EXPLANATORY MEMORANDUM TO

THE ELECTRONIC CIGARETTES ETC. (FEES) REGULATIONS 2016

2016 No. 521

1. Introduction

1.1 This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health, and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument introduces new fees payable by the electronic cigarette (e-cigarette) industry (which includes manufacturers and importers of e-cigarette liquids and hardware and also traders of e-cigarettes who carry out assembly and/or rebranding functions) in relation to the regulatory functions carried out by MHRA for e-cigarette products. The fees are necessary to cover the costs of the work in relation to obligations under the EU Tobacco Products Directive (TPD), principally notifying the products, providing post market vigilance and maintaining the e-cigarette database.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

Other matters of interest to the House of Commons

3.2 This instrument is subject to a negative resolution procedure and has not been prayed against. However, Members may wish to be aware that the Tobacco Products Directive implementation regulations, to which these fees relate and which is due to come into force on the same date of 20 May 2016, has been prayed against.

4. Legislative Context

4.1 The EU Tobacco Products Directive 2014 (the 'TPD') introduces specific provision for the regulation of electronic cigarettes and refill containers for the first time.

4.2 In particular, Article 20 of the TPD:

- requires manufacturers and importers of electronic cigarettes and refill containers to notify the national Competent Authority before placing such products on their market;
- requires Member States to make the notified information publicly available on a website; and
- empowers Member States to carry out certain supervisory functions with regard to electronic cigarettes and refill containers.

4.3 In the United Kingdom, the TPD is transposed by the Tobacco and Related Product Regulations 2016 (the 'TPD Regulations') which are to come into force on 20th May 2016, the same date as this instrument. In particular, Article 20 of the TPD is transposed by Part 6 of the TPD Regulations. Under Part 6, the national competent authority and Member State functions in relation to electronic cigarettes and refill

containers are conferred on the Secretary of State for Health; and, in practice, the MHRA will carry out those functions on behalf of the of the Secretary of State.

4.4 The fees introduced by this instrument relate to the work carried out by the MHRA on behalf of the Secretary of State for Health under the TPD Regulations.

4.5 In parallel, the MHRA is also amending the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003, by which it is established as a trading fund, to enable it to fund the work it carries out in relation to electronic cigarettes and refill containers through fee income. This is being done in a separate (affirmative) instrument: the Medicines and Healthcare Products Regulatory Agency Trading Fund (Amendment) Order 2016.

5. Extent and Territorial Application

5.1 This instrument extends to all of the United Kingdom.

5.2 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

What is being done and why

7.1 From 20 May 2016, in accordance with EU Directive (2014/40/EU) (the Tobacco Products Directive), MHRA will be operating a statutory, electronic, notification scheme for any manufacturers, importers or sellers who wish to assemble or re-brand imported e-cigarette products for the UK market. The MHRA scheme is a direct transposition of the EU Directive, without gold plating, and provides a regulatory framework to assure the safety and quality of e-cigarettes and refill containers of nicotine-containing liquid that make no medical claim. MHRA has been designated to carry out the functions of the Competent Authority for the provisions of the revised EU TPD, on behalf of the Secretary of State for Health. MHRA is introducing new fees to recover the costs of operating this scheme.

7.2 Total costs for the first year are estimated to be approximately £2m based on an anticipated volume (manufacturers, importers and traders who will apply) of approximately 14000. MHRA is aiming to keep costs (and therefore fees) as low as possible, including through the avoidance of gold plating.

7.3 To recover the cost of the scheme, MHRA is introducing a notification fee of £150, a modification fee of £80 and an on-going periodic fee of £60 payable by 1 April every year.

7.4 Government policy is that the costs of measures taken in the TPD (processing notifications, maintenance of the website and supervisory functions) should be recovered by fees from the industry. MHRA is a Government Trading Fund and operates on a full cost recovery basis. MHRA reviews its fees and costs each year to ensure that charges reflect an efficient use of its resources and operational expenditure.

7.5 This instrument introduces new fees in relation to obligations under TPD. The fees apply to persons who manufacture, import and assemble and/or re-brand and then trade e-liquids and e-cigarette hardware on the UK market and will cover notification via the EU Product Registration portal, supervisory functions (post-marketing vigilance) and annual maintenance charges in respect of the website.

7.6 Prior to the revised TPD there was no EU-wide regulatory framework to assure the safety and quality of e-cigarettes that make no medical claim. Notifications will be submitted via a common EU Product Registration Portal and all e-cigarettes already on the market on 20 May 16 (which is the date from which the TPD will apply) will need to be notified within six months to the Competent Authority following that date. After 20 May 16, manufacturers and importers will be required to notify their product six months before they want to place it on the market, though any new product notified on 20 May 16 can be placed on the market at any point over the following six months.

