Title: Fees for e-cigarette notifications **IA No:** DH4058 **RPC Reference No:** **Lead department or agency:** Medicines and Healthcare products Regulatory Agency	**Impact Assessment (IA)** **Date:** 18/04/2016 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Patience Wilson Patience.Wilson@mhra.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: Awaiting Scrutiny

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANDCB in 2014 prices)	**One-In, Three-Out**	**Business Impact Target Status**
£0m	£0m	£0m	Not in scope	Not a regulatory provision

What is the problem under consideration? Why is government intervention necessary?

Due to the revised EU Tobacco Products Directive (2014/40/EU) MHRA must provide a notification system for e-cigarette products already on, or proposed for, the UK market.

The creation of a notification system means that MHRA needs to introduce a new fee to be able to recover its costs.

What are the policy objectives and the intended effects?

It is Government policy to recharge for TPD notification work, and 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.

MHRA's objective is 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.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Do nothing
As this is the baseline it has no costs and benefits. However, this would mean that the notification system would need to be subsidised.

Option 2: Legislate to enable MHRA to recover the costs of implementing the Directive.

There is no alternative to regulation, as MHRA must ensure full cost recovery through charging for its services. The requirement to notify e-cigarette products is statutory, and the scheme therefore requires a new statutory fee.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 04/2017

Does implementation go beyond minimum EU requirements?		No		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** NA	**Non-traded:** NA	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: ..... Date: .....

Summary: Analysis & Evidence — Policy Option 1

Description: Legislate to enable MHRA to recover the costs of implementing the Directive.

FULL ECONOMIC ASSESSMENT

Price Base Year 2016	PV Base Year 2016	Time Period Years 5	Net Benefit (Present Value (PV)) (£m)		
			Low: -	High: -	Best Estimate: 0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	-		-	-
High	-		-	-
Best Estimate	0		1	4.7

Description and scale of key monetised costs by 'main affected groups'

MHRA must set up and run a notification system for e-cigarettes. The cost of the notification system in year one is £2m, and in year 2-5 the cost is estimated to be £0.7m-£0.8m annually. This cost will be passed on to e-cigarette producers, importers and rebranders in the form of fees. There will be a £150 notification fee, £80 modification fee and £60 periodic fee per product. These fees will be reviewed annually to ensure MHRA's income is aligned with its costs.

Other key non-monetised costs by 'main affected groups'

Business who are unable to afford these fees will either have to adapt their buisness models or withdraw from the legal market.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	-		-	-
High	-		-	-
Best Estimate	0		1	4.7

Description and scale of key monetised benefits by 'main affected groups'

If businesses using the service did not pay to cover the costs of the service 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 MHRA is a trading fund the costs would be passed on to businesses, primarily pharmaceuticals. Therefore the benefit of the policy is to businesses, and it is directly equal to the costs.

Other key non-monetised benefits by 'main affected groups'

N/A

Key assumptions/sensitivities/risks — **Discount rate (%)** 3.5

There is a large risk from uncertain volumes. Data from consultation has been used to produce a volumes estimate of 14,000, however this is subject to extreme uncertainty. MHRA will revise its costs and fees in year 2 to mitigate the impact of volumes uncertainty, and insure its income is aligned with its costs.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 1	Benefits: 1	Net: 0	NA

Evidence Base

Problem under consideration

Due to the revised EU Tobacco Products Directive (2014/40/EU) MHRA must provide a notification service for e-cigarette products already on, or proposed for, the UK market.

The creation of a notification system means that MHRA needs to introduce a new fee to be able to recover its costs. This impact assessment only considers the problem of ensuring full cost recovery. The decision to have the system, and the cost of the system its self, has been accounted for in the net present value in the main Tobacco Products Directive impact assessment. The notification system will go ahead regardless of the proposed fee legislation.

Rationale for intervention

It is Government policy to recharge for TPD notification work, and 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.

Description of options considered

Option 1: Do nothing

As this is the baseline it has no costs and benefits. However, this would mean that the notification system would need to be subsidised by MHRA's other customers, such as pharmaceuticals.

Option 2: Legislate to enable MHRA to recover the costs of implementing the Directive.

There is no alternative to regulation, as MHRA must ensure full cost recovery through charging for its services. The requirement to notify e-cigarette products is statutory, and the scheme therefore requires a new statutory fee.

Consultation Evidence

At consultation MHRA invited views on how many notifications it should expect to receive. The estimate of notifications is a key factor when setting the fee level. If an overestimate is used then MHRA will have an accidental deficit, and an underestimate would give MHRA an accidental surplus.

