Executive summary

- Our organization has worked with the regulation of the e-cigarette category since 2014, and its principal was involved in the legislative procedures as a paid lobbyist for the e-cigarette industry.

- We believe that the relevant Regulations have some positive aspects that could be maintained and enhanced:
  - Requiring transparency, quality and safety assurances from market participants is a positive step.
  - This can be built upon through agreed technical standards, enhanced enforcement and clarifications from the regulator that close loopholes that have been exploited to bring inappropriate products to market.

- However, much of the current regulatory regime is arbitrary and restricts the potential of the category to further the public health objective of reducing smoking prevalence in the United Kingdom.

- These restrictions reduce the innovative potential of the category, hit the most addicted smokers hardest, and allow the dissemination of misinformation about relative risks without substantive public challenge. They include:
  - A nicotine limit of 20mg/ml, which is far too low for the most hardened smokers
  - Restrictions on bottle and tank sizes to 10ml and 2ml respectively.
  - A prohibition on all but the most antiquated and least effective marketing and promotion.

- We believe that these restrictions should be repealed at the earliest opportunity with more proportionate safeguards put in their place where necessary.

Recommendations summary

- Repeal of the 20mg/ml limit contained in the Tobacco and Related Product Regulations is the single action that could be taken that would bring the most benefit to smokers. This limit discriminates against the most hardened and addicted smokers. It limits innovation by effectively prohibiting the development of smaller, simpler devices that can deliver nicotine at the same rate as larger, more complex devices.

- Repeal of the 10ml limit on refill container sizes, while not as transformational as repeal of the nicotine limit, would reduce prices and eliminate imbalances in the market.
caused by the rise of “short fill” products, which are designed to circumvent sensible requirements related to transparency, quality and safety of products on the market.

- “Short fill” product should immediately be regulated under the Regulations without delay – this can be done without any legislative change and so doing would, at a stroke, remove inappropriate products from the market.

- A structured enforcement regime, funded by contributions that e-cigarette producers make to MHRA through notification fees, would incentivize producers to improve products that are submitted and increase the understanding of government about the category.

Introduction

I am delighted to respond to the call for written evidence on electronic cigarettes issued by the Parliamentary Science and Technology Committee on behalf of Beckett Associates.

Before I (Peter Beckett) started the firm, I was Head of Public Policy at the Electronic Cigarette Industry Trade Association. I was responsible for that Association’s public policy function during the passage of the Tobacco Products Directive in 2013/14; and for its implementation in the UK. My firm’s Scientific Advisor is Dr Monica Vialpando, a pharmaceutical development scientist who was responsible for research and development at one of the UK’s largest e-cigarette manufacturing and distribution companies.

As our organization is focused on helping e-cigarette companies with regulations, this submission will focus primarily on the impact of regulation on the sector in the United Kingdom. We will not repeat at length the compelling public health arguments regarding e-cigarettes and the health of smokers. These have been made by numerous other organisations (such as the Royal College of Physicians and Cancer Research UK) and individuals (such as Professor Peter Hajek and Clive Bates) that are far better placed to comment on such matters than us. We simply observe that, in our view, robust yet proportionate regulation of the sector should seek to achieve the greatest possible migration of smokers to electronic cigarettes and ensure the continued diversity of the category while minimizing potential risks.

Our suggestions in this paper are actions that we believe can be taken in a regulatory context to help achieve this objective.

The Tobacco and Related Products Regulations (2016)

The Tobacco and Related Product Regulations (TRPR) transposes EU Directive 2014/40 (the Tobacco Products Directive, or TPD). It is the over-arching regulatory framework for e-cigarettes in the United Kingdom. The UK Government made a conscious and welcome effort
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not to gold-plate the Directive during its passage into UK law; and, as such, the Regulations are an almost exact mirror of the Directive.

The rules on electronic cigarettes (Parts 6-7 of the Regulation) can – conceptually at least – be divided into two pillars: sensible requirements on transparency, quality and safety; and arbitrary nonsense resulting from an imperfect legislative procedure at EU level. We will address these in turn, suggesting short and medium-term solutions to problems where practical:

a. **Sensible requirements for producers to notify the Secretary of State of the products they intend to sell, how they are made, what goes into them and what comes out of them; and to take responsibility for their quality and safety.**

While the Regulations themselves are poorly drafted, the EU Expert Committee on Tobacco and MHRA have provided useful guidance notes for producers. The net effect of the legislation and guidance is that the following documentation be submitted for each product:

- A full list of ingredients at the molecular level.
- Toxicological data justifying the inclusion of those ingredients.
- Emissions (or vapour) test results.
- A description of the production process.
- A declaration that manufacturers accept liability for safety issues.

While broadly a helpful regulatory tool, the process lacks uniformity due to no standards being agreed. However, these are currently being discussed by stakeholders within the framework of the European Centre for Standardization (CEN) and we encourage the Committee to engage with lead players in this process. We are happy to make the necessary introductions.

