# Call for evidence on tobacco and vapes

# Action on Smoking and Health (ASH) response

**Declaration of interests:** ASH receives funding for its full programme of work from the British Heart Foundation and Cancer Research UK. We do not have any links with the tobacco industry or any other commercial organisations.

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# Vape and nicotine flavours and ingredients

Do you have evidence to provide on flavours, ingredients and substances, nicotine limits or heavy metals within vaping and nicotine products?

Yes

## Flavours in vapes and nicotine products

Please provide evidence on how vape flavours are currently created. For example, the number of different substances typically used to create a flavour or the strength of such substances. (Optional, maximum 500 words)

There are currently hundreds of vape flavours on the market using thousands of ingredients. Analysis of the UK Tobacco Products Directive (TPD) notifications was undertaken by Nottingham University of the 2016–17 data and looked at 40,785 products. They reported a mean of 17 ingredients per product (includes solvents, nicotine and flavourings). The most common flavouring substances listed were ethyl butyrate (42%), vanillin (35%) and ethyl maltol (33%).<sup>1</sup>

Chemical analyses of commercial refill fluids show wide variation in the number of flavour chemicals per bottle, from 1 up to 50.<sup>2</sup> A variety of studies have assessed the concentration of flavours in liquids also finding heterogeneity.<sup>3</sup>

There is therefore a great deal of complexity in what makes up flavours. This is illustrated by the assessment by the Dutch agency RIVM, which has categorised flavours into a 'flavour wheel' assessing 7500 individual flavours and categorising them into 13 main categories with 90 sub-categories.<sup>4</sup>

ASH research on flavour preferences has found a big shift over time away from tobacco flavours and towards fruit flavours, which are now the most popular flavours. Ten years ago, in 2015, 38% of adult vapers used tobacco flavours, this is now 11% in 2025. Meanwhile fruit flavours have gone from 25% of vapers to 51%. Regulations that seek to reverse this preference among adult vapers could risk undermining a key aspect of product appeal.

A secondary analysis of trial data looking at vaping products for smoking cessation found no conclusive evidence that any particular flavour was associated with improved quit success but did note that people using vapes to quit smoking switch between different flavours, presumably to identify which flavour they prefer. It may be important for there to be a range of flavours on the market for vapes to act as effective cessation tools.

Please provide evidence of any flavours, ingredients or substances within vapes or nicotine products that could pose health risks and that we should consider when developing regulations. For example, risks associated with regulators, binders and sweeteners. (Optional, maximum 500 words)

Ingredients could pose a health risk either through their impact on the body or through increasing appeal/addictiveness among non-smokers who would otherwise not have vaped.

The evidence that vaping is less harmful than smoking<sup>6</sup> is important. If other approaches, such as marketing restrictions, can reduce the numbers of non-smokers who vape then the purpose of regulating ingredients must be to improve safety for those switching, and care is needed to avoid driving them back to smoking.

#### Direct impact on human health

While there is an established body of evidence on the impact of vapes in general on human health, the evidence on specific ingredients is more limited. There is limited assessment of:

- which ingredients/concentrations impact human health
- the impact of inhalation and heating
- whether there is an effect of ingredients in combination with each other and with nicotine.

The Committee on Toxicity noted that this was a gap in the evidence in their statement in 2020. Their 'Framework for Risk Assessing Flavours' provides an approach for reviewing flavours and should be utilised in further research.<sup>7</sup> This framework also provides a way of assessing new ingredients and could be integrated into registration requirements.

Some ingredients may be concerning to health and should be prioritised for scrutiny:

 Aldehyde flavourings (e.g. cinnamaldehyde in "cinnamon"): linked to cytotoxic and irritant effects in vitro and animal studies; the OHID 2022 review flags cinnamaldehyde for regulatory review. RCP's 2024 report also summarises adverse effects.<sup>8</sup>

- Sweeteners (e.g. sucralose): heating sucralose with PG/VG can generate chloropropanols and elevate carbonyls in aerosol, compounds of toxicological concern.<sup>910</sup>
- Synthetic coolants: increasingly used to deliver a strong cooling hit (often in non-menthol flavours); inhalation data are limited and some exposure estimates may be harmful but more research is needed.<sup>11</sup> 12

When regulating ingredients, the risks of reduced appeal to smokers or alternative, riskier ingredients being substituted for banned ingredients must be considered.

There are some ingredients where there may be cause for concern, but regulations may have a greater risk of unintended consequences. Nicotine salts and acid "regulators" increase smoothness of vapes and emerging evidence shows they can deliver high nicotine efficiently. 13 14 15 While this may pose risks for youth uptake, it is also likely to make products more effective for smoking cessation. 16

#### Role of flavours in appeal

Flavours clearly play a role in the appeal of vapes for both adults and children. Efforts to limit flavours to protect children have a high chance of impacting on adult behaviour too. This trade-off will need to be carefully considered.

It is difficult to identify flavours that appeal to adults but do not appeal to youth. For example, the most popular flavours are fruit flavours for both groups (51% adult, 59% youth). The one flavour category that youth are more likely to use than adults is chocolate/dessert/candy flavours which 17% of youth report using compared to 9% of adults. If restrictions were being considered this category might pose fewer risks for adult smoking, but further assessment is needed. <sup>17</sup>

Please provide evidence on what gives vape liquid a colour, and what risks there might be by restricting vape liquid to a clear colour. (Optional, maximum 500 words)

We do not have evidence specifically on this matter. However, we can see the merit of restricting the colour of liquid that could otherwise be use as a marketing tool so long as it does not have implications for the safety or effectiveness of products. Rather than require clear liquids government could consider placing restrictions on flavour colours e.g. nothing that is iridescent, in bright colours such as pink, green, blue or red.

Please provide evidence of effective strategies and methods to limit the flavours in vapes and nicotine products. (Optional, maximum 500 words)

The evidence of the impact of flavour bans from other jurisdictions is mixed and in some of the jurisdictions most similar to the UK market, such as the Netherlands, evaluation of the impact of the policy is still very limited.

A summary of the evidence is set out below:

- In the US individual states and cities have implemented flavour restrictions. This does not prevent purchases across state lines but does increase the barriers to accessing flavoured vapes. Evaluations of these restrictions show significant variation in impact. Most find reduced vaping, despite poor compliance, and some also find increased smoking. 18 19 20 21 22
- The Netherlands implemented a national ban on vape flavours in 2024. They have a list of ingredients that can be used in products, limited to a small number of flavours. Early government evaluation found ~40% reduced vaping and ~22% quit vaping among surveyed users after the flavour ban. However, among those who have stopped vaping, 9% took up smoking and 13% smoked cigarettes more often. Initial insights also indicate significant challenges with cross-border and online sales. Other countries in the EU are considering following the Dutch model including Belgium.
- In Canada, state by state restrictions are in place which vary in nature with the intention to bring in federal restrictions in due course. The impact of these restrictions has started to be assessed with mixed insights. Findings from one study looking at sales data in Canada suggests that flavour bans in some states led to a 9.6% increase in cigarette sales there are criticisms of this study and whether it is a valid measure of impact given that it does not capture all vaping and tobacco sales.<sup>25</sup> The ITC survey which assess self-reported behaviours does not find the same impact on smoking but does find a reduction in vaping across all groups including youth.<sup>26</sup> However, the ITC data also indicates that compliance and cross-border sales are a major issue.

