EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (FEES AMENDMENT) REGULATIONS 2013

2013 No. 525

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 regulations which set out fees payable by the medical devices industry in relation to services provided by, and regulatory functions carried out by the MHRA in relation to medical devices on the UK market. It increases only some of the fees payable (i.e. fees for Clinical Investigation Notifications); the overall effect is to increase fees by about £52000 overall per annum.

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

3.1 Nearly all the costs relating to medical devices regulation work carried out by the MHRA as Competent Authority for the UK is publicly funded through a Service Level Agreement with DH. However, a small proportion of its funding comes from fees charged for specific areas of statutory work. The MHRA is a Government Trading Fund and the Agency must ensure that its income is sufficient, taking one year with another, to meet its expenditure. The MHRA recovers some of its costs for it's medical devices activity. However it cannot be cross-subsidised for this or any of its other statutory functions by other income the Agency receives in relation to medicines regulation.

3.2 The fee increases in this instrument are made in order to ensure that the fees charged for each area of activity properly reflect the cost of that activity. The Agency also charges for registration of some medical device manufacturers and for Notified Body activity but as these fees continue to cover their costs no increase is proposed.

3.3 The Agency undertakes a robust assessment of its fees and costs each year.

4. Legislative Context

4.1 This instrument amends the Medical Devices Regulations 2002 (SI 2002 No 618 as amended) which is the subject of this Explanatory Memorandum.

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 The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health. It carries out the functions of the Secretary of State, acting as the Competent Authority in relation to the regulation of medical devices. This instrument affects some of the medical devices functions of the Agency.

7.2 The costs for the work relating to medical devices regulation undertaken by the Agency are mostly met by funding from the Department of Health. In addition, by virtue of the Government Trading Funds Act 1973, the MHRA has an obligation to at least break even taking one year with another and to set fee levels (where fees can be charged for work undertaken) to achieve this.

7.3 The fees charged by the MHRA are monitored and reviewed annually to ensure, as far as possible, that the fees charged for a particular service, reflect the cost of the work undertaken. This is in line with Treasury guidance on Fees and Charges. This instrument amends the level of some fees charged by MHRA for work in connection with Clinical Investigation notifications to ensure that the full cost of the work undertaken is recovered.

7.4 The cost of compliance associated with this instrument is estimated to be around £52,000 per annum. There are no associated recurring or non-recurring costs for those affected. The total estimated income for MHRA for medical device related work in 2013/2014, taking into account the increased fees and anticipated volumes, is expected to be around £400000.

- Consolidation

7.5 The MHRA has no current proposals to consolidate any of the regulations amended by this instrument, although it continues to keep the matter under review.

8. Consultation outcome

8.1 All relevant trade associations and all companies who had notified medical device clinical investigations to the Agency during the last three years have been consulted during a 4 week period on the proposals to increase these fees (about 190 contacts). There were no specific responses covering these fee increases.

9. Guidance

9.1 This is a straight forward increase to fees and therefore guidance is not considered to be necessary.

10. Impact

10.1 The impact on business, charities or voluntary bodies mainly affects the medical device sector in relation to medical devices. However these effects are considered minimal.

10.2 The impact on the public sector is minimal.

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

11. Regulating small business

The legislation applies to small business. However when compared to the total development costs for a new medical device the impact of these fee increases are considered to be minimal.

12. Monitoring & review

12.1 The fees charged by MHRA are reviewed annually.

13. Contact

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