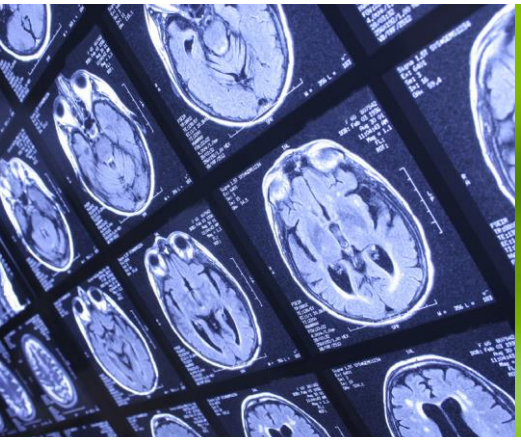
Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Consultation

Increases and additions to current medical devices fees



Consultation period: Six weeks excluding Christmas holidays

This information is also available on MHRA website

1. Summary of the Proposal

MHRA Devices charges fees for

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

These fees do not recover fully MHRA's costs of providing these services:

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. EU 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 the 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 authorising clinical investigations, but not for the amendment of studies after they have been submitted, which is generating additional work.

The shortfall is being subsidised by the Department of Health.

MHRA therefore proposes to increase and amend its fees for these activities in order to collect an additional £221K annually.

It is proposed that the new fees will come into force during the financial year commencing April 2017.

2. The purpose of this consultation and how to respond

Purpose

The purpose of this consultation is to test MHRA's assumptions on the impact of this proposal.

Timing

This consultation will run from 24th November 2016 to 13th January 2017.

The Principles of Consultation

The Civil Service Reform Plan commits the Government to improving policy making and implementation with a greater focus on robust evidence, transparency and engaging with key groups earlier in the process.

For details of the revised principles of engagement, please see http://www.cabinetoffice.gov.uk/sites/default/files/resources/Consultation-Principles.pdf

Regulatory Triage Assessment

MHRA's initial estimates of the impact of the fee changes are set out in a Regulatory Triage Assessment. This should be referred to alongside this consultation document. After the consultation a final assessment will be produced incorporating the information that has been gathered.

Confidentiality of Information

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

Please let us know if you would like any information you provide to be treated in confidence, and please indicate any commercial sensitivities. We will maintain that confidence and resist disclosure under the access to information regimes where possible and in compliance with our legal obligations. We will also consult you and seek your views before any information you provided is disclosed.

How to respond

Responses may be made by writing to:

richard.branson@mhra.gsi.gov.uk

Electronic responses are preferred, but if you wish to send responses by post, the address is:

Richard Branson,
4th Floor, Orange Area,
Devices Division, MHRA,
151 Buckingham Palace Road,
Victoria,
London, SW1W 9SZ.

The closing date for responses is 13th January 2017

Comments or complaints about the consultation

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

By post: Consultations Coordinator
Department of Health
3E48, Quarry House
Leeds
LS2 7UE

By e-mail: consultations.co-ordinator@dh.gsi.gov.uk
(Please do not send consultation responses to these addresses.)

3. The proposed increases and additions to fees

The table below details the changes being proposed:

	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. However the new Medical Device Regulations will lead to earlier re-designation.	**£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**

4. Consultation questions

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.
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.
3. Please provide any relevant comments and evidence on the impact of these fee adjustments.
4. Please provide any additional information on the impact of the fee adjustment on small and micro businesses (1-49 employees)
5. Do you have any other comments on the fee changes?

Your name:

Your organisation:

Are you a Business/Trade body/individual member of the public?:

What size business is your business?

Micro-business:	*10 or fewer employees*
Small business:	*11 - 49 employees*
Medium-sized business:	*50 - 249 employees*
Large business:	*250+ employees*

What type of business is your organisation? e.g. Manufacturer/Distributer/Notified Body: