EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (FEES AMENDMENT) REGULATIONS 2017

2017 No. 207

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 The purpose of the instrument is to increase the fees charged by the Secretary of State (acting by the Medicines and Healthcare products Regulatory Agency) in relation to the regulation of medical devices; and to introduce new fees in respect of new regulatory work the Secretary of State is carrying out in relation to medical devices.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The increases in fees are above the rate of inflation and are explained in paragraph 7.4

Other matters of interest to the House of Commons

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

4. Legislative Context

4.1 Medical devices are the subject of three European Directives which set out a scheme for regulating the placing on the market and putting into service of medical devices. The three Directive are:

- Directive 90/385/EEC on active implantable medical devices (AIMDD);
- Directive 93/42/EEC on medical devices (MDD); and
- Directive 98/79/EC on in vitro diagnostic medical devices (IVDD).

4.2 Those Directives are transposed into UK law by the Medical Devices Regulation 2002 (as amended) (the 2002 Regulations) and confer the functions of the Member State and the national competent authority under the Directives on the Secretary of State in relation to the UK .

4.3 Part VI of the 2002 Regulations make provision for the Secretary of State to charge fees to cover the cost of the work he carries out under the 2002 Regulations.

4.4 A new EU Medical Device Regulation and new EU IVD Regulation (which will replace the existing three Directives) are expected to be adopted in early 2017. However, these new EU Regulations will not apply fully until 2020 earliest and the three Directives together with 2002 Regulations will remain in force until then.

5. Extent and Territorial Application

5.1 This instrument extends to the whole of the UK.

5.2 This instrument applies to the whole of the UK.

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 The MHRA carries out the functions of the competent authority under EU medical devices legislation on behalf of the Secretary of State. Under the terms of its status of a Government Trading Fund, the MHRA should seek to recover in full the costs of its regulatory activities, including activities undertaken under the Medical Devices Directive, through charging fees.

7.2 The MHRA currently charges for:

7.2.1 Regulating Notified Bodies. A Notified Body is a conformity assessment body that licenses medical devices. Notified Bodies are quality assessed and given the right to operate ("designated") and audited by the MHRA. Fees are charged for this work.

7.2.2 Assessing clinical investigations. Proposals to trial new medical devices are quality assessed and authorised by the MHRA. The clinical investigation is intended to yield clinical data to support the eventual marketing (CE marking) of the medical device.

7.2.3 Registration of Class 1 medical devices, custom made devices and in vitro diagnostic medical devices with a competent authority (the MHRA in the UK), which provides them with a CE mark. (Class1 is the lowest risk category of medical device).

7.3 The costs incurred by the MHRA in doing the work for which it currently charges fees are more than the amount of those fees. MHRA has consulted on proposals to increase and modify its fees for three industry activities in order to collect an additional £221,000 annually towards the cost of their administration

7.4 The current fees do not cover the cost of MHRA work because:

7.4.1 When the current fees for auditing Notified Bodies were set in 2010 not all of the costs for full cost recovery were included, in particular the cost of audit preparation work.

7.4.2 EU Implementing Regulation (920/2013) and EU Recommendation (473/2013) have introduced new requirements for additional scrutiny of Notified Bodies, which have increased audit work content and added new re-designation work.

7.4.3 The MHRA fees for the registration of Class 1 medical devices, custom made devices and in vitro diagnostic medical devices were set in 2010. They have been fundamentally reviewed to ensure that they meet the rules of full cost recovery as far as possible. The result indicates that this was not the case with the 2010 fee. The proposed fee anticipates a reduction in cost later in the year due to the introduction of a new digitised system.

7.4.4 Fees are charged for assessing clinical investigations, but not for the amendment of studies after they have been submitted; these are increasing in volume and generating additional work.

Consolidation

7.5 There are no plans to produce a consolidated SI at present.

8. Consultation outcome

8.1 MHRA regularly meets with industry trade bodies and Notified Bodies and had discussed these proposals prior to the consultation. No objection was raised by trade bodies or by Notified Bodies in these informal discussions.

