Medicines & Healthcare products Regulatory Agency

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United Kingdom

Government response to the consultation on statutory fees for producers of e-cigarette products

Produced by Medicines and Healthcare products Regulatory Agency

CPRD NIBSC MHRA

1. The Medicines and Healthcare products Regulatory Agency (MHRA) received 102 responses to its consultation on new fees to cover regulatory activity relating to E-cigarette products under the provisions of the revised EU Tobacco Products Directive (2014/40/EU). Of these, 90 were substantive responses offering opinion or information; the remainder were requests for clarification.

2. The largest group of respondents were small e-cigarette/vaping businesses and the trade associations that represent them; however responses were also received from e-cigarette users, the public, the Royal College of Nursing and Action on Smoking and Health (ASH). Two responses were also received from larger tobacco companies.

3. Of the 90 substantive responses:

    a) 68 respondents (76%) were against the proposals

    b) 4 respondents (4%) agreed with the proposals

    c) 14 respondents (16%) agreed in principle with the charging of fees but expressed concerns about the impact

    d) 4 respondents (4%) provided data or information but did not express an opinion and are judged to be of neutral opinion.

4. 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 currently on the market that will be taken off the market in Year 1). However there remains uncertainty in both this revised volume estimate and the way in which the market will behave following the implementation of the Directive.

5. The consultation asked whether respondents would prefer a fixed fee for a set number of substantial modifications to be added to the periodic fee instead of being charged per substantial modification. Most respondents did not express an opinion and of the small number that did, the feeling was mixed. No new evidence was provided to demonstrate that this would be proportionate and the assumption remains therefore that this would penalise smaller businesses for the larger numbers of substantial modifications made by others. The fee for notifying a substantial modification and the periodic fee will remain therefore separate

and businesses will be charged according to the number of substantial modifications they wish to make. Suggestions of a sliding scale of fees based on turnover, or discounts for multiple applications were also discounted for this reason: they would result in some businesses paying higher costs to subsidise others paying lower costs.

6. Based on the new higher volume estimates provided by industry the fees as proposed at consultation are judged to be high and could run the risk of over recovery against costs. Using the new volume estimate, along with an appreciation of the remaining significant uncertainty, it has been possible to reduce the fees as follows:

Fee Description	**Proposed fee (revised following consultation)** **£**
Initial Notification fee	**150**
Notification (Modification) fee	**80**
Annual (Periodic) fee	**60**

7. Pre-consultation, the proposed fees had been set at £220, £110 and £60 respectively.

8. It is Government policy to recharge costs of regulating e-cigarettes back to the e-cigarette industry and MHRA may not cross-subsidise this work from the taxpayer or other business sectors. However the fees will be reviewed annually to ensure that MHRA's costs relating to the regulation of e-cigarettes continue to be recovered in a fair and proportionate way. Due to the remaining significant uncertainty both in the volumes and the fixed technology costs required to connect to the EU Portal for notifying e-cigarette products, the volume of notifications received in Year 1 and the costs will be reviewed, with upward or downward adjustments to fees being made as necessary in following years to ensure neither under- or over-recovery of costs. This will be done through working with the industry as well as through the use of real data on volumes of notifications being submitted to MHRA.

9. A number of respondents were concerned that as retailers or direct resellers the notification fees would apply to them. They do not, but if a retailer rebrands another company's product, imports directly from a foreign manufacturer or assembles e-cigarette products themselves, they become a producer and must notify their products under the Directive, thereby becoming liable to pay the appropriate fees.

10. Several smaller businesses expressed concern that the fees were disproportionate and when calculated across their product range could reduce the viability of their business. While MHRA

must recover its costs, the new reduced fees will now have a lower impact upon small businesses which are trading legitimately in products that meet EU safety standards, 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. MHRA will continue to work with the sector with the aim of ensuring a fair and proportionate fee regime, both in its structure and cost, that best reflects the sector as it develops.

11. Those expressing an opinion on whether the fees represent ‘gold plating’ of the EU Tobacco Products Directive (two respondents) agree that MHRA has not gold plated the Directive. Others who agreed in principle mostly felt that MHRA had kept the fees as low as possible, but that the volumes had been underestimated. This has now been rectified with the new lower fee based on a higher estimate of notification volumes.

12. MHRA thanks all respondents for their contributions and intends to proceed with legislation to implement the new fees.

13. Annex A contains a list of companies and organisations that responded to the consultation. Annex B comprises a revised Impact Assessment for the new fees.

Medicines and Healthcare products Regulatory Agency

April 2016

ANNEX A

LIST OF RESPONDENTS: COMPANIES AND ORGANISATIONS[1]

Action on Smoking and Health (ASH)
Adcentiv Media Retail Ltd t/a VapourOhm
Alauna Vapour Store
British American Tobacco UK
Broughton Laboratories
Cartridgecom Ltd t/a Vape Monster
CGChemX Ltd
Channel 2015
Chemular Regulatory Consultants
CloudStix
Concept Liquids
Cuts Ice
Decadent Vapours Ltd
ECITA (EU) Ltd
EECBA
Eos Leisure Ltd t/a Vapemate
eShisha Club
Evapo
Fontem Ventures
FRESH Imports 2015
Freshmist E-liquid Manufacturer Ltd
Generals Juices Ltd
Go Vapour UK Ltd
Green Vape Ltd
Ice Vapour
Independent British Vape Trade Association (IBVTA)
JCVAPE
JTI UK
Kick Ash Luxury Vapes
Lee Vapours Ltd
Liberty Flights Ltd
Lime-IT Ltd t/a Crème de Vape
Lonjas UK
Lumoliquids
Madvapes UK Ltd
Nicogreen Ltd

[1] Individual citizens who responded directly, including those who told us they ran an e-cigarette business but did not indicate its name, are not included in this list. Their responses were still included in the analysis.

Nictel (UK) Ltd
Queen Mary University of London
RITCHY EU s.r.o.
Smokijoes
SMOKO
The Ace of Vapez
The Royal College of Nursing
The Vapour Loft Ltd
TJDM Services
Tor Vapour
Totally Wicked Ltd
Valley Vapes
Vape Club
Vape Compliance Ltd
Vape Importers Ltd
Vape Nation
Vapeiteasy.net
VaperCrew eLiquids Ltd
Vapers In Power
Vapes Direct Ltd
Vapourium Ltd
V-juice Corporation
WhiteMist Eliquid Ltd
Wild Juice Chase
Xyfil Ltd
ZD Vapes