Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Regulatory Triage Assessment

Title of regulatory proposal	FMD logo statutory fee
Lead Department/Agency	MHRA
Expected date of implementation	April 2016 SNR 5
Origin	EU
Date	12/08/15
Lead Departmental Contact	rose.geeson@mhra.gsi.gov.uk
Departmental Triage Assessment	Low-cost regulation (fast track)

Rationale for intervention and intended effects

Due to an EU Directive the MHRA must provide a registration and logo system for the UK's online medicine sellers. The MHRA will not be able to recover its full costs unless it introduces a new fee for services provided to online sellers of medicine. Legislation is required to introduce a statutory fee.

Viable policy options

Option 1: Do nothing: This would mean that the online logo scheme would need to be subsidised. This is contrary to managing public money principles.

Option 2: Legislate to enable the 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 the MHRA must ensure full cost recovery through charging fees for its services.

Initial assessment of business impact

Online sellers will be required to pay a fee to obtain their logo from the MHRA. This fee will be set at a best estimate of full cost recovery. If the MHRA does not introduce a fee the costs would be passed on to UK businesses, as it is a Government Trading Fund. Therefore the benefit of the policy is to UK businesses, and it is directly equal to the costs. We estimate the cost of running the scheme to be between £0.3m-£0.5m annually.

One-in, Two-out status

This is an EU regulation with no gold plating, and therefore it is out of scope.

Rationale for Triage rating

This is a zero net cost EU measure with a low impact on business.

Departmental signoff (*SCS*):Patience Wilson Date: 13/08/15

Economist signoff (*senior analyst*): Keith Derbyshire Date:

27/07/2015 **Better Regulation Unit signoff:** Date:

Evidence Base

Problem under consideration

The MHRA regulates medicine safety, quality and efficacy. Under the terms of its status as a government trading fund, the MHRA is obliged to recover in full the costs of its medicines regulatory activities by charging fees for its services.

Due to an EU Directive[1] the MHRA must provide a registration and logo system for the UK's online medicine sellers. This is designed to address the problem of the infiltration of falsified medicines into the regulated medicines supply chain. The provisions of this directive have already been transposed into the Human Medicines Regulations, and came into effect on 1 July 2015. The impact of the policy on the UK has already been considered in a previous impact assessment.[2]

The creation of an online logo scheme means that the Agency needs to introduce a new fee for services provided to online sellers of medicine to be able to recover its costs. This impact assessment only considers the problem of ensuring full cost recovery. The impact of the policy as a whole 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. Legislation is required to introduce a statutory fee.

Policy objectives
To ensure full cost-recovery of new work done by the MHRA under the Falsified Medicines Directive, in line with managing public money principles and the Agency'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 online logo scheme would need to be subsidised.

2. **Option 2: Legislate to enable the 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 the MHRA must ensure full cost recovery through charging fees for its services. The requirement to register is statutory, and the scheme therefore requires a new statutory fee, which can only be introduced by amending the Agency's Fees Regulations.

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[1] EU Directive 2011/62/EU (the 'Falsified Medicines Directive' or 'FMD', published 1 July 2011)
[2] Please see http://www.legislation.gov.uk/ukia/2013/90/pdfs/ukia_20130090_en.pdf, pp.27-29. Impact assessment number 4024.

<table>
<tr><th>Who is affected?</th><th>Impact</th><th>Status</th></tr>
<tr><td>MHRA</td><td>The MHRA will have oversight of a previously unregulated group. In line with managing public money principles the MHRA operates on full cost recovery basis. The full cost of this system will be passed on to online sellers, and so is represented in that category.</td><td>N/A</td></tr>
<tr><td>Online sellers of medicines (e.g. online pharmacies, supermarkets, marketplace traders and other retailers)</td><td>Online sellers will be required to pay a fee to obtain their logo from the 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 policy. Our best estimates of the cost of running the system are shown below. This cost will be passed on to businesses. Please see Annex A for details of fees and calculations.
<table>
<tr><th></th><th>2015</th><th>2016</th><th>2017</th><th>2018</th><th>2019</th></tr>
<tr><td>High cost (000s)</td><td>£355</td><td>£459</td><td>£462</td><td>£465</td><td>£468</td></tr>
<tr><td>Best cost (000s)</td><td>£350</td><td>£443</td><td>£446</td><td>£448</td><td>£451</td></tr>
<tr><td>Low cost (000s)</td><td>£344</td><td>£427</td><td>£429</td><td>£432</td><td>£434</td></tr>
</table></td><td>Direct Annual Transfer Cost</td></tr>
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Benefits and Net Present Value