8.2 Industry trade bodies and the Notified Bodies were consulted from 24th November 2016 to 13th January 2017. This period was considered appropriate in light of the previous discussions that had taken place.

8.3 The MHRA received 10 responses to its consultation.

8.4 The respondents were made up of:

2 distributors

5 manufacturers

3 trade associations – covering 555 members

8.5 To put the number of responses in context, the MHRA estimate that there are 8200 companies manufacturing or distributing medical devices in the UK.

8.6 None of the UK's five Notified Bodies responded, but their fee increases had been discussed in meetings with the MHRA prior to the formal consultation.

8.7 There were 5 consultation questions:

8.7.1 We have assumed that there will be no market impacts from these fees. This means we expect no change in the supply of, or demand for, medical devices. Do you agree or disagree? Please provide evidence where possible.

6 agreed, 1 did not agree.

8.7.2 We have assumed that there are no additional familiarisation costs or administration costs, as fees are already charged in the areas concerned. Do you agree or disagree? Please provide evidence where possible.

5 agreed, 1 did not agree.

8.7.3 Please provide any relevant comments and evidence on the impact of these fee adjustments.

2 said the changes were relatively small, 2 were concerned that the increases were being introduced at a time of other commercial pressures

8.7.4 Please provide any additional information on the impact of the fee adjustment on small and micro businesses (1-49 employees)

2 said the changes were modest, 3 were concerned at the impact of the Notified Body increases being passed on to them as their clients

8.7.5 Do you have any other comments on the fee changes?

3 said the increases were fair, 2 were concerned at the Notified Body ***increases being*** passed on to them as their clients, 2 referred to other potential increases in cost unrelated to this proposal

8.8 MHRA's proposal is in line with Government's policy as articulated in the recent Regulatory Futures Review that the presumption should always be that the regulated bear the cost of regulation.

8.9 MHRA proposals are to recover fully our costs in these fee areas, removing subsidy from DH

8.10 Fees collected in these areas are expected to increase from £251k to £462k p.a. A very small increase to an industry that we estimate turns over £12.8 billion in this country

8.11 None of the consultation responses provided any new evidence or identified any new issues

8.12 The majority of respondents were content with the fee changes proposed. We have noted the concern over increasing costs, and to minimise the burden on businesses MHRA will review its fees regularly to ensure they are set as low as possible, whilst still covering the cost to the MHRA of regulation. This approach is intended to make sure that the government neither profits at the expense of consumers or industry, nor makes a loss for taxpayers to subsidise.

9. Guidance

9.1 The fee increases and amendments will be communicated through the regular meetings with trade Bodies and the Notified Bodies, communication through the trade Bodies to their membership, and targeted communication to service users. The new prices will also be published on the MHRA website.

10. Impact

10.1 The impact on business, charities or voluntary bodies is £0.2million equivalent annual net direct cost to business.

10.2 The impact on the public sector is a benefit of £0.2 million as the costs are currently being subsidised by the Department of Health

10.3 An Impact Assessment is submitted with this memorandum and is 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 businesses if they amend clinical investigations or register Class 1 medical devices with MHRA. None of the five UK Notified Bodies are small businesses, therefore the notified body fee changes do not apply directly to small businesses.

11.2 To minimise the burden on businesses, MHRA will review its fees regularly to ensure they are set as low as possible, whilst still covering the cost to the MHRA of regulation. This approach is intended to make sure that the government neither profits at the expense of consumers or industry, nor makes a loss for taxpayers to subsidise. However no specific action is proposed to minimise regulatory burdens on small businesses Small businesses have been paying for clinical investigations and for the

registration of Class 1 medical devices for many years for the same prices as larger businesses.

12. Monitoring & review

12.1 The MHRA will monitor these fees annually and adjust them to provide full cost recovery; no more, no less.

13. Contact

13.1 Richard Branson at the MHRA Telephone: 0203 080 6086 or email: Richard.Branson@mhra.gsi.gov.uk can answer any queries regarding the instrument.