EXPLANATORY MEMORANDUM TO

THE MEDICINES (PRODUCTS FOR HUMAN USE) (FEES) REGULATIONS 2016

2016 No. 190

1. Introduction

1.1 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.

1.2 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 (which includes traders of pharmaceutical products where this is not their primary function) in relation to services provided, and regulatory functions carried out, by MHRA in relation to medicinal products for human use.

2.2 The instrument decreases a wide range of fees in line with reduced costs of providing these services and introduces new fees for registration with the EU Falsified Medicines Directive (FMD) common logo scheme, as described in more detail below.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 It is proposed that various fees are decreased by between 5% and 15% to ensure that MHRA brings its fee recovery better into line with the cost of providing its services (as required by the terms of its Trading Fund status, Recommendation 2 of MHRA's recent Triennial Review[1] and HM Treasury guidance on management of public money), whilst continuing to carry out its full range of responsibilities for public health protection.

3.2 The fee decreases in this instrument are set against a background of efficiency savings that MHRA has achieved over the last few years, such as recent reductions in head count (125 posts or 14% over 3 years from 2014) and accommodation costs (33% over the same period. MHRA is also currently replacing its IT systems, which will modernise how it interacts with industry and reduce overall costs.

3.3 Since 1 July 2015, in accordance with EU Directive 2011/62/EU (the Falsified Medicines Directive), MHRA has operated a statutory common logo scheme for UK-based online sellers of human medicines to the public. The MHRA scheme is a direct transposition of the EU Directive, without gold plating, and makes it easier for potential consumers to check whether websites selling medicines are operated by legal suppliers. MHRA is introducing new fees to recover the costs of operating this scheme.

[1] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/447306/MHRA_Triennial_Review_Report.pdf

3.4 Total costs for the first year are estimated to be approximately £0.4m based on an anticipated volume (traders who will apply) of approximately 4000. MHRA is aiming to keep costs (and therefore fees) as low as possible, including through the avoidance of gold plating.

3.5 To recover the cost of the scheme, MHRA is introducing an application fee of £100 and an on-going annual service fee of £97 payable by 1 April every year. In addition, there will be a £100 supplement in the first year only for online sellers who registered before 1 April 2016 and did not pay an application fee. These figures have been set to recover the estimated costs and no more. The consultation sought further evidence of likely volumes, with a view to revising the fees if necessary based on any additional data, however no further data was received. The fee levels will be reviewed annually to ensure they continue to represent a fair reflection of the cost of operating the scheme.

Other matters of interest to the House of Commons

3.6 As this instrument is subject to a negative resolution procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons do not arise at this stage.

4. Legislative Context

4.1 This instrument revokes and re-enacts in consolidated form the Medicines (Products for Human Use) (Fees) Regulations 2013 (S.I. 2013 No. 532). This instrument also amends the Human Medicines Regulation 2012 (S.I. 2012 No. 1916), the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004 No. 1031) and the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 (S.I. 1995 No. 449).

4.2 The instrument is being made to decrease medicines fees levels to realign income and costs.

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 required regulations to be made in relation to the regulation of online sellers of medicinal products. This instrument provides for new fees to apply in relation to these activities.

5. Extent and Territorial Application

5.1 This instrument extends to all of the United Kingdom.

5.2 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 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 MHRA is responsible for, amongst other things, the regulation of human medicines. MHRA is a Government Trading Fund and operates on a full cost recovery basis.

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

7.2 MHRA charges a variety 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 on-going drug safety, monitoring and enforcement. These fees can 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 MHRA in relation to medicines. The instrument applies a decrease of between 10% and 15% to the majority of medicines fees and a further 5% decrease on annual 'periodic' fees. These decreases are necessary to ensure that the fees imposed on the industry reflect the costs to MHRA in carrying out their regulatory functions while maintaining fee income at levels consistent with Government guidelines.

7.4 In summary, MHRA will decrease all Marketing Authorisation and Variation applications by 10% with the exception of:

- Decentralised RMS (Reference Member State) fees which will reduce by 15%;
- Periodic Fees which will reduce by 5%;
- The New Active Substance fee which will reduce to the same level as the Complex fee.

7.5 Fees relating to an application for a manufacturer's licence, a manufacturing authorisation or wholesale dealer's licence or applications for variations to such licences or authorisations and associated inspections remain the same. Similarly, fees for registration for brokering human medicine or manufacturing, importing or distributing active substances or associated inspections or compliance report have not changed. Fees for matters relating to issuing Export Certificates also have not changed.

