EXPLANATORY MEMORANDUM TO

THE MEDICINES (PRODUCTS FOR HUMAN USE) (FEES) REGULATIONS 2013

2013 No. 532

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 medicinal products for human use.

2.2 The instrument increase all fees, introduce some new fees, simplify the structure of other fees and make other amendments consequential to the implementation of the Human Medicines Regulations 2012 as described in more detail below.

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

3.1 It is proposed that fees are increased by 2.8 % and periodic fees increased by a further 5% to ensure that the Agency can recover its costs and carry out its full range of responsibilities for public health protection.

3.2 The fee increases in this instrument need to be set against a background of efficiency saving that the Agency has achieved over the last few years by working more closely with the pharmaceutical industry. On average, over the last three years, there has been a minus 2% per annum reduction in fee levels, after the effect of simplification measures and removals of certain fees are excluded. The compound inflation figure over the same period is 13%.

3.3 New EU legislation, strengthening post-marketing surveillance of medicines, came into force in July 2012. This legislation requires the European Medicines Agency and member States to do more work on monitoring the safety of medicines. The European Medicines Agency (EMA) will in the future charge industry for some of these activities and reimburse Member States for the work they have done. This fee regime is currently not yet in place and in the meantime the MHRA is raising its periodic fees to fund both the new and the ongoing activities required by legislation.

4. Legislative Context

4.1 This instrument revokes and re-enacts in consolidated form the Medicines (Products for Human Use) (Fees) Regulations 2012 (S.I. 2012 No. 504); the Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2012 (S.I. 2012 No. 2546). This instrument also amends the Medicines for Human Use (Clinical

Trials) Regulations 2004 (S.I. 2004 No. 1031 as amended). The following redundant legislation is revoked:

- the Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1998 (S.I. 1998 No. 574).
- the Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1999 (S.I. 1999 No. 566)
- the Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 2000 (S.I. 2000 No. 592)
- the Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2003 (S.I. 2003 No. 625)
- Medicines for Human Use (Fees Amendments) Regulations 2006 (S.I. 2006 No. 2125)
- Medicines (Products for Human Use) (Amendments relating to Fees for Variations) Regulations 2009 (S.I. 2009 No. 3222).

4.2 The instrument is being made to increase medicines fees levels to ensure full cost recovery for the work MHRA carries out to fulfil its public health responsibilities. The instrument also simplifies the number of fees for clinical trials, provides a reduction in the fee price for new manufacturers of simple substances also serving as active pharmaceutical ingredients and introduces a standalone inspection of service providers providing pharmacovigilance services to Marketing Authorisation Holders.

4.3 Directive 2011/62/EU of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use will require Regulations to be made in relation to the regulation of brokers of medicinal products and importers, manufacturers and distributors of active substances. This instrument provides for new fees to apply in relation to these activities from the coming into force of Regulations (expected to be in spring 2013) made to transpose Directive 2011/62/EU under section 2(2) of the European Communities Act 1972.

4.4 The instrument also makes consequential amendments to the fees provisions that are necessary to correctly reflect the consolidation of earlier medicines legislation into the Human Medicines Regulations 2012.

5. Territorial Extent and Application

5.1 The Regulations apply 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 The MHRA is a Government Agency responsible for, amongst other things, the regulation of medicinal products for human use. 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. The MHRA reviews its fees and costs each year to ensure that charges reflect an efficient use of its resources and operational expenditure.

7.2 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 new licence applications), some are charged for each time an activity takes place (e.g. fees for variations to existing licences) and others are charged annually (i.e. 'periodic') fees that are intended to cover the costs of activities such as ongoing drug safety, monitoring and enforcement. These fees can only be amended through secondary legislation.

7.3 This instrument sets out fees payable by the pharmaceutical industry in relation to services provided and regulatory functions carried out by the MHRA in relation to medicines. The instrument applies an increase of 2.8% to all medicines fees and a further 5% increase on the annual 'periodic' fees. These increases are necessary to ensure that the fees imposed on the industry reflect the costs to the MHRA in carrying out their regulatory functions while maintaining fee income at levels consistent with Government guidelines.

