultation letter was also posted on the MHRA's website. The consultation period ended on 11 March 2005 and a total of 25 replies were received. A brief analysis of the consultation is included in the Regulatory Impact Assessment and a more detailed analysis on the MHRA website.

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

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