



Regulatory Triage Assessment	
Title of regulatory proposal	MHRA e-cigarette fee
Lead Department/Agency	Medicines and Healthcare products Regulatory Agency
Expected date of implementation	May 2016
Origin	EU
Date	11/09/2015
Lead Departmental Contact	rose.geeson@mhra.gsi.gov.uk
Departmental Triage Assessment	Low cost EU regulation
<p>Rationale for intervention and intended effects Due to an EU Directive MHRA must provide a notification and vigilance service for e-cigarette producers. MHRA will not be able to recover its full costs unless it introduces a new fee for this service.</p>	
<p>Viable policy options</p> <p>Option 1: Do nothing: This would mean that the e-cigarette notification and vigilance service would need to be subsidised. This is contrary to Managing Public Money principles.</p> <p>Option 2: Legislate to enable MHRA to recover the costs of implementing the Directive, in line with Managing Public Money principles and the organisation's status as a Government Trading Fund.</p> <p>There is no alternative to regulation, as MHRA must ensure full cost recovery through charging fees for its services.</p>	
<p>Initial assessment of business impact</p> <p>Producers of e-cigarettes will be required to pay a fee to make a notification to MHRA. This fee will be set at a best estimate of full cost recovery. If MHRA does not introduce a fee the costs would, most likely, be passed on to other businesses. Therefore the benefit of the policy is to businesses. The benefit is directly equal to the costs to e-cigarette producers.</p> <p>The cost of administering the scheme is estimated as between an average of £0.15-£0.35M per year, with a best estimate of around £0.23M.</p>	
<p>One-in, Three-out status</p> <p>OUT OF SCOPE. These fees are required to directly fund an EU Directive with no gold plating. There is a zero net impact on business.</p>	
<p>Rationale for Triage rating</p>	

The cost and impact of having a notification system are assessed in the main Tobacco Product Directive impact assessment. This impact assessment only considers the issues of ensuring the businesses who use the service pay for the service.

Departmental signoff (SCS): Patience Wilson **Date: 05/10/15**

Economist signoff (senior analyst): Keith Derbyshire **Date: 21/09/15**

Better Regulation Unit signoff: Frank Brown **Date: 14/10/15**

Evidence Base

Problem under consideration

Under the terms of its status as a Government Trading Fund, MHRA is obliged to recover in full the costs of its regulatory activities by charging fees for its services.

Due to the revised EU Tobacco Products Directive, MHRA must provide a notification and vigilance service for e-cigarette products already on, or proposed for, the UK market.

The creation of a notification and vigilance service means that MHRA needs to introduce new fees for services provided to e-cigarette producers to recover its costs. This impact assessment only considers the necessity of ensuring full cost recovery. The impact of the policy as a whole on the UK has already been analysed in a previous impact assessment.

Rationale for intervention

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.

Policy objectives

To ensure full cost-recovery of new work done by MHRA under the revised EU Tobacco Products Directive, in line with Managing Public Money principles and MHRA's status as a Government Trading Fund.

Description of options considered

1. Option 1: Do nothing

As this is the baseline it has no costs and benefits. However, this would mean that the notification and vigilance service would need to be subsidised.

2. Option 2: Legislate to enable MHRA to recover the costs of implementing the Directive, in line with Managing Public Money principles and the organisation's status as a Trading Fund.

There is no alternative to regulation, as MHRA must ensure full cost recovery through charging fees for its services.

Who is affected?	Impact																								
MHRA	MHRA will have oversight of a previously unregulated group. In line with Managing Public Money principles MHRA operates on full cost recovery basis. The full cost of this service will be passed on to e-cigarette producers, and so is represented in that category.																								
Producers of e-cigarettes	<p>Producers of e-cigarettes will be required to pay a fee to make a notification to MHRA. This fee will be set at a best estimate of full cost recovery + 3.5% as required by the Managing Public Money rules. We will review the fee in year two of the regulations being implemented.</p> <p>Our best estimates of the cost of running the service are shown below. MHRA is currently designing the front end of the electronic notification service within the scope of the European Commission’s centrally developed portal which will form the back end. The following cost figures are rough estimates and will therefore be subject to change¹. These costs will be passed on to businesses.</p> <table border="1"> <thead> <tr> <th></th> <th>2016/17</th> <th>2017/18</th> <th>2018/19</th> <th>2019/20</th> <th>2020/21</th> </tr> </thead> <tbody> <tr> <td>High cost estimate (000s)</td> <td>£930</td> <td>£192</td> <td>£193</td> <td>£194</td> <td>£195</td> </tr> <tr> <td>Best cost estimate (000s)</td> <td>£593</td> <td>£142</td> <td>£143</td> <td>£143</td> <td>£144</td> </tr> <tr> <td>Low cost estimate (000s)</td> <td>£360</td> <td>£94</td> <td>£94</td> <td>£94</td> <td>£94</td> </tr> </tbody> </table>		2016/17	2017/18	2018/19	2019/20	2020/21	High cost estimate (000s)	£930	£192	£193	£194	£195	Best cost estimate (000s)	£593	£142	£143	£143	£144	Low cost estimate (000s)	£360	£94	£94	£94	£94
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Benefits and Net Present Value

If MHRA did not charge the e-cigarette producers new fees for this notification and vigilance service, it would need to fund the service via other income. We have not conducted analysis on how this would be funded as not achieving full cost recovery is not a viable option.

MHRA is primarily an industry funded Government Trading Body. It is likely the “other income” would come from fees charged by MHRA to other businesses for different services. This would be cross subsidisation, and a violation of Managing Public Money principles.

The benefit of this fee policy is to those businesses that would have funded the service if e-cigarette producers did not. Therefore the benefits of this fee policy to businesses are directly equal to the cost of the policy to e-cigarette producers.

Therefore the business net present value is zero.

Risks

Due to uncertain volumes there is a risk of an accidental surplus or deficit. We will seek better data to set the first years fees during consultation to mitigate this risk.

Small and Micro Business Assessment

Small and micro businesses are not exempt from the EU Tobacco Products Directive. They have to be in scope because of the EU law. In line with its status as a Trading Fund, MHRA is obliged to recover the costs of work done under the Directive, but are aiming to keep costs and fees as low as possible. We will develop a clear communications campaign to ensure that all businesses are clear on what is required and what compliance looks like, thereby minimising familiarisation costs.

¹ The cost has been estimated over a five year period. Projections beyond five years would be spurious as, due to a developing IT change programme, we do not know what IT services will be in place.

As this is a previously unregulated group, we do not have data on the likely number of small and micro businesses that will be affected. We will seek further information on the likely impact on small and micro businesses as part of the consultation process.

One In Three Out

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Consultation Questions

1. Are the proposed fee levels tolerable, or will they cause a significant impact on your business's finances?
 - a. Are you a small/micro business?
2. Do you have any data or information on the number of notifications and variations MHRA should expect to receive?