If businesses using the service did not pay to cover the costs of the service the MHRA would be required to fund it.

We have not explored how this would be funded as not achieving full cost recovery has not been deemed a viable option. As the MHRA is an industry funded trading body it is likely the costs would be passed on to UK businesses. Therefore the benefit of the policy is to UK businesses, and it is directly equal to the costs.

Therefore the net present value is zero.

Risks

Due to uncertain volumes there is a risk of an accidental surplus of deficit. We will seek better data during consultation to mitigate this risk.

Small and Micro Business Assessment

Small and micro businesses are not exempt from the EU common logo scheme for online sellers of medicine. They have to be in scope because of the EU law, and because their exemption would pose a substantial risk to public health. In line with its status as a Trading Fund, the MHRA is obliged to recover the costs of work done under the Directive, but the MHRA is aiming to keep costs and fees as low as possible. We have also developed a clear communications campaign to ensure that all businesses are clear what is required and what compliance looks like, thereby minimising familiarisation costs.

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 Two Out
This is an EU regulation with no gold plating, and therefore it is out of scope.

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 that will improve the volumes estimates?

3. Do you have any data to inform our assumption on how many businesses will register beyond year one?

Annex A: Logo Fee Calculation

The MHRA is currently designing the system for processing logo applications. **The following cost figures are rough estimates and will therefore be subject to change.** 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 systems will be in place.

Cost	2015	2016	2017	2018	2019
High cost (000s)	£362	£466	£469	£472	£475
Best cost (000s)	£350	£443	£446	£448	£451
Low cost (000s)	£344	£427	£429	£432	£434

Volumes	2015	2016	2017	2018	2019
Register high volume (low fee)	6177	309	309	309	309
Register best estimate	3989	199	199	199	199
Register low volume (high fee)	1800	90	90	90	90
Renew high volume (low fee)	0	6177	6486	6795	7104
Renew best estimate	0	3989	4188	4387	4587
Renew low volume (high fee)	0	1800	1890	1980	2070

Given the estimated costs and volumes shown above, we expect the application fee (for inclusion on the register, and thereby for the logo) to be £100, and the periodic

fee to be £97. These levels were calculated by analysing the costs and volumes. We will seek further clarification during consultation, and we will reassess our fee levels in year two of the policy.

Assumptions and Caveats

Processing Cost

- These costs are rough internal estimates. Resourcing and IT solutions will be finalised during the consultation period, and therefore these costs will be subject to change. The confirmed figures will be presented in the final impact assessment
- We do not expect there to be an additional familiarisation cost to business, as this would be counted in the creation of the scheme rather than the setting of the fee.

Volumes

- The data on volumes is very weak; we have presented the best estimates, and we will seek better data via consultation.

- The high volumes estimate is based on estimates of the number of UK online medicines sellers provided during informal conversations with industry, plus all of the companies registered with the General Pharmaceutical Council.

- The best volumes estimate is based on estimates of the number of UK online medicines sellers provided during informal conversations with industry, plus 50% of the companies registered with the General Pharmaceutical Council.

- The low volumes estimate is based on estimates of the number of UK online medicines sellers provided during informal conversations with industry, and it assumes the General Pharmaceutical Council companies who are online are among these.

- We have no data on which to estimate registrations past year one, therefore we have made a crude 5% assumption. We will seek better data via consultation.