Testing of E-cigarette liquids or "vaping" liquids

Thank you for your letter of 16 January about the Science and Technology Committee enquiry on e-cigarettes. Please accept my sincere apologies for the delay in our response.

As you know, the MHRA is the Competent Authority for a notification scheme for e-cigarette and refill container (e-liquid) consumer products under the Tobacco and Related Products Regulations 2016 (TRPR) which implement the EU Tobacco Products Directive 2014/14/EU (TPD) in the UK.

Non-nicotine containing vaping liquids

Your first question relates to the notification of vaping liquid products that do not contain nicotine (referred to as short fills or zeros). Short fill products are base flavour e-liquids, to which nicotine can be added by the consumer using a notified nicotine shot. These products offer consumers the option to purchase e-liquid products in larger bottles, typically 30-50ml. The short fill market reduces costs for producers, as the only products requiring notification with the agency are the 10ml nicotine shots.

“Electronic cigarette” and “refill container” are defined in regulation 2 of the UK Tobacco and related Products Regulations 2016 (TRPR), reflecting the definitions used in the TPD. The definitions are as follows:

"electronic cigarette" means a product that—

a. can be used for the consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank (regardless of whether the product is disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges); and

b. is not a medicinal product or medical device;"

“refill container” means a receptacle that—

a. contains a nicotine-containing liquid, which can be used to refill an electronic cigarette; and

b. is not a medicinal product or medical device;"

Thus, refill containers (e-liquids) are defined separately to e-cigarette products and do not currently fall within the definition of an e-cigarette component (accessory). The definition of a refill container excludes products that do not contain nicotine when sold.

Producers of e-liquid products that do not contain nicotine when sold are therefore not required to submit a notification for the product and are not subject to other TRPR requirements such as the 10ml volume restriction. These products continue to be regulated under the General Product Safety Regulations (GPSR).

The Government consulted on the implementation of the Directive in 2015 and wanted to ensure its implementation was proportionate. Industry responses at that time showed support for regulation of short-fill products prior to implementation.

In late 2017, we were approached by members of industry and asked to consider a voluntary system of notification of non-nicotine containing vaping products via the EU Common Entry Gate (EU-CEG) portal. This approach demonstrated that a large proportion of the industry support the regulation of these products in line with the requirements of the TRPR.

The Agency has not undertaken a formal evaluation of introducing a requirement to notify non-nicotine containing vaping products. Although a system of voluntary notification could be seen as improving consumer safety, in the absence of any legal obligation for producers under the TRPR, it is likely that it would also cause confusion for consumers, sections of the
industry and enforcers as well as having the potential to create an unfair commercial advantage for those choosing to notify products.

The Agency is aware of concern in the industry that products that do not contain nicotine when sold could potentially include harmful ingredients as they do not fall under scope TRPR. MHRA is collaborating with the Department of Health and Public Health England, who are carrying out research into the safety of e-cigarette products. Together with the compliance work undertaken by Trading Standards and trade bodies, this research will provide clearer view of the risks of these products.

**Notified products**

Secondly, you ask about the notification process and numbers of e-cigarette products.

There were completed notifications for 33,758 products, comprising 30,831 e-liquid products and 2,927 e-cigarettes, on our published list up to 31 January 2018. The remainder are either incomplete and still being processed for publication or are notified products that have subsequently been withdrawn by the producer. For the reporting period of 2017/18 we have so far received 2,956 submissions for e-cigarettes and 10,916 for refill container products.

At the time of establishing the scheme, we were uncertain as to how many notifications we would receive and in establishing a fee regime, recognised this would need to be carefully reviewed in the light of experience. To date the agency has received more than double our original projected notifications.

We have therefore received more income than expected. Although our costs have also increased to handle the additional volume, we have calculated that the income from the initial notification fee will be sufficient to cover the costs of running the modification and safety surveillance schemes for 2017/18 and 2018/19.

We operate on a cost recovery basis and have therefore decided not to charge producers the annual fee of £60 due for each notification before April 2019. We have also not charged the substantial modification fee since it has proved easier than expected to process these changes. In effect this means that the single £150 notification fee covers both the initial processing, publishing and checking for completeness of a new notification and also the ongoing costs of updating notifications and safety surveillance through the Yellow Card scheme for 2017/18 and 2018/19. The revenue generated from the initial notification fee for these products amounts to £5.34 million.

We have committed to review regularly the fees in the light of the numbers of products received and costs. It is likely that revenue from notification fees will decrease substantially in the coming years, due to market innovation and the rise in popularity of short fill liquids.

**Checking and vigilance procedures**

As mentioned above, it is the role of the Agency to process notifications submitted via the EU-CEG portal to ensure that the data provided by producers meets the requirements of the TRPR. This process is carried out weekly and includes manual sampling of notification data to check that the information present includes submitter safety declarations, emissions test data, product and ingredient information and that the size and strength limits in the TRPR are not exceeded. If a submission does not meet the requirements for publication we will carry out further checks of the submitter’s notifications and enter into communication in order to assist them in achieving compliance.
Notification data is stored and checked using the EU-CEG portal. The portal has limited functionality, however recent improvements have enhanced our ability to check notifications for information. This process is ongoing with submitter outcomes considered on a case by case basis. Where appropriate data is shared with relevant partner agencies and products may be subject to removal from the UK published list of notified products.

Turning to post-market vigilance work, consumers and healthcare professionals can report side effects and safety concerns with e-cigarettes and e-liquids through the Yellow Card reporting system. We also accept reports on products that do not contain nicotine when sold to ensure they are received by the appropriate Trading Standards authority. Our vigilance team reviews all reports to identify any new safety concerns. If a concern is identified, we work with manufacturers to identify any ingredients of concern in their products and with Trading Standards to take any further action necessary.

The Agency has received 39 Yellow Card reports of adverse reactions with e-cigarettes since the legislation came into effect. The reports generally include reactions which are either known side effects of nicotine replacement therapy or expected reactions taking into consideration the demographic of patients using e-cigarettes (current or former smokers). The majority of the reports are for respiratory type reactions (including cough, dyspnoea), or gastrointestinal problems including nausea and vomiting.

No evidence of new risks has been identified as a result of the Yellow Card data collected so far.

We have referred over 60 complaints to Trading Standards and have corresponded and collaborate with them on a number including complaints of high strength nicotine selling to consumers (72mg/ml) and an e-liquid being presented as a food product. We have had 7 product quality complaints which have been shared with Trading Standards and 5 reports of physical product safety concerns. These were mostly isolated incidents and although shared with Trading Standards, we did not see any patterns of concern emerging. Additionally, we have referred complaints of non-compliance on a number of products to eBay and Amazon, which has resulted in the removal of listings.

Finally, under the regulations, producers of vaping products take responsibility for the safety and quality of their products under expected conditions of use. They must have a system for collecting information about all of the suspected adverse effects on human health of products and regularly review this information. If they have reason to believe that a product is unsafe, not of good quality or not compliant with the regulations, they must immediately inform the Agency and take appropriate corrective action. This may include modifying or withdrawing the product if a risk to health is identified or recalling product from the market should this be necessary.

Responsibility for enforcement is shared with Trading Standards bodies and we are working with local authorities to ensure retailers adhere to the requirements of the regulations. We are currently working with the Department of Health and Social Care and the Chartered Trading Standards Institute to deliver a programme of work intended to provide a clearer picture of compliance within the retail sector. We do not undertake testing of notified products but are supporting work undertaken by Trading Standards. We will continue to work with partner agencies such as Trading Standards in order to establish robust intelligence sharing and multi-agency intervention against those businesses failing to comply with the requirements of the regulations.

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