Much of the evidence from other jurisdictions indicate that flavour bans tend to lower vaping even in a context where compliance with the law is poor. Both Canada and the US have seen declines in youth vaping following flavour and other restrictions. However, the public-health net effect hinges on whether combustible smoking rises (among youth or adults who would otherwise vape), given smoking's much higher absolute risk. From the current available evidence, it is not possible to be confident that flavour restrictions in the UK would not lead to increases in smoking. Breaches of the law are also common even in the context of whole country restrictions such as the Netherlands. Flavour restrictions should be pursued with caution and consideration for what action is needed to mitigate risks.

Please provide evidence on the presence of heavy metals in vape liquids and nicotine products and any associated risks. (Optional, maximum 500 words)

There is substantial evidence that heavy metals can be found in vape liquids. This appears to be linked to interaction between liquids and devices.<sup>27</sup>

The primary causes for the presence of metals appears to be from product components. Heating coils and electrical joints contain metals which can corrode and release metals into the liquid and then the aerosol.<sup>28</sup> It is possible that mandatory standards on these components could reduce metals.<sup>29</sup>

#### **Nicotine**

We are seeking to better understand the nicotine content and absorption rates in nicotine products, such as nicotine pouches, including the risks and benefits which may occur at specific strengths.

Please provide evidence on how nicotine or other substances in nicotine products are absorbed by the user. You may wish to consider the risks and benefits of the amount of nicotine absorbed and the speed at which it is absorbed. (Optional, maximum 500 words)

There are a variety of different factors which influence the way in which nicotine is absorbed. Some of this is about the type of product e.g. smoked products deliver nicotine swiftly at high peaks, NRT delivers nicotine more slowly and at lower peaks. Other relevant factors are the composition of the product, how the product is used, and how experienced or addicted the user is.

### 1. Product Type

Different delivery systems influence how much nicotine is absorbed ("bioavailability") and how fast it reaches the bloodstream.

- Combustible cigarettes: Nicotine from a smoked cigarette is absorbed very rapidly via the lungs. One early study found that arterial nicotine peaked in regular smokers within minutes of inhalation.<sup>30</sup> Since inhalation goes straight into pulmonary circulation, absorption is very efficient.
- Vapes: The amount and rate of nicotine absorption depends heavily on device type the aerosol generation, nicotine concentration, and the user's puffing behaviour. A pooled review concluded that absorption from ecigarettes is influenced by device + liquid + user technique.<sup>31</sup>
- Oral / buccal nicotine products (e.g. nicotine pouches, lozenges, gum):
   Absorption is slower because the nicotine must cross the mucosal tissue (or be swallowed) and often undergoes partial first-pass metabolism.
- Patches: These deliver nicotine steadily via the skin, resulting in much slower onset (hours) and lower peaks, intended for sustained baseline rather than rapid spike.

### 2. Nicotine Type and Chemistry

The chemical form of nicotine, its pH/ionisation, and other formulation factors affect how easily it crosses biological membranes.

- Freebase nicotine: This is the "traditional" form used in many e-liquids and tobacco smoke. It has a higher pH, which can make inhalation harsher, particularly at higher concentrations.
- Nicotine salts (protonated nicotine, often combined with an acid such as benzoic or lactic acid): These lower pH and reduce throat-irritation, making inhalation smoother, and may allow higher concentrations or faster uptake.<sup>6</sup>

## 3. User Experience & Behaviour

How the person uses the product – their inhalation technique, frequency, device settings, and their physiology/tolerance – plays a major role in actual absorption.

- Puffing topography: Volume of each puff, duration, number of puffs, inter-puff interval. Longer, deeper puffs deliver more aerosol to the lung alveoli (higher surface area) and thus more efficient absorption.
- Depth of inhalation / breath-hold: Deeper inhalation leads to more delivery to alveolar region rather than just upper airway.<sup>32</sup>
- User's experience and adaptation: Experienced users often "self-titrate" (adjust puffing to achieve desired nicotine levels). New users may absorb less because of less efficient technique.<sup>33</sup>

There are pros and cons of different types of nicotine delivery. Delivery which most closely resembles smoking may make it easier for smokers already addicted to switch but create greater risks that uninitiated nicotine users develop a dependence. Conversely the risk of low-nicotine delivery modes, such as NRT, are that they are insufficient substitutes for those highly addicted. This may have particular implications for disadvantaged groups where smoking rates are highest. In any regulatory model there will be a trade-off.

Please provide evidence or information on the impacts on businesses from having to adjust manufacturing or operating practices to meet new regulatory changes, such as those set out in this section of the call for evidence document. (Optional, maximum 500 words)

There is good reason to think that businesses can easily adapt to regulatory changes in the vaping category. Manufacturing of the global vape category is concentrated in China. There is a high level of expertise in adapting products to the different regulatory contexts globally. Analysis of the manufacturing process in China by academics and the University of Waterloo indicates that product design to shipping of a new vape design is a 30 day process.<sup>34</sup>

Evidence of this is clear from the pace of change around vape devices when new rules were introduced to require products to be reusable and rechargeable. Near identical products were rapidly bought to market which met these requirements at very similar price points to the previous single-use products.

It seems likely that the technical challenges of clearly articulated changes to product composition should be straightforward for manufacturers to implement.

They also appear unlikely to be unduly costly in the context of the significant profits in the vape category. The University of Edinburgh undertook an analysis of profit margins among small convenience stores in September 2019 and 2022. In these retail settings, profit margins from vapes were around 37% in 2022. It is likely that manufacturers' margins are even greater than this, suggesting the ability to manage changes.

While it may be reasonable to expect that businesses could swiftly comply with changes to product requirements it is important that regulations are proportionate and easy to enforce to maximise compliance.

For example, over the last couple of years there was consumer demand for so called 'big puff' products. Some consumers wanted products that contained more than 2mls of e-liquid and initially these were only available illegally. While their availability was as a result of gaps in enforcement the solution came from innovation in the legal market where products were redesigned to meet both consumer demand and regulations. When products were legally available consumers switched to them.

As product regulations are developed the government must be mindful that sufficient enforcement is in place, careful that regulations that restrict products are necessary and that regulations cannot be 'got around' through creative design.

Regulators need to find a balance between appropriate regulations to reduce youth appeal and maintain product safety and fundamentally damaging the utility and appeal of vapes to adult smokers. As noted elsewhere this is probably best achieved by targeting promotional aspects rather than product design and contents in the first instance.

Please provide evidence on whether the limits on nicotine levels in nicotine vapes should be re-assessed, or if the current maximum limit of 20mg per ml is sufficient. (Optional, maximum 500 words)

The view of members of the SFAC and UK E-Cigarette Research Forum is that the current nicotine level is appropriate.<sup>36</sup> The majority of current adult vapers (84%) report using nicotine strengths within the legal limit and only 2.4% report using above legal limits (the remainder don't know but are likely to be using legal products). Just under a third of vapers report they have reduced their strength over time (30%). This indicates that the current level is broadly appropriate for the vast majority of users.