7.4 The fee increases are designed to:

- reflect the correct cost of undertaking each area of work;
- cover essential unavoidable costs for the MHRA 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
- ensure that the MHRA can effectively carry out its responsibilities to safeguard public health.

7.5 The other main changes in this instrument are listed below.

- The fee structure for clinical trials has been simplified with the previous nine fee types reduced to three. In particular, the annual clinical trials fee and the fee for Phase IV notifications have been removed as these fees are no longer needed. A fee for protocol amendments has been introduced to reflect the cost to the MHRA in carrying out this work. These changes will still ensure full cost recovery of the costs but with a fee structure that is easier to administer.
- New fees are introduced for the inspection of pharmacovigilance service providers. Currently, such providers can be inspected multiple times as part of the inspections of Marketing Authorisation holders to whom they provide services. The new provisions will make the best use of resources and reduces the burden of inspection on both Marketing Authorisation holders and the service providers.
- New fees are introduced in relation to obligations under Directive 2011/62/EU. The fees relate to persons who broker medicinal products and those who import, manufacture or distribute active substances. The fees will cover the application process, any associated inspection, variation to registration details and the consideration of an annual compliance report by the MHRA. These fees are necessary for the MHRA to recover the costs of these new activities form when Regulations impose the new requirements (expected to be in spring 2013).

- The fee payable by new manufacturers of simple substances also serving as active pharmaceutical ingredients is being reduced. The reduction reflects the lower cost of assessing such simple substances.
- This instrument updates references to earlier medicines legislation that has been consolidated in the Human Medicines 2012.

- Consolidation

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

8. Consultation Outcome

8.1 Following Department of Health and Her Majesty's Treasury agreement to the proposals, a 6 week public consultation exercise was carried out (with Ministerial agreement). Two meetings were held with industry associations before the public consultation exercise to explain the changes.

8.2 In total, 12 responses to the consultation were received, representing a range of organisations manufacturers, importers and distributors and representative associations. Nearly all responding organisations accepted the general 2.8% increase in all medicines fees. However, a third of the respondents did not support the additional increase on periodic (annual) fees. Some respondents commented that the increases came after low or no increases in fees and acknowledged that it was important for the UK that the MHRA is adequately resourced.

8.3 The standalone pharmacovigilance inspections for service providers were welcomed, as were the reduced fees for certain listed, new sources of known Active Pharmaceutical Ingredients.

8.4 One response expressed strong concern at the level of the fees related to the implementation of Directive 2011/62/EU. In general the proposal to simplify Clinical Trial fees was supported but one respondent expressed concern that the changes would make it more difficult to cost a trial and there could be increased costs for trials of short duration.

8.5 In response, the MHRA has reviewed the list of simple substances also serving as Active Pharmaceutical Ingredients, and added eighteen further substances, including sodium chloride, and removed four others.

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 The main impact on business, charities or voluntary bodies is that the fees they pay to the MHRA related to medicines regulation (for example, for medicines licence applications, scientific advice meetings or clinical trials applications) will increase by 2.8%, with periodic (annual) service fees increasing by a further 5%. The changes to fees mainly affect the private sector, and in particular the pharmaceutical industry. Some business organisations will become subject to fees under the Regulations for the first time as a result of the implementation of the Directive 2011/62/EU.

10.2 Similarly, increases in medicines fees will impact those public sector bodies, such as some NHS bodies and academic research bodies, who pay fees related to medicines legislation (such as those bodies involved in clinical trials).

10.3 An Impact Assessment has not been prepared for this instrument.

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 lower periodic fees for products with low turnover and extended terms of payment of a number of capital fees. 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.

11.2 During the consultation, the MHRA asked two specific questions related to small businesses – firstly, whether the proposed fee increases would have any impact on barriers to market entry or the structure of competition; secondly, whether the numbers of small businesses on the MHRA's records presented an accurate picture of the actual number who could come into contact with MHRA. Of those affected by the increase in fee levels, an eighth said that they felt the increases would have a negative impact on small businesses and the costs would either be passed to consumers or the products removed from the market.

12. Monitoring & review

12.1 The level and structure of medicines fees charged by the MHRA are reviewed annually.

13. Contact

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