7.7 Producers will have to notify each product, including each different strength/flavour combination or a substantial modification of an existing product.

8. Consultation outcome

8.1 Following Department of Health and Her Majesty's Treasury agreement to the proposals, a three week public consultation exercise was carried out (with Ministerial agreement). Consultation feedback was that the MHRA had potentially underestimated the size of the market and that fees were too great. Opinion was mostly against the imposition of the fees as proposed at consultation.

8.2 In total, 102 responses to the consultation were received by the closing date, including 90 substantive ones, representing a range of organisations including manufacturers, importers and distributors/retailers and some representative associations. 68 respondents were against the proposals, the smaller businesses being almost universally against the proposals for fees, citing underestimation of the size of the market and large operating costs such as toxicology tests, in combination with the notification fees, against small profit margins. There were also several members of the public/consumers who responded individually and were mostly against the fees (or any form of regulation at all upon the industry).

8.3 In some cases the opinions were based on misconceptions about the way in which the fees were to be charged. Many thought that retailers who purely re-sold e-cigarette products would also be charged notification fees. This is incorrect unless the retailer wishes to either re-brand another company's product, imports directly from a foreign manufacturer or assembles e-cigarette products themselves. MHRA sent out clarification on this and other areas of uncertainty before the final week of the consultation and responded on an ad-hoc basis to other queries to help enable respondents to understand better the position before responding.

8.4 Four respondents agreed with the proposals, 14 more agreed in principle but expressed concerns about the impact and 4 others provided data or information but expressed no opinion. Among those who were supportive in principle were Action on Smoking and Health (ASH) and the Royal College of Nursing.

8.5 The consultation asked respondents whether they had a preference for a fixed fee instead of being charged per notification. Most respondents did not express an opinion

and, of the few that did, opinion was mixed. The fee therefore will remain on a per notification basis.

8.6 New information was provided at consultation that previous volume estimates had been too low. Based on calculations and estimates provided by industry and trade associations, it is now estimated that MHRA may expect as many as 14,000 notifications in the first year (20 May 16 to 31 Mar 17). This is the median number of notifications based upon a set of the most credible data and estimates, accounting for possible attrition in the first year (products on the market before the coming into force of the new regulations that will be taken off the market in Year 1). This means that MHRA is able to adjust the fees to a lower level from that proposed in the consultation. As a result, fees will now have a lower impact upon small businesses who are trading legitimately in products that meet EU safety standards under the TPD, and also upon the consumers to whom some or all of this cost may have been passed on. It is also likely to have a lower impact upon the variety of products available to ex-smokers or those wishing to quit.

8.7 MHRA aims to charge businesses fees equal to the cost of services they have received. In line with Managing Public Money principles MHRA will not require businesses or the taxpayer to subsidise the cost of the notification scheme for another business.

9. Guidance

9.1 Guidance and information regarding the notification scheme and fees payable will be made available on the MHRA website prior to the commencement of the scheme.

10. Impact

10.1 Several smaller businesses expressed concern that the fees were disproportionate and, when calculated across their product range, could reduce the viability of their business. The revised fees are hoped to ease this burden but there will inevitably be some impact. It is anticipated that some smaller businesses might revert to retailing only their most popular products in order to save money on notifications, thus having a potentially downward effect on innovation, and the number of new products becoming available, at least from these smaller producers. It is assessed that the impact of this legislation on charity or voluntary sector bodies is nil.

10.2 The EU Directive makes it clear that these products must be notified. For MHRA there is no current alternative to cost recovery through fees in order to fund this work. The MHRA has made the best estimate it can with the data available, but relatively little is known about the likely behaviour of this new market following the coming into force of the new regulations. MHRA will therefore work together with the industry going forward in order to ensure the fees remain fair and proportionate.

10.3 As the full cost of undertaking this activity will be funded through fee income, there will be no impact on the public sector. Any delay in implementing the fees legislation would result in MHRA undertaking the activity without cost recovery. This would potentially result in cross subsidisation from other areas of its business in order to fund the work.

10.4 An Impact Assessment is submitted with this memorandum and will be published alongside the Explanatory Memorandum on the legislation.gov.uk website.

11. Regulating small business

11.1 The legislation applies to activities that are undertaken by small business.

11.2 It is recognised that although regulatory fees are likely to represent a greater proportion of outgoings for smaller businesses than for larger businesses. The fees are likely to have a greater impact on small or micro businesses with very low turnovers or profit margins. The lower level of fees (compared to that proposed in the consultation) will reduce this impact.

11.3 MHRA is not offering a discounted small business rate as this would lead to cross-subsidisation from increased fees paid by other e-cigarette producers, the pharmaceutical industry or the Taxpayer.

12. Monitoring & review

12.1 The level and structure of fees charged by MHRA for e-cigarette products will be reviewed annually.

13. Contact

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