If you have any other evidence on flavours, ingredients or emissions for vaping products and nicotine products, please include it here. For example, you may wish to consider the risks to oral health when using nicotine pouches. (Optional, maximum 500 words)

It is vital that government proceed quickly with regulating promotional elements on vapes and how flavours are marketed as a first step as this is less complex than regulating ingredients and less likely to have unintended consequences on adult users.

ASH has held discussions with a wide variety of experts in the UK and abroad in preparing for this call for evidence submission. In our view the government should commission further expert assessment to inform the development of regulations in this complex area. There remain a number of key questions that still need to be answered and for which the evidence may be incomplete.

If the Government decides to progress with bans on specific flavours it will further need to understand:

- What is the intended policy goal for banning flavours, how and when will it be assessed and what action could be taken if this goal is missed?
- What are the criteria for banning some flavours and keeping others?
- How to ensure alternative, more harmful ingredients are not introduced as regulations are applied
- How to mitigate any risks of returning to smoking
- How to limit the use of illegal products
- What testing regime is needed to ensure compliance and how this can be funded

There is significant uncertainty around the impact of prohibiting some ingredients or flavours. For example, whether alternative ingredients<sup>37</sup> are more or less safe or the impact of flavour restrictions on behaviours. The UK needs to ensure it has sufficient evaluation and monitoring capacity and the scope to flex regulations in light of unintended consequences or changing context.

In addition, the government should commission further specific work to assess an appropriate limit on nicotine for nicotine pouches and assess whether further ingredients restrictions could improve product safety while not damaging product appeal as a cessation tool. These products have rapidly grown in awareness and uptake with limited restrictions. A more standardised approach to strengths will likely improve the usability of these products for cessation.

## Tobacco flavours and accessories

We are seeking evidence to better understand the impact that flavoured tobacco products and accessories have on tobacco consumption. We are also seeking evidence on whether introducing or amending legislation is necessary.

Do you have evidence to provide on tobacco flavourings or tobacco accessories?

Yes

Please provide evidence on the effectiveness of banning characterising flavours for cigarettes and hand-rolled tobacco on reducing tobacco consumption. (Optional, maximum 500 words)

Evidence from post-ban evaluations in Great Britain indicates that characterising-flavour bans *can* reduce use of menthol cigarettes – especially among young people and in areas with effective implementation – but the current regulations have significant gaps.

A population-based survey of adults in Great Britain (2020–2023) found that after the May 2020 menthol flavour ban, menthol cigarette smoking among all adults who smoke remained common (about 16% at baseline, with little overall decline). However, menthol use fell significantly among 18–24-year-olds. This suggests the ban reduced consumption of menthol cigarettes in key groups where flavours are particularly important to product appeal and initiation, but other, probably more addicted smokers, found ways to continue smoking menthol tobacco. Most menthol smokers' purchases remained from legal sources, with relatively low cross-border and illicit purchasing and no evidence that illicit supply was driving overall persistence of menthol use.

At the same time, sensory and chemical testing of cigarettes sold in England in 2021–2022 found that 4 of 16 tested brands still had clear menthol/mint characterising odour and detectable menthol-related chemicals, indicating non-compliance with the ban.<sup>39</sup> Several other products showed discordance between chemical content and perceived characterising flavours, highlighting how subjective flavour definitions and permissive additive rules allow products to retain cooling or fruity properties while formally claiming compliance. The authors conclude that more stringent policies, such as outright bans on menthol and other minty flavourings and on non-essential additives, would provide clearer rules and likely be more effective in removing these products' appeal.

For the government to ascertain that a cigarette does contain a characterising flavour, it currently requires detailed chemical analysis as well as the opinion of an expert user panel which has to be convened each time. This is both costly and time-consuming. Even having established that a flavour is present, any ruling is subject to industry challenge and further delay.

At the same time, the industry can effectively circumnavigate the current regulations by withdrawing products under review and replaced them with a similar product with only minimal changes to formulation/naming. Thereby starting the investigation timetable anew.

In addition to the concerns about cigarettes that still have menthol flavouring, there has also been an increase in use of cigarillos, which can still be sold with flavours, and other products which can legally impart flavour to tobacco such as flavoured filters.

Characterising-flavour bans can reduce menthol cigarette use. However, the gaps in the current regulations that allow flavour accessories, flavoured cigarillos and flavour-creating additives leave substantial menthol-like products on the market, limiting the impact on tobacco consumption. Extending bans to all flavours and additives is likely to achieve greater and more equitable reductions in flavoured tobacco use and, over time, overall smoking.

Tobacco companies found to be in regular breach of the characterising flavour ban should be subject to fines, as opposed to the current sanctions which effectively amount to a removal of the offending product(s).

# Please provide evidence on the use of ingredients that give cigarettes or handrolled tobacco a particular flavour or sensation. (Optional, maximum 500 words)

Manufacturers use a wide range of additives to create or enhance flavours, sweetness, cooling, or smoothness. These additives serve no functional manufacturing purpose and are designed to modify the smoker's behaviour and smoking experience.

Flavour and sensation-modifying agents influence the sensory profile of cigarettes and RYO tobacco, additives can modify harshness, aroma, sweetness, and inhalation ease even when used at concentrations too low to trigger a characterising flavour. These are well established in the literature, for example menthol and related cooling additives alter the sensory experience of smoking through well-defined physiological mechanisms. Menthol activates cold-sensing TRPM8 receptors, producing a cooling effect even at very low concentrations. It also desensitises irritant pathways (including TRPA1 and TRPV1), which reduces the perceived harshness of smoke and masks irritation caused by nicotine and combustion products, making smoke feel smoother and easier to inhale. Synthetic cooling agents such as WS-3 can recreate strong cooling sensations without producing a menthol aroma, and there is evidence from the US that manufacturers have substituted menthol with WS-3 in response to flavour bans. Ingredients including sugars, sugar derivatives, glycerol, propylene glycol, cocoa, liquorice and triacetin contribute sweetness, creaminess and reduced harshness and modify taste and mouthfeel.

A characterising flavour is defined by TPD and TRPR as "a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or combination of additives, including but not limited to fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during consumption." The legislation does not specify sensory thresholds or maximum allowable levels of menthol or other sensory modifiers, and there is no consensus within sensory science on what constitutes "clearly noticeable." This creates a regulatory environment where ingredients can alter the sensory experience of smoking without meeting the legal definition of a characterising flavour.

An analysis conducted by the Nicotine Research Group at King's College London examined 20 cigarette products sold after the characterising flavour ban. Menthol was detected above the quantification limit in seven products. Analogues of menthol, menthone, isomenthol, isopulegol, pulegone, methyl salicylate, eucalyptol, piperitone, WS coolants were below the quantification limit. Two additives were clearly detectable in all products: Dihydroxyacetone (cooling and sweet taste), Triacetin (creamy/sweet, and also a filter plasticiser). These additives are not required for manufacturing; their function is to modify taste, mask harshness, and increase palatability. An odour assessment with an untrained panel of 50 adult smokers detected a noticeable menthol odour in four products. The panel also detected fruit like odours in six products, confectionary like odours in one product, and sweet or cooling odours in several others.

