Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

CONSULTATION DOCUMENT

To all licence holders, e-cigarette producers, sellers, online sellers and representative associations
Our Ref: MLX 390
Issued: 08/01/2016
Respond by: 29/01/2016
Enquiries to: *consultations@mhra.gsi.gov.uk*

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY E-CIGARETTE FEES – PROPOSALS FOR 20 May 2016

INTRODUCTION

1. The aim of this consultation is to seek the views of stakeholders on proposals to introduce proportionate fees for obtaining Notifications for the placing on the UK Market of e-cigarettes that are classified as consumer products and covered by the revised Tobacco Products Directive.

2. This proposal introduces new fees for producers and importers of e-cigarettes in order for MHRA (as the UK Competent Authority) to cover the costs of processing the notifications and undertaking the post marketing vigilance work. There has been no gold plating of the e-cigarette elements of the Directive by the UK and the fees passed on to business will be the minimum possible to ensure the costs incurred by MHRA in undertaking the directed activity are recovered.

3. The implementation date for these changes is 20 May 2016.

4. The proposed fees may be reviewed should data obtained during consultation enable the further refining of cost estimates and as further guidance is received from the EU Commission on the implementation of the scheme.

NEW FEE FOR SELLERS OF E-CIGARETTES TO THE PUBLIC

5. From 20 May 2016, in accordance with the revised EU Tobacco Products Directive (TPD), MHRA will manage an electronic notification system for e-cigarette products intended for the UK market. The notification system will be connected to an EU Portal and MHRA will handle those notifications relating to products for the UK market are correct, complete and compliant and will also oversee a post-marketing vigilance system, which includes reacting to information which raises concerns about the safety of a product. MHRA will also perform other post-marketing activities, including a contribution to EU arrangements for annual reporting and compliance. The Department of Health has already consulted on the revisions to the Directive and further information can be found at the following link: https://www.gov.uk/government/consultations/draft-regulations-on-the-sale-and-manufacture-of-tobacco-products

   The MHRA scheme is a direct transposition of the EU Directive, without gold plating.

6. Products that require a notification are limited to the whole or component elements that specifically contain, or could contain nicotine in the form of e-liquid. Therefore products such as disposable units and tanks will require a notification; however equipment such as mouthpieces, batteries and other elements that we would qualify as an individual component will not.

7. Total costs, inclusive of fixed cost overheads like IT, for the first year are estimated to be approximately £0.6m (when a larger number of notifications are expected) and £0.1m per year thereafter. The electronic notification system is still under development, so these costs will be developed when new information becomes available. To deliver the notification system, staff across a number of areas within the Agency are required in addition to the IT:

   - Information Processing - Staff to review submitted notifications and assess the correctness of data within the categories which will be monitored by the Agency. Estimates of numbers of staff required are based on the time to complete a notification and the estimated volumes of notifications.

   - Finance – Staff will be required to raise invoices and follow up on unpaid invoices. Submission is likely to be received from companies based in locations worldwide, providing an added degree of complexity to chasing debt.

   - Pharmacovigilance – Staff will be required to monitor responses to reports (including via the yellow card website, which monitors adverse events) and use this data to form actions and responses (trading standards, public health warnings etc).

- IT/Communications – Staff will be required to either generate the publication of the notifications manually or check and monitor that any system generated publication has produced the correct results. Information pertaining to the notification will need to be published and staff will be required to check that this has occurred correctly and (for example) any commercially sensitive documents have not been published.

- Process Manager – A manager responsible for ensuring that the end to end process, from receipt of information from the portal to publication of information on the notifying organisation, has occurred correctly.

8. In all cases staffing numbers are dependent on the number of notifications received. Estimates of the number of notifications MHRA will receive are subject to significant uncertainty because:

    - We have limited data on how many products are currently on the market.

    - The costs of generating notification information may deter companies from putting all of their products through the notification process. We do not have an estimate of the attrition rate and we welcome information from industry on this.

    - The revised TPD could lead to market changes which will affect the number of products on the market.

9. The initial financial modelling to determine the fees shown in this consultation was calculated based on the number of products in the Nielsen data set. We recognise that this data is limited, and it does not account for attrition in the market due to the new regulations. A second round of financial modelling will be conducted to include the evidence from this consultation and the TPD main consultation to provide the final fee levels. **We welcome information from industry on the number of notifications the MHRA should expect to receive.**

10. We are aiming to keep costs (and therefore fees) as low as possible, including through the strict avoidance of gold plating, and careful consideration has been given to the level of fees we intend to charge in order to recover the costs. These estimates are the best available to the MHRA at present but are based on limited data due to the relatively recent emergence of the market. **We expect estimates may be refined following this consultation and also as more information emerges from the EU on the details of the scheme over the next few months.**

11. Due to the uncertainty around volumes there is a risk that the fee set in year one may lead to an accidental deficit or surplus. If this occurs the MHRA will review fees

options for year two to ensure that industry is not over or undercharged for this service, in line with the principles of Managing Public Money and the terms of MHRA's Trading Fund Order.

12. To recover the cost of the scheme, MHRA proposes to introduce a Notification fee of **£220** for a new product and an ongoing annual periodic fee for service thereafter of **£60.** A Notification (Modification) fee of **£110** will also be applicable to cover the cost of processing a notification for modification to an existing product. Alternatively, companies may prefer a fixed fee, covering a number of modifications, to be added to the Periodic Fee and we have provided opportunity to comment on this in the response template.

13. These figures have been set in order to recover only the estimated costs and could be revised based on any further evidence from this consultation, further information from the EU and as more market data becomes available. In all cases adjustments to fees will be set at the minimum possible to safely recover the cost.

