EXPLANATORY MEMORANDUM TO

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

2012 No. 2546

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 amends the Medicines (Products for Human Use) (Fees) Regulations 2012 (S.I. 2012/504) It updates certain cross-references to Regulation (EC) 1234/2008 which is being amended from 2nd November 2012 by Regulation (EC) 712/2012. The instrument also amends a provision in relation to periodic fees to clarify that that provision is qualified by a provision in Schedule 4. These amendments are necessary to ensure that the MHRA may continue charging fees for variations of marketing authorisations on the same basis when the amendments to Regulation (EC) 1234/2008 come into force in November 2012 and to clarify the periodic fee provisions.

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

3.1 The MHRA does not receive any central funding for the medicines element of its work. This is fully funded by fees paid by the industry. The MHRA is a Government Trading Fund and the Agency must therefore ensure that its income is sufficient, taking one year with another, to meet its expenditure.

3.2 The instrument amends specific cross references in the Fees Regulations that are consequential to the amendment of Regulation (EC) 1234/2008 by Regulation (EC) 712/2012. The instrument will help ensure that the MHRA can continue to charge appropriate fees for the grouped variations of marketing authorisations provided for in the amended Regulation (EC) 1234/2008. No changes are required to fee categories or levels.

3.3 In its memorandum to the Department of Health in relation to the Medicines (Products for Human Use) (Fees) Regulations 2012 (S.I. 2012/504), the Joint Committee on Statutory Instruments raised the point that the sole provision in Part 4 of Schedule 4 to that instrument appeared to qualify regulation 33(1) but that Part was not introduced by a provision of a regulation, by which regulation 33(1) is expressed to be qualified. In its response to the memorandum, the Department of Health agreed with the Committee and in accordance with its undertaking to amend the Regulations at the next practicable opportunity, the Department makes a suitable amendment to regulation 33(1) in this instrument.

4. Legislative Context

4.1 This instrument amends the Medicines (Products for Human Use) (Fees) Regulations 2012 to update specific cross references to Regulation (EC) 1234/2008 as amended by Regulation (EC) 712/2012.

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

- *What is being done and why*

7.1 Regulation 20 of the Medicines (Products for Human Use) (Fees) Regulations 2012 provides that holders of a marketing authorisation for medicinal products may make applications for multiple variations to the authorisation on the payment of a fee to the MHRA. Some types of fees for variations are identified by reference to their descriptions under Article 7(2) of Regulation (EC) 1234/2008

7.2 From 2nd November 2012, Regulation (EC) 1234/2008 is being amended so that the relevant multiple variation provisions are provided for in sub-paragraphs (a) to (c) of Article 7(2) instead of sub-paragraph (a) and (b) only. This effect of this change needs to be incorporated into the Medicines (Products for Human Use) (Fees) Regulations 2012 by way of an amendment to regulation 20 so that the MHRA can maintain the fees for such applications on the existing basis once amendments to Regulation (EC) 1234/2008 come into force in November 2012. There is no change to the types of authorisations to which such fees would apply or to the amount of fee payable.

7.3 Without the amendments to the Medicines (Products for Human Use) (Fees) Regulations 2012 the MHRA will not be able to charge a fee for some types of variation applications after 2nd November 2012.

7.4 Regulation 33 provides for periodic fees to be payable in relation to Authorizations, Registrations, Licences and Authorisations relating to medicinal products. The amendment to Regulation 33(1) corrects a minor technical issue in the wording so that Part 4 of Schedule 4, by which the regulation is qualified, is introduced in that regulation. There is no change to the policy on the purpose of this provision.

- *Consolidation*

7.5 The amendments made by this instrument will be consolidated in a new set of the Medicines (Products for Human Use) (Fees) Regulations that are expected to be made in 2013.

8. Consultation Outcome

8.1 A shortened 4 week public consultation exercise was carried out (with Ministerial agreement). Two meetings were held with industry associations where the changes were explained and the consultation document was placed on the Agency's website. No responses were received to the consultation.

8.2 The amendment to regulation 33 is a minor and technical amendment and the Ministers considered that no interests were substantially affected by this amendment.

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 not been prepared for this instrument as there are no new costs on business, charities, voluntary sector or public sector.

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 generally considers further assistance and targets small businesses in its consultation process each year. However, reducing fees below the 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 charges by the MHRA are reviewed annually.

13. Contact

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