A key finding was the discordance between chemical presence and sensory detection. Some additives were detected chemically but did not reach the sensory threshold defined by the characterising flavour test. Others produced a sensory experience despite low measured concentrations. This highlights a significant limitation of the current regulatory approach: the perceptibility-based definition allows manufacturers to use additives strategically to influence sensory experience while remaining technically compliant.

Please provide evidence on how the use of flavours for other tobacco products (such as heated tobacco, shisha or chewing tobacco) impacts tobacco consumption. (Optional, maximum 500 words)

Currently flavours are banned in cigarettes and handrolled tobacco but not in other tobacco products. This should be addressed. Cigarillos have grown in appeal among young people, <sup>43</sup> likely linked to menthol products still being available in colourful non-standardised packaging, at low prices, and in 10- packs. It is notable that JTI recently bought a new flavoured cigarillo product to market. <sup>44</sup>

Shisha and oral tobacco products are also subject to fewer regulations to restrict flavours and packaging than cigarettes and hand rolled tobacco. It is likely that the inclusion of flavours in products like shisha undermines understanding that these are

harmful tobacco products. The impact of continued use of these tobacco products is concentrated in some ethnic groups in the UK exacerbating inequalities.

One qualitative study of cigar/cigarillo, shisha, and chewing tobacco users found that flavours were an important part of the appeal of cigarillos and shisha. Cigar/cigarillos user: "I felt like regular cigars are more harsh than cigarillos and I like that cigarillos have flavours. The regular cigar taste, I'm not really a fan." Shisha user: "Yeah, we've got loads of different flavours that we're collecting. So yeah, that's fun." Participants also cited the lower price of cigarillos compared to cigarettes and the perception that cigars were seen as cool, especially among men.<sup>45</sup>

Another qualitative study<sup>46</sup> found that flavours play a central role in making shisha appealing to students by creating an experience that feels smooth, pleasant and far removed from cigarette smoking. Participants consistently described the fruit flavours as making the smoke "smell nice" and "like a candy," masking the fact that they were inhaling tobacco and helping them perceive it as less harsh and therefore less harmful. The flavours enhanced relaxation and novelty, with students enjoying the taste as well as producing smoke rings and other playful behaviours that added to the fun. Several noted there would be "no point in smoking if it wasn't flavoured," highlighting how flavour is integral to the product's appeal. The attractive aromas also made shisha more socially acceptable, even to non-smokers who enjoyed the smell, reinforcing the idea that it was benign. Overall, flavours increased the sensory pleasure, reduced perceived risk, and strengthened shisha's social and cultural appeal, contributing directly to its popularity among young people.

Please provide evidence on how the use of flavoured tobacco accessories (for example crush balls and flavoured filters) impacts tobacco consumption. (Optional, maximum 500 words)

Despite the ban on menthol, flavoured filters continue to be sold and marketed as a way to consume tobacco with a menthol flavour, undermining the ban. This is exacerbated by weaker marketing restrictions on filters than on tobacco products, allowing products to be packaged in appealing ways which encourage use. This loophole must be closed.

Please provide evidence or information on the impacts on businesses from having to adjust manufacturing or operating practices to meet new regulatory changes, such as those set out in this section of the call for evidence document. (Optional, maximum 500 words)

When the menthol characterising flavour ban was introduced in the UK in 2020, this followed a 3-year transitional period. In practice, menthol products continued to be notified to the UK market right up until May 2020, as the tobacco industry continued to promote their menthol products until the eve of the ban. Given the current practice of the industry to introduce (and remove) hundreds of new cigarette products/brand

variants each year, with marginal changes to formulation and manufacturing, the issue of such changes isn't around the cost/practicality to the industry but around maintaining competitive advantage over other companies.

The tobacco industry is already required to comply with chemical testing around tar, nicotine and carbon monoxide within their products. Introducing new chemical testing for flavours would result in a small increase in their fees payable to DHSC to fund such testing but would ensure that the current legislation is not just being adhered to in theory, but is being robustly monitored and enforced.

# **Vapes**

#### Size and shape

We are interested in any evidence relating to the size and shape of vapes including:

- how different vape sizes and or shapes appeal to young people
- the potential benefits of introducing maximum or minimum limits
- the potential benefits of standardising size and or shapes

Do you have evidence on the different types of vapes available for purchase particularly regarding their shape and size or the appeal of products to young people?

We recommend prohibiting vapes which are designed to resemble other products, particularly youth-appealing products. This should include cartoon or youth-appealing characters, toys, milk shakes/sweets/candy, USB sticks, highlighters, gaming or other devices, and makeup. While these products do not appear to be widespread in the UK, there are examples of enforcement agencies seizing vapes designed to resemble products which have youth appeal.<sup>47</sup>

In New Zealand, the law states that: "Cartoons and toys cannot be present on vaping and smokeless tobacco products. Those products must not have any feature that depicts cartoons or toys." Manufacturers, importers, distributors and retailers are also prohibited from selling vaping or smokeless tobacco products that have any feature that depict cartoons or toys.

In Canada, the Tobacco and Vaping Products Act prohibits the promotion or sale of a vaping product that has an appearance, shape, or other sensory attribute or a function that could make the product appealing to young persons.<sup>49</sup>

The law should allow manufacturers some flexibility in the shape and size of products, as having a range of different sizes and shapes may be an important part of the appeal of vapes to adult smokers.

#### Tank sizes

The TRPR places requirements on vape tank sizes, limiting device tanks to 2ml and refill tanks to 10ml. Over recent years manufacturers have developed devices where multiple refill tanks are attached to the device itself. The government wants to better understand the current situation, and we need evidence to determine whether tank size limits are effective.

We are interested in evidence relating to vape tank sizes including:

- the effectiveness of current limits
- the optimal capacity for a vape tank
- the benefits and risks of connecting vape refill tanks to the device
- how many refill tanks should be connected to a device at one time

## If you have any evidence on vape tank sizes, please include it here.

The current 2ml limit on tank sizes was introduced via the EU Tobacco Products Directive in 2014 and subsequently transferred into UK law by the Tobacco and Related Products Regulations 2016 (TRPR). The vaping market has evolved significantly since then, and many products now come with a built in 10ml refill tank in addition to a 2ml pre-filled tank. This extends the e-liquid capacity to 12ml while still complying with the TRPR.

There is clear consumer demand for higher capacity products. Data from YouGov commissioned by ASH shows that 44% of adult daily vapers in Great Britain use more than 2ml of liquid a day (as of 2023, the last time this question was asked).<sup>50</sup>

As such, there may be a case for increasing the tank size limit to around 10-12ml to reduce the number of refill containers being discarded and improve the appeal of products as an alternative to smoking. The number of tank size options should be limited (for example, 2ml, 5ml and 10ml) to minimise the risk of tanks being used as a marketing tool for product differentiation.

If the government chooses to maintain the current size limit, we recommend limiting vapes to a single 10ml refill tank to minimise the number of tanks being disposed of. Other jurisdictions such as New Zealand, Australia, Canada and the US do not have federal limits on tank sizes (although some states/provinces have introduced local restrictions). Larger tank sizes do not appear to impact the addictiveness of vapes. The rise in youth vaping in Britain since 2020 appears to have been primarily driven by 2ml single-use vapes – not larger capacity products. One study comparing indicators of vaping dependence among youth in Canada, England, and the US found similar levels of perceived addiction to vapes across the three countries – although Canada's rate was slightly higher. Larger tank sizes would also be better for the environment because they require fewer refill containers.