The current notification process could be improved going forward, by:

i. **A structured enforcement regime**

While producers notify their products to the Secretary of State (for practical purposes, the Medicines and Healthcare Products Regulatory Authority); enforcement on the ground is the responsibility of Trading Standards. This leads to a postcode lottery. This issue must be resolved if the Regulations are to improve the quality of products for adult smokers. We note the submission from the Independent British Vape Trade Association in this regard:
• Trading Standards have only actioned just over half of reports received nationally from businesses and consumers regarding non-compliant vaping products.
• Only 36.8 per cent of local authorities surveyed have actioned every one of the reports of vaping non-compliance they have received.
• 40.6 per cent of local authorities have carried out no investigations into non-compliance.
• When surveyed only 43.5 per cent of IBVTA members had been contacted by their local Trading Standards officer prior to or following the full implementation of TRPR.
• On average IBVTA members have seen a 24 per cent reduction in business since the TRPR came into force, causing some businesses to close.

We cannot help but agree with the conclusions of IBVTA on this issue:

*If “doing the right thing” is not to become a disincentive, as well as a competitive disadvantage, it is vital that these regulations are enforced.*

The industry is likely to be happy to – and indeed likely already has – invested time and resources into bringing non-compliant products to the attention of Trading Standards Officers; and it is high time that Trading Standards took action.

In order to take such action, resources are needed. This should be readily available: MHRA has so far received 40,000 notifications under the Regulations, each subject to a £150 fee and a £60 annual maintenance charge. MHRA have thus far used some of this surplus to relieve manufacturers and importers of some of the future fee burdens. We believe that money raised from this exercise should instead be dedicated to ‘on the ground’ enforcement, including analytical testing of products (including refill containers without nicotine). We would ask the Committee to request that MHRA account for how this money has been spent, or will be spent in the future.

**SUGGESTED ACTION:** MHRA to use notifications fees to fund Trading Standards’ enforcement of the Regulations and instigate a structured programme of product testing to ensure that the Regulations are adhered to. Science and Technology Committee to investigate current use of these resources in an open and transparent way.

ii. **Guidance requiring all eliquid designed for use with nicotine, whether nicotine containing or not, to be notified to the Secretary of State**
An unforeseen issue has arisen in the implementation of the Regulations due to non-nicotine containing liquid for use in an e-cigarette not being expressly covered under the definitions. This, combined with the requirement for 10ml bottles, has led to the unintended rise of an unregulated grey market in non-nicotine containing eliquid being sold with the express purpose of the customer adding their own nicotine. These are sold in the form of highly concentrated “short fill” bottles, which are 60ml bottles that contain 50ml of eliquid and significantly higher concentrations of flavouring substances. The consumer then mixes this with a 10ml bottle of unflavoured eliquid with a concentration of 18mg/ml (a nicotine “shot”). This is popular with a number of consumers because it reduces the cost of vaping.

This problem has arisen because the Regulations require 10ml bottles and we do not feel comfortable arguing for a system where consumers are forced to pay higher prices because of rushed and inflexible legislation. However, it is in the interests of safety that “short fills” meet the same transparency, quality and safety requirements as any other electronic cigarette. Other organisations responding to this consultation, such as BMSW Ltd and the UK Vaping Industry Association, have conducted testing on such products and found them to contain substances that are banned in e-cigarettes and refill containers containing nicotine.

We understand that changing the Regulations to remove the 10ml limit, while by far the most desirable course of action, is difficult at this moment given the current political timetable. We therefore propose a solution that would keep “short fill” on the market while ensuring their quality and not requiring a change in the Regulations.

While MHRA have so far considered that “short-fills” are outside the scope of the Regulations, we believe that such activity does fall within the scope of the Regulations as they stand and would like to see the Government enforce this requirements for products where it is obvious that nicotine is intended to be added. We note that that [MHRA guidance on product types](#) advises the following:

> From the definition of electronic cigarette and refill container it follows that the TPD is only applicable to electronic cigarettes that contain nicotine or can be used with a nicotine-containing liquid.

It is clear to us that “short fill” products are clearly intended for use with nicotine containing liquid and that therefore MHRA should be requiring that they be subject to the same controls on notification, ingredients, testing and quality that apply to nicotine-containing e-cigarettes.
SUGGESTED ACTION: MHRA should urgently issue guidance clarifying that “short fill” products – bottles of unflavoured liquid that are clearly intended to be mixed with nicotine – are regulated under the Regulations.

b. Incomprehensible and arbitrary nonsense that restricts the capacity of the product category to better public health by reducing the scope for innovation, curtails product choices (particularly for the heaviest smokers) and leaves misinformation unchallenged.