Although the data is still subject to uncertainty, MHRA now has more evidence on the size of the market than it had prior to consultation. The new evidence demonstrates that previous estimates were too low. MHRA has responded to this by revising it's costs and lowering its fees from the level proposed at consultation. The revised volume estimates are as follows:

Number of notifications in Year 1	14,000	This is derived from the median estimate, provided by consultation respondents, of the total number of notifications MHRA will receive in Year 1.
Number of modifications	14% of the Year 1's notifications	This figure is taken from the median estimate of submissions consultation respondents predicted for year 2 onwards. Respondents were unclear on what constituted a modification as this is yet to be fully defined. With no better data on which to base estimates, it is assumed that half of the predicted volume of year 2 submissions are notifications, and the other half modifications.
Number of notifications in Year 2 +	14% of the Year 1's notifications	

Costs

MHRA: MHRA will have oversight of a previously unregulated group of products. In line with Managing Public Money principles MHRA operates on full cost recovery basis. The full cost of this system will be passed on to e-cigarette producers. If the fee is set at the wrong level, MHRA is at risk of making an accidental surplus or deficit.

Producers/importers of e-cigarettes: Producers of e-cigarettes will be required to pay a fee to make a notification. Producers may pass the cost on to consumers.

ECigIntelligence estimated that there are between 800-1100 companies in the e-cigarette market, and no consultation responses provide better evidenced estimates. This market is not clearly divided in to producers and retailers. Many retailers either rebrand e-cigarettes or create e-cigarette products at the point of sale and they would be required to notify those products. However some these businesses will be solely retailers, and therefore will not be submitting notifications.

The fee levels have been calculated based on an estimate of the cost of MHRA setting up and running a notification system. The costs are expected to drop after year one, after the initial surge of applications has been processed. The costs provided for year 2 onwards are rough estimates and will be subject to change when more volumes data is available. Due to the high level of uncertainty in volumes there is a

strong risk of an accidental surplus or deficit. MHRA will review its fees in year two when it has volumes data to ensure its income is aligned with its costs.

In year one the volume required to break even on costs is 13,195, 6% below the main volume estimate. The fee has been set at this level due to the uncertainty around volumes, and MHRA's duty set out by HM Treasury to make a 3.5% return on its activities. The fees will be set on a yearly basis, to ensure they reflect full cost recovery. No businesses will pay the periodic fee in year one, as you begin paying that in the second year of notification. At consultation, no businesses indicated that they wished to make modifications in year one.

Year One Fee Levels		
Notification	Modification	Periodic Fee
£150	**£80**	**£60**

Total Costs (£m)	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5
	£2m	£0.7	£0.7	£0.8	£0.8

Benefits and Net Present Value

As MHRA is a trading fund, its income comes from the businesses it regulates. If e-cigarettes producers do not pay to cover the costs of regulating the e-cigarette market then MHRA would be required to fund it. Consequently the costs would be passed on to MHRA's other customers, businesses such as pharmaceuticals. Therefore the benefit of the policy is to businesses that would have borne the cost of the system in the absence of fees for e-cigarette producers. The benefit to business of the fees legislation is directly equal to the costs.

Therefore the net present value is zero.

Risks and assumptions

- Due to uncertain volumes there is a risk of an accidental surplus or deficit. To mitigate this risk we will review costs and volumes in year 2 and make further proposals for adjusting the fees if appropriate. This means the costs and fees for year 2-5 are illustrative, and will change when MHRA is in a better position at the end of year 1 to make a more informed judgment of future volumes.
- The familiarisation costs of the notification system are accounted for in the main TPD impact assessment. There are no additional familiarisation costs from charging a fee, as businesses would still be required to notify in the absence of a fee.

- Many respondents misunderstood the structure of the fee, assuming retailers and manufacturers must notify the same product. When calculating volumes, data from those with clear misunderstandings have been removed.
- When calculating volumes, some respondents did not explain how they produced figures, so their credibility could not be verified.
- Some respondents were unclear whether it was a notification per stock keeping unit or per product. This means industry may have underestimated the number of notifications.
- Some respondents did not realise that separate notifications are required for different Propylene Glycol and Vegetable Glycerine usage; therefore some respondents may have underestimated the number of notifications by at least 50%.
- It is not possible to predict the impacts of the Tobacco Products Directive on supply and demand. This adds further uncertainty to the figures.

Small and Micro Business Assessment

We have had no clear data from consultation regarding how many small and micro businesses are in this sector. Industry has previously estimated that around 90% of the sector is SMEs, and this seems like a viable estimate as the majority of consultation respondents identified themselves as small businesses.

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 MHRA is aiming to keep costs and fees as low as possible. We will develop a clear communications campaign to ensure that all businesses are clear what is required and what compliance looks like, thereby minimising familiarisation costs.

One In Three Out

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