Regulatory Triage Assessment

Title of measure	Increasing fees for medical devices regulation
Lead Department/Agency	Medicines and Healthcare Products Regulatory Agency
Expected date of implementation	April 2017
Origin	Domestic
Date	17/08/16
Lead Departmental Contact	Richard.Branson@mhra.gsi.gov.uk
Departmental Triage Assessment	Low-cost regulation (fast track)

Rationale for intervention and intended effects

The MHRA's current fees for:

- Auditing and designating notified bodies
- Registering class 1 medical devices, custom made devices and in vitro diagnostic medical devices.
- Clinical investigations

do not recover fully the MHRA's costs of providing them. The shortfall is being subsidised by the Department of Health (DH). The objective is to fully fund these regulatory activities through fees.

Viable policy options (including alternatives to regulation)

1. Do nothing. Under-recovery is subsidised by DH while there are pressures to reduce DH funding.

2. Raise fees to recover the cost of regulatory work.

Initial assessment of impact on business

This policy transfers the cost of regulatory activity away from the tax payer on to the medical device industry being regulated.

This policy will save the tax payer, and cost industry, £221k per year.

This give an EANDCB in 2014 prices, 2015 present value of £0.2m

This gives a net present value of £0

BIT status/score

This proposal is to amend the funding of regulatory work, but not the regulatory regime and so is out of scope of OITO. This has been confirmed by the RPC.

Rationale for Triage rating

This is a low cost measure.

Departmental signoff (*SCS*): Date:

Economist signoff (*senior analyst*): Peter Benett Date: 5/9/2016

Better Regulation Unit signoff: Frank Brown Date: 25/08/2016

1. Problem under consideration

a. The MHRA carries out the functions of the competent authority under EU medical devices legislation on behalf of the Secretary of State. The broad nature and legal underpinning of this work is summarised in Appendix 1.

b. The MHRA currently charges fees for:

- Regulating notified bodies:

  Notified bodies license 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.

- 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.

- Registration of Class 1 medical devices, custom made devices and in vitro diagnostic medical devices:

  Devices are registered with a competent authority, which provides them with a CE mark.

however, the costs in these areas are not being fully recovered:

i. The fees for auditing notified bodies have not increased since 2010. They neither cover the full audit cost nor the cost of audit preparation work.
ii. Implementing Regulation (920/2013) and recommendation (473/2013) have introduced requirements for additional scrutiny of Notified Bodies, which have increased workload.
iii. There is no fee in place in UK for the re-designation audits of Notified Bodies. These audits were introduced under Implementing Regulation (920/2013)
iv. The fees for the registration of class 1 medical devices, custom made devices and in vitro diagnostic medical devices have not increased since 2010 and do not cover the full cost.
v. Fees are charged for clinical investigations, but not for the amendment of studies after they have been submitted, which is generating additional work.

c. There are pressures for DH funding to be reduced.

d. This proposal is to amend the funding of regulatory work, but not the regulatory regime and so is out of scope of the business impact target. This has been confirmed by the RPC.

2. Rationale for intervention;

MHRA seeks to set charges to recover costs. 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.

3. Policy objective;

To recover all costs of providing services to industry.

4. Description of options considered (including do nothing);

a. **Preferred Option:** Introduce the following amendments to fees:

	Current fee	Proposed fee	Volume 2015/16	Number of companies expected to pay	MHRA annual income from current fees	MHRA annual income from proposed fees
NOTIFIED BODIES				There are 5 notified bodies in UK. Designation audits are only carried out for new market entrants Audits are carried out annually or more in special circumstances. Re-designation audits take place every five years	**£172,250**	**£333,057**
Designation Applications:						
Initial application for designation	£3,840	£8,252	1			
Re-application to address ground for rejection of a previous application	£960	£2,063				
Application for extension to scope	£1,880	£6,504	4			
Audits:						
Initial designation audit	£4,760	£15,904	1			
Surveillance	£3,840 to £7,670	£10,160	5			
Witnessed Audit	£3,840	£4,404	10			
Re-designation applications:						
Re-designation application fee	£0	£8,252	2			
Re-designation audit	£0	£15,904	2			
Follow up Audit - Major Closure	£0	£3,876	2			
Follow up Audit - Special Clinical	£0	£2,586	2			
Follow up Audit - Process Specific	£0	£3,876	2			
TSE Applications UK notified bodies	£0	£532	5			
In addition to each of the above, fees for time spent on audit and travel:						
half day rate for auditing	£271	£361.20	268			
Hourly rate for travel	£75.24	£90.30	217			
Accomodation, travel, subsistence and out of pocket expenses	Charged at cost					
REGISTRATION OF CLASS 1, CUSTOM and IVD MEDICAL DEVICES	**Current fee**	**Proposed fee**		Av. 620 registrations per year and 360 amendments across 804	**£68,600**	**£98,000**
Registration fee	£70	£100	620			
Registration change request	£70	£100	360			
CLINICAL INVESTIGATIONS	**Current fee**	**Proposed fee**		58 investigations per year across 57 companies.106 amendments to studies per year.	**£0**	**£30,870**
Clinical investigation: Class I, IIa, or IIb other than implantable or long-term invasive: Amendments to studies	£0	£207	34			
Clinical investigation: Class IIb implantable or long term invasive, Class III, and active implantable: Amendments to studies	£0	£331	72			
TOTAL					**£240,850**	**£461,927**

Under this option the £221k regulatory cost will be transferred from HMG to the Devices industry.

This give an EANDCB in 2014 prices, 2015 present value of £0.2m

This gives a net present value of £0

Pros

- Costs for notified body audits and designations, the registration of class 1, custom and IVD registrations, and amendments to clinical investigation studies will be recovered.
- DH shortfall subsidising will be avoided in these areas.