Other than the sensible measures detailed above, the Regulations are largely negative and give rise to significant public health challenges. Arbitrary restrictions on the size of refill containers, tanks and a very low cap on nicotine content have no basis in science and we have never heard a coherent defence of them by anyone, including the European Commission officials that drafted them.

i. Reducing the scope for innovation and curtailing product choice

The TRPR requires that e-cigarettes contain a maximum nicotine concentration of 20mg/ml. The limit has severely restricted innovation in the efficacy of smaller devices that are likely to appeal to older and more traditional smokers. Where a device is smaller and operates at lower power ranges, it is unable to produce a high vapour density from the liquid being vapourized. As such, it needs to have a higher concentration of nicotine in order to deliver a comparable dose. Given how low the upper limit of 20mg/ml is, a floor is put on innovation on minimizing devices. Smaller, simpler devices with higher nicotine concentrations are known to appeal to the more hardened older smoker with a lower tolerance for technology.

The 20mg/ml figure was reached by the EU institutions as part of the last-minute compromise that gave birth to TPD. Part of the justification for this was that, according to a study cited by the Commission, this was more or less the same as the nicotine one gets from a cigarette. The author of that study, Dr Konstantinos Farsalinos, immediately rebuked the Commission for misappropriating his research, instead claiming was that it actually showed that 20mg/ml was equivalent to about one-third of a cigarette.

This makes it difficult for e-cigarettes to compete with their combustible counterparts when it comes to nicotine delivery; nicotine limits for most tobacco products are non-existent, and where they do exist (for cigarettes and hand rolling tobacco) that limit is 1mg/stick (roughly equivalent to 10 inhalations) in mainstream smoke (i.e. the smoke that is inhaled). This is much higher than the nicotine levels contained in the vapour of any e-cigarette we have ever had tested (around 500 to date). In short, the dangerous product (cigarettes) is allowed to deliver much more nicotine than the less dangerous product (e-
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cigarettes). This puts heavy smokers – those at most risk of disease – at a disadvantage when trying to quit using an e-cigarette.

**SUGGESTED ACTION:** The Government should use the first opportunity it has to remove this requirement for electronic cigarettes sold in the United Kingdom. No limit is required other than that provided for in the Poisons Act.

The Regulation also limits bottles of eliquid to 10ml in volume tanks to 2ml. These pointless restrictions were another result of the last-minute inter-institutional horse trading at EU level that led to the TPD being passed. They serve no purpose from a safety perspective and many vapers see this as regulatory spite handed down by a European Commission angry that Parliament rejected its initial proposal to prohibit the entire category. I have never seen a viable justification for these restrictions other than the dynamics of an inter-institutional negotiation where one party (the European Council, backed by the Commission) wanted to restrict the products legally available as much as they could.

2ml tanks limit even further the ability of product designers to make more effective products for smokers and bottle size restrictions have led to multiple problems.

Bottle size restrictions also have the undesirable effect of making vaping more expensive, which is crucial given how many smokers are motivated to switch by the cost differential. It has also led to the issue of a grey market in “short fills” as described above. And in an age where we are trying to rid ourselves of plastic bags and water bottles, the Regulation mandates the manufacture of tens of millions of tiny plastic bottles that cannot be refilled (under EU rules the nozzle must be securely fixed) and must be thrown away after use.

**SUGGESTED ACTION:** The Government should use the first opportunity it has to remove this requirement for electronic cigarettes sold in the United Kingdom. No limit is justified from a public health perspective.

**ii. Leaving misinformation unchallenged**

The Government, industry and major anti-smoking charities rightly complain about the level of misinformation about e-cigarettes in the public domain: only 13% of adults can correctly identify that e-cigarette use is much less dangerous than smoking. This alarming degree of public misunderstanding is fueled by media coverage of headline-friendly studies that focus on the risks of vaping but do not convey a balanced picture in relation to the risk of vaping in relation to smoking.
This has substantive public health consequences: if a smoker believes that there is no difference, why switch?

Electronic cigarette companies would like to be able to help combat misinformation, but they are prevented from doing so by undue restriction on what they can say and where they can say it. The Regulations forbid them from making comparative claims on their packaging and they cannot claim that their products help smokers to quit.

The Committee on Advertising Practice does appear to have recognized this problem and is working to provide e-cigarette companies with leeway within the Regulations; for example by permitting comparative claims on advertising if they are justified. However, the fact remains that while it is at least possible to convey some positive messages on harm reduction, companies have very few channels through which they can convey these messages, as they can only utilize display advertising and a number of antiquated forms of marketing such as direct mail (the CAP even suggests that advertisements delivered by fax are legal) and cinema advertising, which has limited reach and potential in conveying messages about reduced risk.

Prior to the Regulations, the Committee on Advertising Practice worked closely with industry to produce guidelines for e-cigarette advertising that worked well and were fit for purpose.

**SUGGESTED ACTION:** Regulations prohibiting e-cigarette advertising should be repealed and that the 2014 CAP guidance should be re-instated as the relevant regulatory instrument.

*January 2018*