#### Digital screens

#### Please provide evidence on the role of digital screens on vapes.

# For example, whether there may be benefits or detriments and whether there is a need to place limits on the use of digital screens.

We recommend prohibiting digital screens and other 'smart' features on vapes to minimise the risk of products appealing to children. A limited exception could be made for small screens with information that could impact device safety/usability, such as battery life and heat/wattage.

Digital screens indicating battery levels and wattage are a common feature on vaping products in the UK. Recently, e-cigarette manufacturers have launched a new generation of vaping products known as 'smart vapes', featuring built-in smart technology features and mobile apps. <sup>52</sup> These features do not contribute to the core functionality of vapes and primarily serve to increase product appeal, with evidence of viral TikTok posts featuring smart vapes. <sup>53</sup>

The inclusion of digital screens/smart features in vaping products is unnecessary and opens the door to products which may appeal to children. In October 2024, the US FDA wrote to several vape retailers "for selling and/or distributing unauthorized disposable e-cigarettes with designs and functionalities that resemble smart technology, including phones and gaming devices." The FDA warned that the products are likely to appeal to youth because the designs help to conceal the nature of the products – such as in the case of a vape designed to look like a Game Boy. Many vapes do not have digital screens and removing these is unlikely to significantly impact the user experience for the majority of adult vapers.

There should be a limited exception for small screens showing functional information such as battery life and heat/wattage. Wattage is particularly important information for users as overheating e-liquid can result in potentially harmful emissions.

### Requirement to be child resistant

# Please provide evidence on the effectiveness of child resistant measures on vapes.

The main value of child resistant measures on vapes is likely to be for reducing the risk of poisoning/harmful exposure to e-liquid. Evidence from the 2022 OHID review found that almost all cases of people reporting poisoning from vapes were young children who swallowed e-liquids. There were 2 deaths recorded. Accidental ingestion is the most common cause of nicotine poisoning, although other incidents included getting nicotine in eyes, or skin irritation from handling liquids. The focus of regulation should be to ensure that e-liquid refill containers and tanks are leakproof, have child/tamper resistant caps and packaging.

New Zealand has introduced regulations mandating that vapes sold in New Zealand "require two simultaneous or five sequential actions to activate" and must automatically shut off after 10 minutes of inactivity. Child resistant measures on vapes themselves (e.g. requiring multiple actions to activate a vape) may be effective for preventing very young children from using vapes but is unlikely to present a significant barrier to older children or teenagers.

Adding too much complexity to the use of vapes risks disadvantaging older adults, or those with physical or learning disabilities.

## **Additional information**

Please provide evidence on other elements of a vape that the government should consider regulating and why.

The government should require all vapes to include a quick-release battery to improve recyclability. Vape batteries are often sealed within the devices, meaning that the products must be dismantled by hand and the battery removed so that the other components can be safely recycled. These batteries are often soldered into the product which can make removing them challenging and potentially hazardous. This process could be streamlined if all vapes included a quick-release battery which could be easily removed as in New Zealand. This could also help to extend the life of vaping products by allowing users to replace the battery rather than purchasing a new vape.

The government should limit the maximum wattage on vapes to reduce emissions of harmful chemicals like formaldehyde. The 2024 Royal College of Physicians evidence review of vaping concluded that levels of toxic thermodegradation products (acrolein, formaldehyde and acetaldehyde) are higher in "high power mod devices used with low nicotine concentration liquids, and lower with low power, high nicotine pod devices." One study from 2016 found a steep increase in toxicants at a battery output of 15W and above – corresponding to 200–250 °C on the heating coil. 55

The government should review the composition of vape atomisers and coils to identify materials least likely to produce toxic thermodegradation products. The 2024 RCP review found "wide variation in metal presence and concentration depending on the materials used to construct the device and the coils."

### Heated tobacco devices

We are interested in any evidence relating to the size and shape of heated tobacco devices, including:

- how different heated tobacco devices sizes and or shapes appeal to people
- the potential benefits of introducing maximum or minimum size limits
- the potential benefits of standardising size and/or shapes

#### Size and shape

# Do you have evidence on heated tobacco devices (such as the health impacts and the size shape and appearance of heated tobacco devices)?

Heated tobacco devices (HTPs) should be subject to the same standards and requirements as for all tobacco products. Any regulations which are applied to vaping products to reduce youth appeal should also be applied to HTP devices. Regulation of HTPs should reflect the increased risk of tobacco compared to vapes.

#### **Additional information**

# If you have any other evidence on heated tobacco devices (such as on health impacts and size shape and appearance) please provide it here.

Heated tobacco products are not risk-free and are not currently recommended for smoking cessation by NICE. While it is possible that they expose users to fewer toxins than cigarettes, all tobacco products are harmful to health and heated tobacco products contain many of the same harmful chemicals as combustible tobacco.

HTPs are relatively new to the market, and as a result, there is limited independent research on their long-term health impacts.<sup>56</sup> A recent large independent analysis of the health impacts of heated tobacco products focused on biomarkers of potential harm - biological indicators that signal physical changes or effects within the body.<sup>57</sup> The findings revealed a complex picture: while heated tobacco products showed both potentially harmful and beneficial effects compared to traditional cigarettes, the observed benefits among smokers were inconsistent. The researchers also raised concerns about the methodological rigour of the evidence base. Many of the trials were of short duration and conducted in conditions that do not reflect real-world use. Notably, 29 of the 40 studies included in the review were sponsored or conducted by tobacco companies - organisations with a clear vested interest in demonstrating reduced harm.

# Licensing

## Licensing scheme objectives

We want to ensure that only responsible retailers who do not pose any undue public health or crime risk will be able to have a tobacco and vape licence and sell products to the public. So, we propose that the overarching objectives for the licensing scheme are to:

- Protect public health to ensure that retailers and their practices are not posing any undue or excessive risk to the health of the public, particularly children
- Prevent crime to ensure that retailers do not pose any undue crime risk and that only law-abiding retailers can sell these products to the public

#### Do you agree with the proposed licensing scheme objectives?

Agree

#### Please explain your answer

A public health objective is essential to ensuring that the licensing scheme can be used as a lever to improve public health. However, the wording of the current objective could be improved by changing 'undue and excessive' risk to 'unnecessary' risk. The use of 'undue and excessive' would place the onus on licensing authorities to defend their decisions to limit retailers or availability on grounds that they are preventing undue or excessive risk. Whereas 'unnecessary risk' puts the onus on those seeking licenses to justify why a given risk (e.g. of an additional licence being granted) is 'necessary' for a reasonable purpose e.g. to ensure that communities have reasonable degree of access to vapes/tobacco.

The system should be designed to shift the burden of proof away from licensing authorities making decisions with the intention of protecting public health and onto those seeking licences.

A similar change from 'undue' to 'unnecessary' would improve the wording of the crime objective too – or simply remove 'undue' so that it reads 'ensure that retailers do not pose a crime risk'. Guidance relating to these objectives should emphasise both individual and population health and crime risks.