14. Notifications will be submitted via a common EU Product Registration Portal and all e-cigarettes already on the market on 20 May 2016 will need to be notified, and therefore the new fees paid, within six months to the Competent Authority following that date. After 20 May 2016, manufacturers and importers will be required to notify their new product six months before they want to place it on the market, though any new product notified on 20 May 2016 can be placed on the market at any point over the following six months. The normal process would be that, when the information is brought through from the EU portal to the MHRA, the notifying organisation will be set up as a customer on the MHRA systems and an invoice raised to them, with a pause in assessment of the notification until a fee is received.

15. At this stage the likely cost of the notification fees on industry is not fully known but estimated to be under £1M annually. Although low, smaller sellers are likely to be more affected than larger ones by the proposed fees. However we consider that there is no viable alternative in order to cover the cost of these functions. We would welcome your views on the impact on businesses (see below).

16. We have planned a clear communications campaign to ensure that all businesses understand what is required and what compliance looks like, thereby minimising familiarisation costs. This activity will start once we have a clear steer on the specifics of implementation from the European Commission.

17. The fee proposals set out in this document are designed to meet the following goals:

    - For industry, proportionate fees that will enable MHRA to conduct the new functions efficiently and effectively.

    - For MHRA, full cost recovery of new work done under the revised EU TPD, in line with the principles on managing public money and MHRA's status as a Government Trading Fund.

HOW TO RESPOND

18. Any comments on these proposals should be sent to: *consultations@mhra.gsi.gov.uk* by **29 January 2016** using the reply sheet provided at Annex B and using the subject reference of "Fees Consultation **MLX 390**".

19. There are **five specific questions listed on the reply sheet** on which we would be grateful for any views or information. Emailed responses are preferred, but if you wish to send responses by post, the address is: E-cigarette Fees Consultation c/o Matthew Garland, 5th Floor, Teal Area, 151 Buckingham Palace Road, Victoria, London, SW1W 9SZ.

CONFIDENTIALITY OF INFORMATION

20. We manage the information you provide in response to this consultation in accordance with MHRA's Information Charter.

21. Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

22. If you would like the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could identify any

information you wish to be withheld (which may be either all or part of your response) and explain to us why you regard it as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an absolute assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on MHRA.

23. MHRA will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

24. More information about the Freedom of Information Act can be found on the website of the Ministry of Justice – www.justice.gov.uk/guidance

IMPACT ASSESSMENTS

25. In giving your views on the proposal described in this document, it would be particularly helpful if you could identify and quantify the effects these proposals are likely to have on your business. We would particularly like to hear from smaller companies.

THE PRINCIPLES OF CONSULTATION

26. The Civil Service Reform Plan commits the Government to improving policy making and implementation with a greater focus on robust evidence, transparency and engaging with key groups earlier in the process.

27. For details of the revised principles of engagement, please see http://www.cabinetoffice.gov.uk/sites/default/files/resources/Consultation-Principles.pdf

28. Policy proposals relating to the implementation of the revised Tobacco Products Directive have been considered in the separate public consultation *(https://www.gov.uk/government/consultations/draft-regulations-on-the-sale-and-manufacture-of-tobacco-products).*For this reason we consider that for this consultation covering fees only, a four-week consultation period is appropriate.

COMMENTS OR COMPLAINTS

29. If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

By post: Consultations Coordinator
Department of Health
3E48, Quarry House
Leeds
LS2 7UE

By e-mail: consultations.co-ordinator@dh.gsi.gov.uk
(Please do not send consultation responses to these addresses.)

ANNEX A

DETAIL OF PROPOSALS

1. Introduction of fees for producers and sellers of e-cigarettes

The proposal is to introduce fees to cover the cost of processing Notifications of e-cigarettes, Modifications to Notifications and ongoing services in accordance with the Tobacco Products Directive (2014/40/EU).

Notification fee: £220

Periodic (service) fee: £60

Notification (Modification) Fee £110

The MHRA is aiming to charge fees at the minimum level required to ensure cost recovery. We have planned a clear communications campaign to ensure that all businesses are clear what is required and what compliance looks like, thereby minimising familiarisation costs.

The proposed fee levels will be reviewed and revised pending evidence from this consultation, further information from the EU and as more market data becomes available.

NEW FEES RESULTING FROM IMPLEMENTATION OF THE TOBACCO PRODUCTS DIRECTIVE (2014/40/EU)

Fee Description	Current fee £	Proposed fee £
Notification		
Initial Notification fee	None	**220**
Periodic (service) fee	None	**60**
Notification (Modification) fee	None	**110**

ANNEX B

RESPONSE TO CONSULTATION LETTER (MLX 390)
MHRA E-CIGARETTE FEES FOR 2016/2017

Please complete the proforma below and return to: *consultations@mhra.gsi.gov.uk* by **Date**.

Name: ……

Company Name: ……
……

General comments

Specific questions:

E-CIGARETTE FEES

These fees are being introduced in order for the MHRA to recover the cost of the work of processing notifications and undertaking the post marketing vigilance work for e-cigarettes.

1. Do you agree or disagree with the levels of the proposed fees in Annex A? If you disagree, please explain why.

2. Would you prefer a fixed fee covering a number of modifications to be added to the Periodic Fee? Please provide any information that could justify a change towards this alternative model.

3. Are the proposed fee levels tolerable or will they cause a significant impact on your business's finances? (please indicate if you represent a small or micro business)

4. Please provide any data or information that will assist us to refine our volume estimates for notifications in Year 1 (16/17) and subsequent modifications.

5. Please provide any data or information that will assist us to refine our volume estimates for notifications after Year 1 (17/18 onwards)