7.6 The other main change in this instrument is the introduction of new fees in relation to obligations under Directive 2011/62/EU (the Falsified Medicines Directive). The fees apply to persons who trade medicinal products online and will cover registration with the FMD logo and verification scheme and annual maintenance charges. There are some online sellers who have already registered since the scheme became operational on 1 July 2015 and will not have paid an initial registration fee since legislation was not in place. For these sellers a one off supplement of £100 will be added to the first year's periodic fee to balance this. These fees are necessary for MHRA to recover the costs of these new activities.

8. Consultation outcome

8.1 Following Department of Health and Her Majesty's Treasury agreement to the proposals, a four week public consultation exercise was carried out (with Ministerial agreement). Industry associations were fully updated at the MHRA's regular Medicines Industry Liaison Group meetings before the public consultation exercise to explain the changes. Industry's feedback was that the maintenance of quality and service levels were of greater importance than cost savings and they wanted to see MHRA adequately resourced for this. Subject to that, the fee reductions were welcome.

8.2 In total, 10 responses to the consultation were received, representing a range of organisations manufacturers, importers and distributors and representative associations. Nearly all responding organisations welcomed the general 5 to 15% decrease in medicines fees and most had no comment on the proposed FMD common logo fees. However, two respondents did raise objections to the proposed FMD common logo fees, citing the cheaper, voluntary, General Pharmaceutical Council scheme. They also opposed the full FMD common logo fee being charged to community pharmacies due to upcoming economic pressures. However this was balanced by two other respondents who said that they would be happy with the proposed fees.

8.3 In response, MHRA advised that this is a harmonisation measure laid down in EU Directive 2001/83 (as amended) with the common logo designed to be recognisable throughout the EU. As such the Directive does not allow private registration schemes such as the GPhC scheme to be used in place of the EU common logo. However, companies are able to use voluntary online logos in addition to the mandatory FMD common logo if they wish.

8.4 MHRA aims to charge businesses fees equal to the cost of services they have received. In line with Managing Public Money principles MHRA will not require businesses or the taxpayer to subsidise the cost of the logo for another business. MHRA will therefore be maintaining one fee for all online sellers.

8.5 No additional information was provided to inform further the volumes assumptions for the FMD common logo. Therefore MHRA is proceeding with the fees set out at consultation.

9. Guidance

9.1 Guidance and information regarding fees payable by the pharmaceutical industry can be found on the MHRA website at:
https://www.gov.uk/government/publications/mhra-fees

10. Impact

10.1 The main impact on business, charities or voluntary bodies is that the fees they pay to MHRA related to medicines regulation (for example, for medicines licence applications, scientific advice meetings or clinical trials applications) will decrease by between 10% and 15%, with periodic (annual) service fees decreasing by 5%. The changes to fees mainly affect the private sector, and in particular the pharmaceutical industry, which will see a total saving of approximately £5m per year. Subject to quality and service levels being maintained, this aspect has been seen as a positive impact on businesses. Some business organisations (online sellers) will become subject to fees under the Regulations for the first time as a result of the implementation of the Directive 2011/62/EU. This will inevitably be seen as a negative impact by some, although the consultation has shown that this has been well balanced by businesses that either accept or welcome it and the fees have been set at the minimum possible level, with no gold plating of the scheme.

10.2 Similarly, decreases 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 (for example, those bodies involved in clinical trials).

10.3 Impact Assessments are submitted with this memorandum and will be published alongside the Explanatory Memorandum on the legislation.gov.uk website.

11. Regulating small business

11.1 The legislation applies to activities that are undertaken by 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 reduction in existing fees is likely to be beneficial to all businesses, including small ones. The new FMD common logo fees are likely to have a greater impact on small or micro businesses with very low turnovers or profit margins. Every effort has been made to assess the volumes and calculate the costs as accurately as possible and to charge the minimum fee necessary to recover the actual cost of the scheme. Reduced fees below costs incurred would lead to cross-subsidisation from increased fees paid by other companies, so it is not possible to offer general fee reductions for smaller companies. Whilst MHRA operates a number of provisions to assist smaller companies in some areas, such as lower periodic fees for products with low turnover and extended terms of payment of a number of capital fees, given the low level of the new fees, such provisions are not appropriate for the FMD common logo scheme.

12. Monitoring & review

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

13. Contact

13.1 Caroline Robson Singh at MHRA (Tel: 020 3080 6299 or e-mail: caroline.singh@mhra.gsi.gov.uk).