International evidence indicates that tobacco licensing schemes are more effective when public health is an explicit objective. Hungary's scheme, which is built around public health goals, led to an 85% reduction in tobacco retailers and a 27.6-percentage-point drop in underage sales. However, in countries where the motive for introducing licensing was economic (France, Spain and Italy), there have been none of these impacts.<sup>58</sup> <sup>59</sup>

Evidence from alcohol licensing in England shows that public health teams have limited influence because the Licensing Act 2003 does not include a public health objective. Qualitative evidence shows that public health teams want an explicit objective to strengthen their position. 61

In Scotland, where alcohol licensing includes a public health objective, public health teams report having a clearer mandate to shape decisions. <sup>62</sup> However, interpreting the public health objective has been difficult and vulnerable to legal challenge. <sup>63</sup> This highlights the need for precise wording and strong guidance to support consistent application. <sup>64</sup>

The alcohol licensing system should not be used as a model for delivering on the public health objective, as it does not generally deliver improvements in health or

crime outcomes even where public health teams make considerable efforts to engage with the alcohol licensing system.<sup>65</sup> It is also ineffective at reducing the availability of alcohol – even through measures such as 'overprovision' or cumulative impact assessments.<sup>66</sup> Licence numbers (and therefore availability/outlet density) continue to grow even in areas designated as 'overprovision' or suffering 'cumulative impact'.

There is also evidence that a standalone objective focused on protecting children could strengthen the scheme. Jurisdictions that have achieved public health gains through licensing often cite child protection framing as an important enabler.<sup>59</sup>

An additional objective focused on environmental protection may also be helpful to ensure retailers comply with obligations under WEEE and related regulations.

### **Decision making**

What factors should be taken into consideration when making decisions on the granting of a premises licence? In your answer you may want to consider factors such as the location and density of retailers and whether businesses are fixed or mobile as well as any other factors you consider relevant.

Local authorities should have the ability to limit the number or density of retailers (e.g. per head of the population), as well as the granting of licenses in specified areas (such as near schools). <sup>59</sup> These powers should be backed up by a clear legal framework and national guidance to support implementation.

The agreed licensing objectives should provide the starting point for decision making on granting licences. To assess the impact on public health a range of factors should be considered including the existing level of harm from tobacco in the local area, the level of deprivation. Models similar to the Alcohol Licensing Data Matrix should be developed to guide decision making.<sup>67</sup>

The protection of children from harm should be considered – this might guide decisions around location of tobacco retailers such as considering the proximity to educational settings.<sup>59</sup>

Impact on the community – ensuring that residents are given the opportunity to object to the granting of a new licence. This might include providing templates to support objections, having a named member of staff for people to contact or making the environment less formal and more relaxed.

Licensing authorities should have access to information they might need to make decisions about personal and premises licences, including whether the retailer has not had a licence refused elsewhere – this will require a national database of tobacco and vape licences that should be accessible to local licensing teams.

The tobacco retail license should be linked to the tobacco Track and Trace system. Anyone who applies for a tobacco license must have an Economic Operator ID (EOID) to enable them to legally purchase tobacco for onward sale. Anyone who does not have an EOID should not be eligible for a license and losing the EOID should result in them having their tobacco license removed.

The sale of products which are not registered under the new product registration scheme should be ground to reject/revoke the retail licence.

All retailers should have a policy document in place and agreed with all delivery providers, to ensure that age of sale is checked at point of delivery as well as at point of sale. A copy of the agreed policy must be available for inspection by enforcement officers at any time.

# What factors should be taken into consideration when making decisions on the granting of a personal licence?

Factors to consider in the granting a personal licence should cover:

- Ensuring that the individual is a fit and proper person to supervise sale of the
  relevant products including declaring relevant criminal convictions and providing
  a basic criminal conviction disclosure form, as is the case with alcohol licensing.
  Any convictions or warning letters issued about the sale of any illegal tobacco,
  vapes or nicotine products, or the sale of any products with an age restriction to
  children, or the breach of any offences related to the sale of tobacco vapes and
  nicotine products would bar an individual from applying for a personal license.
- The identity of the applicant should be verified and verifiable with specific contact details provided. Anyone applying for a personal license should declare whether they have been subject to a closure order at any point in the past.
- Ensuring that the person has completed a course and has an accredited qualification, and that this includes information on the harms of tobacco.
- Over 18 years of age.

Should factors affecting decisions on the granting of licences be shaped by local priorities or nationally set criteria, or both? In your answer, please provide examples of criteria that you believe should be set at a national level and any criteria which should be left to local decision making.

The objectives of the licensing scheme should be set at a national level. The interpretation of the objectives through the lens of local priorities should be done at a local level through the setting of regular statements of licensing policy or similar – this should consider local harm and vulnerability, cumulative impact and how the scheme can be used to improve public health in the local context e.g. ensuring retailers are trained on tobacco harms and signposting to local stop smoking services.

Clear guidelines should be set nationally to ensure that there is clarity in the objectives of the scheme, and how they can be interpreted locally. This could include sharing best practice on how the scheme can be used to advance public health goals.

In Scotland the Licensing (Scotland) Act 2005 puts a duty on licensing boards to assess overprovision in their areas and to reject new licences if they deem that granting it would lead to overprovision. This approach could be applied to tobacco and vape licensing by requiring licensing boards to assess the supply of tobacco and nicotine products in their area using local sales and prevalence data. This would allow them to identify when a particular product is being oversupplied and reject any new licence applications (while ensuring that tobacco availability does not exceed that of nicotine products). However – as discussed above – there are significant limitations in the application of overprovision in Scotland which would need to be addressed for tobacco and vapes licensing.

How should licensing authorities reach decisions about whether to grant a licence? In your answer you may want to consider what structures are needed to make decisions as well as the extent to which interested parties should be engaged in the process. Please explain your answer with reference to the operation of existing licensing schemes.

- Licensing decisions should be made within the framework of the licensing objectives.
- Local licensing committees or boards should be established to develop licensing policy and make decisions on the granting of licences. Committees are bound by Article 5.3 of the Framework Convention on Tobacco Control which requires public bodies to protect policy from the tobacco industry guidance to committees should clearly set out how they should implement Article 5.3.
   Members of the board should be trained on these duties and clear guidelines should be developed to cover this and other elements of good governance.
- Local authorities should be able to draw on a national database of information about businesses that have been refused a license in other areas, who have breached the conditions of their license or had a licensed removed.
- Relevant local agencies should be formally consulted on licensing decisions and given the opportunity to object if they feel that granting the licence would contravene an objective.
- There should be opportunity for the public to make representations they should be supported to do this appropriately, and licensing committees should ensure they are open and welcoming to members of the public.
- Tools and guidance should be provided to support people to contribute and to make decisions e.g. alcohol licensing data matrix equivalent and access to a national database of licence holders and rejected licences.

- Decisions should be made with reference to local licensing policy, and other relevant local and national policy such as the local Health and Wellbeing Strategy and Joint Strategic Needs Assessment.
- Licensing committees should include representation from public health, licensing, trading standards, environmental health, waste management, and any other relevant agencies.

