DRUG AND DEVICE BULLETIN

FEBRUARY 11, 2016

SHOOK
HARDY & BACON

NEW MHRA FEES FOR MARKET SURVEILLANCE IN THE UK – ANOTHER COST FOR THE MEDICAL DEVICE INDUSTRY?

As a result of continued reduction in government funding, the UK Medicines & Healthcare products Regulatory Agency (MHRA), recently indicated that it is seeking to recover an additional £8 million annually from the UK medical device industry to support its functions.

In 2016, those currently active in the UK device market are likely to see proposals for a range of increased fees, such as for auditing notified bodies, Class I registrations and clinical investigations. However, perhaps more controversially, the MHRA is also considering whether to introduce a new fee for its market surveillance activities.

Enforcement is the only activity for which the MHRA does not currently charge, so it is an obvious channel to explore. As such fees already exist with medicines in the UK (in the guise of charges per product licence), the approach already has some traction. The MHRA argues that it currently undertakes substantial work in monitoring the performance of devices, their compliance with EU regulations, and taking enforcement action where necessary, but with the device industry continuing to grow, regard now needs to be given to the funding of such activities.

What can the UK medical device industry expect?

The MHRA has indicated that it is currently carrying out an internal review of the funding arrangements for the agency's device work. The outcome of this internal review – and any proposed changes to the status quo – may lead to a formal Consultation with stakeholders. There is no indication as to when the MHRA's internal review will be completed, albeit that the MHRA's expectation that any new fees will be implemented as from April 2016 now seems unlikely.

The UK government is clearly conscious of the potential adverse impact that charging additional fees could have on the UK device market. In the Department of Health's (DoH's) July 2015 Triennial Review of the MHRA, the DoH acknowledged that it did not want to make the UK a less

Shook offers expert, efficient and innovative representation to clients targeted by litigation and regulation. By partnering with companies to navigate the complex operational, technological and regulatory challenges of today's global business environment, we are able to manage emerging threats and overcome potential obstacles at every step in the decision-making process.

For more information about the MHRA's activities and medical device regulation in Europe, please contact:

Alison Newstead
+44 (0)20 7332 4664
anewstead@shb.com

For more information about our Pharmaceutical and Medical Device Practice, please contact:

Madeleine McDonough
816.559.2342
202.639.5600
mmcdonough@shb.com

attractive marketplace to the medical device industry than other EU countries by introducing direct charges and additional administrative burdens. This is certainly an issue that stakeholders are likely to follow up if a consultation goes ahead.

What approach may be taken if the MHRA does adopt a new fee structure?

The DoH's 2015 Triennial Review suggests that *"the most likely approach is to apply a charge based on turnover on all medical devices sold in the UK."* Other EU jurisdictions can provide some insight as to possible approaches: Austria, Belgium, Croatia, Denmark, France, Italy, Latvia, Lithuania, Portugal and Spain have all implemented various measures to attempt to recoup the full costs of regulating medical devices. Approaches in these countries include fees on those who place products on the EU market, fees related to numbers of employees of economic operations and sales taxes.

The Irish Health Products and Regulatory Agency (HPRA) has also recently carried out a Public Consultation on "*The Introduction of a Fee Based Funding Model to Support the Conduct of Medical Device Regulatory Activities by the HPRA*." The ultimate aim of the HPRA is to create a self-funding regulatory regime for medical devices in Ireland. The HPRA Consultation closed in August 2015 and the outcome has yet to be published. The suggested fee models put forward in the Consultation include: (a) charging medical device manufacturers/economic operators an annual fee for the HPRA's surveillance services, based on the company size and activity; (b) applying an additional fee to manufacturers holding authorized representative status; (c) charging a specific annual fee to authorized representatives (up to a maximum limit); and (d) charging an annual fee to distributors proportionate to their size. It is clear that such proposals could affect numerous stakeholders in the device industry in Ireland, including manufacturers/economic operators, distributors and authorized representatives.

Responses to this Consultation will be a useful indicator for the MHRA and could potentially influence the outcome of its internal review in the UK.

The possibility of a pan-European funding framework for medical devices is unlikely to be achievable in the short term. Until then, a fragmented approach across Europe is likely, with governments trying to achieve a delicate balance between ensuring that the activities of competent authorities are cost-effective and maintaining an attractive marketplace for medical device industry investment.