Cons

- Current government policy is opposed to increasing costs to business.

b. Do nothing

Pros:

- No increase in cost to industry

Cons:

- Costs for notified body audits and designations, the registration of class 1, custom and IVD registrations, and amendments to clinical investigation studies will not be fully recovered.
- Under-recovery is subsidised by DH while there are pressures to reduce DH funding.

5 Risks and assumptions

Assumptions:

- The market will be unaffected by fee.
- The amount of work on which each fee has been based is expected to remain constant in the short to medium term.
- Fees will be reviewed annually. This review will include the impact of the new medical device and IVD regulations over the next three to five years.
- We have assumed that there are no additional familiarisation or administration costs, as all businesses affected already pay fees.
- The current ways of working will continue, pending renegotiation of UK's relationship with the European Union

Assumptions will be tested during consultation.

Risks:

- Changes in ways of working may result from the renegotiation of the UK's relationship with the European Union. Fees will be reviewed and adjusted in line with the outcome of HMG negotiations on Europe.

6. Summary and preferred option with description of implementation plan.

a. The MHRA is seeking to recover an additional £221k per year to recover its costs on:

- Auditing and designating notified bodies
- Registering Class 1, custom made and IVD medical devices
- Amending clinical investigation studies

by changing its fees as set out in 4a.

b. The income from these fees would increase by £221k. This is currently subsidised by DH funding.

c. It is proposed that these changes will come into force in April 2017.

All key stakeholders and industry will be invited to participate and discuss proposals during consultation.

7. Specific Impact tests

a. Small and Micro Business Assessment

Notified Bodies

There are five notified bodies in the UK, none of which are small or micro.

Class 1, custom made and IVD Registrations

The fees for registrations have historically been the same for all organisations regardless of size.

We have estimated how many of the businesses impacted are small and micro by taking a sample of 60 and looking in to each one. We will test our findings at consultation.

We estimate that 58% of the 897 class 1 registrations and amendments in the last year were for small or microbusinesses.

Amendments to Clinical Investigation studies

The fees for clinical investigations have historically been the same for all organisations regardless of size.

We estimate that 13 of the 58 clinical investigations (22%) in the last year were for small or micro UK businesses. A further 5 were for UK

universities. The rest were for multinationals primarily domiciled outside of UK, predominantly the USA.

As the fee is small (£207 or £331) and for amendments to studies, it is not thought to have a disproportionate impact on small or micro businesses.

b. Equality test

The proposals are not thought to lead to any unlawful discrimination, harassment or victimisation of any particular group by gender, race, religion, ethnicity, sexuality, sexual orientation or disability.

c. Competition Test

The proposals are not thought to have an impact on competition

d. Sustainability Test

The proposals are not thought to have an impact on sustainability.

e. Environmental Test

The proposals are not thought to have an impact on the environment.

During the consultation we will test the assumptions around small and micro businesses and look to identify any relevant points that may not have been taken into account in this assessment. MHRA will endeavour to ensure communications are as clear as possible to support small and micro businesses.

Appendix 1: European legislation underpinning medical devices work

1. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for the oversight of medical devices regulation in the UK, the framework for which is set by European legislation.

2. Medical devices are regulated in the UK under a broader framework of regulation covering medical devices. Legislation in the UK (in the form of the Medical Devices Regulations 2002) stems from three main European Directives:
    a. Directive 90/385/EEC on active implantable medical devices (AIMDD);
    b. Directive 93/42/EEC on medical devices (MDD); and
    c. Directive 98/79/EC on *in vitro* diagnostic medical devices (IVDD).

    New Medical Device Regulations and new IVD Regulations are expected to enter into force in early 2017. The Medical Device Regulations will be implemented over a three year transition period and the IVD Regulations over five years.

3. Both the current and new legislation has a dual objective: firstly, to provide manufacturers with a single set of regulatory requirements that, once met, provide free and unhindered access to the EU market and secondly, to provide users of medical devices and patients a high level of confidence that devices, when used in accordance with the manufacturer's instructions, are acceptably safe and perform as claimed.

4. The Directives set out a list of essential requirements which all devices must meet before being placed on the market, as well as imposing various other regulatory requirements upon the manufacturer. The essential requirements concern matters such as the safety and performance of the device and the amount and type of information given to the user of the device by way of the label and instructions for use.

5. Under the MDD, devices are placed into four categories according to risk – classes I, IIa, IIb and III – where class I is the lowest and class III the highest risk. A manufacturer of class I devices can self-certify conformity with the essential requirements, whereas all other devices will require assessment by an independent third-party organisation, known as a Notified Body, of which there are around 80 across Europe. A manufacturer can select any Notified Body across Europe irrespective of location, provided that their field of expertise covers the device being considered.

6. There are various options set out within the Directives which a manufacturer may choose to demonstrate compliance with the essential requirements to a Notified Body, termed conformity assessment. These will involve, broadly, an assessment of the manufacturer's quality control systems, manufacturing processes, or individual testing of each device type. The aim is to match the level of control of the device – and thus the depth and challenge of the conformity assessment procedure adopted – to the perceived risk associated with the product.

7. Once a device has been demonstrated to meet the essential requirements, a manufacturer places a CE mark on the device and is free to place the device on the market in all EU countries without further controls.

8. The Directives are implemented and overseen by a competent authority in each EU Member State; in the UK this is the MHRA. Broadly speaking, the role of the competent authority is to implement the provisions of the Directives, to appoint and control Notified Bodies, to assess and authorise clinical investigations of

non-CE marked devices and to monitor and investigate adverse events and field safety corrective actions (including recalls) occurring in their country.