If there are any other factors that should be considered in the administration of the licensing scheme, please outline them here. In your answer, you may want to consider transparency of decision-making, requirements to publish information and the process for appealing decisions.

The workings of the licensing committee/board should be transparent and information about decisions should be published and open to scrutiny. Consideration needs to be given to how to prevent decisions being overturned on legal challenge. In Scotland, licensing boards need to provide evidence of a 'causal link' between provision of a licence and alcohol harm – this is regularly used in legal challenge by industry.

We recommend that there are separate licences for tobacco and nicotine products. A combined tobacco and vapes licence would mean that retailers who do not currently sell tobacco but do sell vapes/nicotine pouches, would then be able to sell tobacco, potentially increasing the number of tobacco retailers. Ireland have introduced a tobacco and nicotine inhaling licensing scheme with different fees for the different products. <sup>68</sup> Differential fees could be a way to recognise the differential impact on public health from tobacco and nicotine products.

### **Licensing conditions**

Please outline any examples of licensing conditions which you believe could be imposed on a premises licence to support the objectives of the scheme.

- Conditions imposed should all relate directly to the objectives of the licensing scheme.
- Conditions related to the public health objective could include limits on the types/size of shop, mandatory training in smoking cessation and local support available for licence holders and staff.
- Conditions related to protecting children from harm could include time limits on when tobacco could be sold (e.g. not between 2:30-4:30 to avoid after school hours).
- Conditions could also be varied where tobacco is consumed on the premises, for example shisha or cigars. Local authorities should be able to place additional conditions for the protection of public health and employees.

Please outline any examples of licensing conditions which you believe could be imposed on a personal licence to support the objectives of the scheme.

- A requirement for the personal licence holder to be present on site during certain times (e.g after school hours to monitor potential underage sales).
- A requirement for personal licence holders to relating to maintain their knowledge of the law and smoking cessation/role of other nicotine products.

Please provide your views on which licensing conditions could be determined by local councils, and which conditions should be mandatory for all licence holders.

- As set out previously the general objectives and thorough guidance on how the objectives can be pursued should be set out nationally.
- At a national level, conditions could be set in relation to:
  - The need to comply with environmental regulations
  - Age verification systems and processes
  - Provision of CCTV and to make this available to enforcement officers on request
  - Requirements for relevant documentation to be kept e.g. financial paperwork, refusals logs, training registers and to make this available to enforcement officers on request.
- Examples of local conditions/guidance should be provided nationally.
- Local licensing authorities should have the flexibility to make conditions locally with reference to their local context and policy.

### Licensing fees

What is an appropriate fee structure for premises licences and why is this the case? In your answer, please consider whether fees should vary depending on the type of retailer or other characteristics, such as the size of the business and the products they sell. Please also consider fees under existing schemes.

The fees should be set at a sufficient level to fund the administration and enforcement of the scheme. Fees should be linked to inflation to ensure that the cost of administering the scheme does not outstrip fee levels. For example, alcohol licence fees were set in 2003 and have never been revised, meaning that administration and enforcement is increasingly funded by taxpayers rather than businesses. This could be achieved by mandating that fee levels are reviewed regularly or applying an RPI increase each year. This should be set out in regulations to ensure that fees do not stagnate.

Different fee structures should apply for tobacco and nicotine products to recognise their relative harms e.g. in Ireland there is an annual licence fee of 1,000 euros for tobacco and 800 euros for nicotine products. An additional reduced fee should be considered for settings where vapes are being actively provided as an alternative to

smoking and in support of smoking cessation. This includes healthcare settings, pharmacies and prisons.

The fee structure should factor in the costs to stakeholders from being consulted on licensing decisions. In Scotland, there has been significant investment of public health staff time in responding to consultation on alcohol licensing decisions.

What is an appropriate fee structure for personal licences and why this is the case? In your answer, please consider fees under existing schemes.

Personal licence fees should apply the same principle as premises licence fees; they should cover the full costs of administration and reflect the relative harms of tobacco vs nicotine products.

Please provide your views on whether fees should be set at a national or local level. In your answer, you may want to refer to the operation of existing schemes.

The priority for the fee system should be ensuring that it is cost recovering, enforceable, and is secure from legal challenge. We do not have strong views about whether fees should be set nationally or locally. However, both approaches have pros and cons which should be considered.

### Nationally set fees

#### Pros:

- Creates a level playing field for retailers.
- Simple to administer and enforce.
- Could be linked to inflation in the regulations to ensure that fees enable cost recovery, while also promoting public health.

#### Cons:

- Risk that fees will fail to keep up with inflation (like alcohol licensing fees) if there is no mechanism to increase fees with inflation in the regulations.
- Doesn't account for local/regional differences in costs for retailers and local authorities.

### Locally set fees

#### Pros

- Fees can be linked to the actual cost of administering the scheme in each locality.
- Potentially easier to increase fees with inflation compared to nationally set fees.

#### Cons

- Would create inconsistency across different localities, potentially making enforcement challenging.
- Potentially exposes local authorities to legal challenge if fees are perceived as too high or punitive.

- May require local authorities to spend a disproportionate amount of time deciding on fees and subsequently dealing with any challenges.
- A local fee system based on cost recovery may make it difficult to implement differential fees for tobacco and vape/nicotine product licences.

#### **Duration and renewal of licences**

How long should a licence be granted for? In your answer, please consider both personal and premises licences.

Tobacco and vapes licences should not be granted indefinitely. Instead, they should expire after a period of time at which point the licence holder must renew the licence. This will ensure that retailers understand and continue to live up to their obligations under the scheme. A licence duration of 3 years should be sufficient to ensure the scheme is robust without placing an unreasonable burden on retailers and licensing authorities.

How should the renewal of licences be managed? Please consider the renewal of both personal and premises licences and explain your answer with reference to the operation of existing schemes.

- The renewal process should seek to minimise the administrative burden on retailers where possible.
- Licensing officers should regularly check in on licensed premises to ensure that they are operating in line with the law and the conditions imposed on the licence holder/retailer
- In alcohol licensing people are able to request the review of if they have concerns this should be the case for tobacco and vapes licences

### Online sales licensing

How should a retail licensing scheme be administered for online retailers and compliance monitored? In your answer, you may want to consider whether the approach taken should differ from the approach for physical premises, and/or refer to the operation of existing schemes.

Online retailers should be required to have a licence and should be held to the same standards and conditions as physical premises. New Zealand requires vape outlets to have a bricks and mortar retail premises to sell vaping products to the public. <sup>69</sup> This approach should be applied to online retailers of tobacco and nicotine products in the UK to aid enforcement.

Special consideration should be given to age verification for online retailers as a large proportion of vape sales are online – 39% of adult vapers and 10% of underage vapers buy online according to the 2025 ASH/YouGov Smokefree GB survey. We recommend

that online retailers have a policy document in place and agreed with all delivery providers, to ensure that age of sale is checked at point of delivery as well as at point of sale. A copy of the agreed policy must be available for inspection by enforcement officers at any time.

Longer term, the Government should consider whether online sales of tobacco products should be banned: one of the key recommendations of the Khan review included the following: "introduce a tobacco licence for retailers to limit where tobacco is available. The government should also ban online sales for all tobacco products, ban supermarkets from selling tobacco and freeze the tobacco market to stimulate innovation in tobacco-free alternatives."

