Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Regulatory Triage Assessment

Title of regulatory proposal	Medicine fee changes
Lead Department/Agency	MHRA
Expected date of implementation	April 2016 SNR 5
Origin	Domestic
Date	12/08/15
Lead Departmental Contact	rose.geeson@mhra.gsi.gov.uk
Departmental Triage Assessment	Deregulation (fast track)

Rationale for intervention and intended effects

The MHRA charges a range of statutory fees for various types of licence applications among other activities. Managing public money's basic principle is to set charges to recover full costs. The MHRA needs to reduce its fees to align income and costs.

Viable policy options

1. Do nothing
2. Adjust fees to a level which is expected to achieve full cost recovery

Initial assessment of business impact

The MHRA currently has a customer base of approximately 4000. The fee reduction should save MHRA customers £5m per annum from 2016/17.

One-in, Two-out status

This measure does not alter the scope of current regulations; it merely reduces the fees within current regulations. Therefore it is out of scope.

Rationale for Triage rating

This is a deregulatory measure.

Departmental signoff (*SCS*):Patience Wilson Date: 13/08/2015

Economist signoff (*senior analyst*): Keith Derbyshire Date: 27/07/2015

Better Regulation Unit signoff: Frank Brown Date: 20/08/2015

Evidence Base

The Medicines and Healthcare Products Regulatory Agency (the Agency) is an Executive Agency of the Department of Health and a government trading fund, with a mission to protect and improve the health of millions of people every day through the effective regulation of medicines and devices, underpinned by science and research.

The Agency's regulatory centre (the MHRA) is responsible for the following in relation to its medicines statutory fees:

- Assessing the safety, quality and efficacy of medicines, and authorising their sale and supply in the UK
- Carrying out post-marketing surveillance of medicines, monitoring adverse reactions and taking action to safeguard public health
- Testing medicines to identify and address quality defects, monitoring the safety and quality of imported medicines, investigating internet sales and counterfeit medicines
- Ensuring compliance with UK and European standards through inspection
- Regulating clinical trials of medicines

A licence is required before any medicine can be used to treat people in the UK. This licence can be approved by the MHRA, or by the European Medicines Agency.

The policy issue and rationale for Government intervention

The MHRA charges a range of statutory fees for various types of licence application and variations to existing licences and also other activities such as those outlined above.

Managing public money's basic principle is to set charges to recover full costs. This approach is simply intended to make sure that the government neither profits at the expense of consumers or industry, nor makes a loss for taxpayers to subsidise.

The MHRA needs to reduce its fees to align income and costs.

Policy objectives and intended effects

- To set fees in line with guidance in *Managing Public Money* to allow full cost recovery.[1]
- To reduce the risk of generating surpluses in excess of those needed to fulfil the financial objective set by HM Treasury.
- To maintain fee stability for our customers over the medium to long term.
- To maintain our reputation as a fair, efficient and proportionate regulator.

Policy options considered

- Do nothing
- Adjust fees to a level which is expected to achieve full cost recovery

[1] Including the need to fulfil the financial objective set by HM Treasury to achieve a return, averaged over a five year period (1 April 2013 to 31 March 2018), of at least 3.5% in the form of surplus on ordinary activities before interest and dividends expressed as a percentage of average capital employed.

Expected level of business impact

The MHRA charges fees to those that use its services. This is mainly the pharmaceutical industry. The MHRA currently has a customer base of approximately 4000 of which approximately 20 claimed payment easements as Small and Medium Enterprises in 2014/15.

Business savings from lower fees
The MHRA has a good record of generating efficiencies. For example, the MHRA has recently downsized its headquarters in London and over the past few years has gained efficiencies in its licensing activity through economies of scale generated as a result of higher volumes of activity.

The Agency will be passing these efficiencies on to its customers in the form of fee reductions that should save its customers £5m per annum from 2016/17.

The fee changes are:

Product Licensing	-10%
Clinical Trials	-10%
Service Fees	-5%

Removing barriers to entry in the market
Lower fees will reduce the obstacles businesses have to overcome to produce medicines. Theoretically lowering fees and providing more stability long term could allow smaller companies to enter the market. We have no evidence to support this benefit; we will seek views at consultation.

Familiarisation costs
Businesses will check and pay fees regardless of this change. Therefore we do not expect any familiarisation costs.

OITO
This is a fee reduction of a current regulation, and the scope of the regulation is not changing, therefore this is “out of scope” of OITO.

RISKS

- HM Treasury’s *Managing Public Money* acknowledges that volumes of activity and costs are difficult to predict with certainty and that they may fluctuate causing accidental surpluses or deficits. The MHRA is no different and has made surpluses in previous years due to rapid growth in volumes of fee chargeable activity, with its last in-year deficit being in 2005/06. The MHRA has experienced a decline in volumes of fee chargeable activity since a peak in 2011 and is predicting further decline in volumes in 2016/17. There is a heightened risk that the new fee level will result in an accidental deficit, although there also remains the risk of an accidental surplus.

- There is a risk that we are increasing uncertainty for businesses by adjusting fees. Our customers have consistently said that they appreciate the quality of service we provide and would like it to be maintained and the majority see fees as secondary to the quality of service. By adjusting fees downwards the MHRA is increasing the risk that fees may have to increase in the following year if volumes and costs varied significantly from plans. Such fee volatility

has been avoided in recent years but if that happened it would make it more difficult for our customers to plan budgets.

- If the above risks occur, there is a risk of damage to the MHRA's reputation, and to the MHRA's relationships with its customers, who have a choice of international regulators to deal with when applying for licences for the EU market.