

Medicine and Healthcare Products Regulatory Agency Consultation

E-Cigarette Fees

Response from Action on Smoking and Health

About ASH

1. ASH is a health charity set up by the Royal College of Physicians in 1971, working towards the elimination of harm caused by tobacco. ASH receives core funding from the British Heart Foundation and Cancer Research UK and has received project funding from the Department of Health for work to support delivery of the Government's tobacco strategy for England. ASH does not have any direct or indirect links to, or receive funding from, the tobacco industry.

General Observations

2. Our approach to the regulation of electronic cigarettes, and any consequent fees or costs to producers and sellers of these products, is based on our assessment of the evidence of the risks of using these products, on who is likely to use them, and on whether they are likely to contribute to a reduction in smoking prevalence.
3. The latest ASH estimate is that there are about 2.6 million adults in Great Britain using electronic cigarettes.¹ Of these, approximately 1.1 million are ex-smokers while 1.4 million continue to use tobacco alongside their electronic cigarette use. Regular use of the devices is confined to current and ex-smokers and use amongst never smokers remains negligible.
4. We note that a review of the evidence commissioned by Public Health England (PHE) in 2014 found that the hazard associated with electronic cigarette products currently on the market *"is likely to be extremely low, and certainly much lower than smoking"*.² Other reviews have reached similar conclusions, with one putting the risks of vaping at less than 5% of the risks of smoking,³ and another concluding that *"Electronic cigarette [EC] aerosol can contain some of the toxicants present in tobacco smoke but at levels which are much lower. Long term health effects of EC use are unknown but compared with cigarettes, EC are likely to be much less, if at all, harmful to users or bystanders."*⁴
5. Following the publication of some reports suggesting that electronic cigarettes may pose greater risks than previously thought, PHE commissioned a further expert independent evidence review. This review also concluded that electronic cigarettes, when used as intended, are significantly less harmful than smoking.⁵ The review notes that most of the chemicals causing smoking-related disease are absent in electronic cigarettes and the chemicals that are present pose little danger. Alongside publication of the review, PHE issued a statement noting that while not risk free, electronic cigarettes carry a fraction of the risk of smoking cigarettes and have the potential to help smokers quit smoking.⁶
6. Therefore, ASH believes that regulatory policy and practice in relation to electronic cigarettes should:
 - Discourage their use by people who have never smoked and by children
 - While ensuring that accurate and up to date advice is available to current smokers of any risks from these products, make their use as part of attempts by smokers to quit their habit both easy and affordable.

ASH therefore believes that regulatory costs to producers and sellers, including the cost of obtaining Notifications for placing e-cigarettes on the UK market, should be kept as low as reasonably possible. We welcome the general approach of this consultation document, which can be summarised as setting fees at the lowest possible level consistent with covering the costs of the MHRA in processing Notifications and in subsequent vigilance work. We agree with the proposition in paragraph 5 of the consultation document that *“the MHRA scheme is a direct transposition of the EU Directive, without gold plating”*, and consider this to be the correct approach.

Specific Consultation Questions

Level of Fees (Questions 1 and 3)

7. ASH supports the proposed fee levels but notes that these may need to be adjusted after implementation to reflect the actual costs to MHRA of administering Notifications and conducting vigilance work. Nielsen ScanTrack data suggests that the e-cigarette market in the UK was worth over £400 million in 2014, and grew by 13% during 2015.⁷ We therefore do not consider the proposed fee levels to be excessive.

Fixed Fees and Modifications (Question 2)

8. ASH suggests that the fee arrangements should reflect the actual characteristics of the e-cigarette market. Absent relevant regulatory intervention, it is likely that this will include the development of brand identities in the following way (derived from the tobacco industry’s use of branding for cigarettes, and more generally from the use of branding for a wide range of consumer products):
 - A brand is launched, with either no or a small number of variants
 - That brand identity is subsequently “stretched” to include a wider number of variants. (The existing brand identity gives the new variants a competitive advantage.)
9. In the case of electronic cigarettes, variants are likely to be introduced in respect of both nicotine content and flavourings, both of which have potential public health implications and should therefore require Notification in each case. In the case of nicotine content, it is likely that a range of content for e-liquids could assist smokers seeking to quit, as they might progress from higher to lower nicotine products and then to giving up nicotine use altogether. Given consumer loyalty to brands, this process might be encouraged most effectively if these products were grouped under the same brand identity.
10. It is therefore suggested that, in order both to reduce regulatory costs to producers and sellers and to maximise the potential public health benefits of switching from smoked tobacco to e cigarettes, the Notification process should encourage the inclusion of brand variants in the initial Notification, payable through a single initial fee, rather than requiring repeat payments for each brand variant. We recognise that this approach might mean some changes to the current suggested fee structure, in order to cover MHRA’s costs.
11. ASH considers that flavourings do require monitoring, as it is possible that any particular substance used to impart flavourings to electronic cigarettes might pose a potential health risk. Therefore, we consider that variations in products in relation to flavourings should require specific Notification and Modification fees. Again, we suggest that different flavourings under the same generic brand identity could form part of a single original Notification. We also suggest that MHRA should specifically consider how use of

different flavourings in notified products should subsequently be monitored as part of vigilance work.

Volume Estimates (Questions 4 and 5)

12. Such information as ASH currently has about electronic cigarette use and about the size of the electronic cigarette market in the UK is summarised in paragraphs 1 to 7 of this consultation response. As previously stated, we agree that the MHRA should charge the minimum level of fees required to cover its cost.

¹ Calculations by ASH. As part of annual Smokefree Britain surveys commissioned by ASH and conducted by YouGov, questions on electronic cigarette use have been included since 2010. Using the findings of the YouGov surveys and applying these to the most recent population data ASH has applied the proportions of electronic cigarette use by smoking status in the 2015 YouGov survey to the most recent available ONS mid-year GB population estimates (2013).

² Britton, J. and I. Bogdanovica, Electronic cigarettes: A report commissioned by Public Health England. London: Public Health England, 2014.

³ Nutt, D.J., et al. Estimating the harms of nicotine-containing products using the MCDA approach. European Addiction Research, 2014; 20(5): 218-225.

⁴ Hajek. P et al. Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. Addiction 2014; 109(11): 1801-1810.

⁵ McNeill A et al. E-cigarettes: an evidence update. A report commissioned by Public Health England. PHE, 2015

<https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>

⁶ E-cigarettes: a new foundation for evidence-based policy and practice. Public Health England, 2015 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/454517/E-cigarettes_a_firm_foundation_for_evidence_based_policy_and_practice.pdf

⁷ Nielsen ScanTrack data cited in Convenience Store, 25 Sept. 2015 (p30)