### **Exemptions from licensing**

Please provide evidence of any exemptions which you believe are necessary as part of the retail licensing scheme.

There should be no exemptions to the licensing scheme. It is important that everyone involved in the sale of tobacco or non-medicinal nicotine products has been assessed as a fit and proper person and is compliant with licensing conditions.

### Implementing a licensing scheme

How can the licensing scheme be implemented effectively? In your answer, please consider the application process for existing retailers during the implementation of the scheme and whether it should differ from applications after the scheme has been implemented.

The introduction of the scheme needs to find a balance between being robust and administratively simple to apply for and enforce. However, the evidence is clear that previous changes to tobacco regulations have not significantly burdened retailers. A 2022 survey of small retailers commissioned by ASH found that three quarters of UK retailers (76% and 77%) felt that some previous regulations (banning point of sale displays and introducing plain packs) were not a burden or had a positive impact om their business. 81% of retailers supported the introduction of a tobacco licensing scheme. The government should not be deterred from introducing a robust licensing scheme by concerns about the burden on retailers.

We recommend setting up a national database of licences that can be easily accessed locally to allow for cross-checking. A national database also allows national reporting of data from the scheme.

How long is required to implement the licensing scheme? In your answer, please consider the time required, following the introduction of regulations, to set up the scheme as well as the time required for applications to be processed.

A scheme should be introduced as soon as it practically possible and should be in place by the end of this parliament. Other measures in the bill (such as the generational ban) should not be delayed as a result of the licensing scheme.

If there is anything else that should be considered in the implementation of the scheme, please outline it here. In your answer, you may want to consider any support retailers and local councils will require to effectively implement the scheme.

There should be no 'grandfather rights' smoothing of the process for retailers who already have an alcohol licence as this would disadvantage retailers who do not currently sell alcohol (e.g. vape retailers).

Each council should establish a taskforce to oversee implementation, with representation from local licensing officers and enforcement teams as well as other stakeholders in the delivery of the scheme such as public health.

We recommend that HMRC provides local authorities with data on which retailers hold an Economic Operator IDs through the tobacco track and trace system. This will enable councils to scope out how many retailers in their area will need a tobacco retail licence.

### Impact of a licensing scheme

Please provide evidence of the impacts on retailers or any other businesses of implementing a licensing scheme. In your answer, you may want to consider any relevant evidence from the implementation of existing licensing schemes for other products and relevant international examples.

Previous changes to tobacco regulations have not significantly burdened retailers (such as banning point of sale displays and introducing standardised packs). Three quarters of retailers say these have been no burden or had a positive impact. 81% of small convenience retails support the introduction of a tobacco retail licence.<sup>71</sup>

Please provide evidence of potential public health benefits as a result of implementing a licensing scheme. In your answer, you may want to consider any relevant evidence from the implementation of existing licensing schemes for other products and relevant international examples.

Tobacco is a uniquely harmful consumer product that kills up to two in three of lifetime users. There are no other legal products on the market that compare in terms of the harm it causes. However, any type of enterprise can currently sell tobacco, in contrast to other harmful products like alcohol, which require retailers to hold a licence.

A licence is a valuable regulatory tool that allows enforcement agencies to more effectively enforce existing regulations and places tighter controls on the supply chain. A licence for tobacco retailers would support the already effective illicit tobacco

strategy. It will provide an important additional tool to ensure the market for vapes and other nicotine products is controlled, supporting the enforcement of the planned 2026 excise tax on vape liquids and future regulations.

The licensing scheme in Hungary, set up with a strong public health objective, reduced the number of retailers (by 85%) and rate of sales to underage smokers (by 27.6%).<sup>59</sup>

# Registration

Do you have evidence or views to provide on product registration?

Yes

Please provide evidence on the effectiveness or ineffectiveness of the current notification system for tobacco and herbal smoking products. (Optional, maximum 500 words)

The current notification system has several key limitations which the new registration scheme must address:

**Powers** – Under the current system, the competent authority does not have the powers to carry out routine pre- and post-market testing of products, or additional activity to improve compliance. This limitation was demonstrated following the ban on menthol cigarettes, when the government was unable to routinely test products to identify compliance with the ban. This meant that they had to rely on product marketing and brand names to identify non-compliant products. Manufacturers also reported their competitors' products for breaching the ban (for example, BAT wrote<sup>72</sup> to DHSC to report several JTI products). This issue was compounded by a lack of clarity on whether the competent authority could use revenue raised through notification fees to fund product testing. The competent authority must have the powers and funding to carry out pre-and post-market testing.

**Fees** – The current fee level for notifying tobacco products is insufficient to fund the current notification system and will need to be significantly increased for the new registration system. Currently, rolling tobacco is significantly cheaper for manufacturers to notify as is not subject to the annual testing fee of £1,000 (which only applies to cigarettes). The fees for cigarettes, rolling tobacco and all other tobacco products should be equalised to reduce the profitability of non-cigarette tobacco products which are already taxed at a lower rate than factory made cigarettes. The fee level should reflect that tobacco is the most lethal consumer product in existence.

**Notification platform** – The current notification platform requires manufacturers to submit notification information via an excel spreadsheet which then has to be manually transferred to the UK notification system. The new registration system should use a tailored online portal comparable to the equivalent notification platforms in the EU. This

will make the process more efficient and help to reduce the administrative burden on the competent authority.

Gaming the system - Another potential limitation of the notification function is the ability of the tobacco industry to introduce and withdraw products at short notice and repeatedly, in an attempt to undermine enforcement action (e.g. introduction of a menthol ban). This results in the enforcement agencies constantly having to react to the manipulation of the market by tobacco manufacturers and suppliers. One solution would be to limit the number of products able to be notified by one company at a time, and to not allow products (or significantly similar products) to be reintroduced to the market within a pre-defined period.

Please provide evidence on the effectiveness or ineffectiveness of the current notification system for nicotine vaping products. (Optional, maximum 500 words)

The current MHRA notification scheme has several important limitations which the new registration scheme must avoid:

Powers – The MHRA is only authorised to consider whether notified products are in line with the Tobacco and Related Products Regulations 2016 (TRPR) – specifically whether products include any banned ingredients, whether the nicotine strength is legal and the volume of e-liquid in products. The MHRA cannot review compliance with other regulations such as Classification, Labelling and Packaging (CLP) Regulations, food standards regulations, and secondary regulations that will be introduced using powers in the Tobacco and Vapes Bill. This means that products which are compliant with TRPR but not compliant with other regulations can still be notified and published by the MHRA. This creates confusion for retailers and consumers who understandably think 'notified' means compliant, and puts trading standards in a difficult position when they have to seize MHRA-notified products. The competent authority must be authorised to ensure products conform with all relevant regulations and to revoke/refuse registration for non-compliant products.

**Fees** – Currently, manufacturers are only required to pay a one-time notification fee, meaning that they have no incentive to remove old products from the MHRA register. This means that thousands of products which are no longer sold on the UK market are still notified with the MHRA, creating an avoidable administrative burden for the agency. An annual fee would ensure that manufacturers have an incentive to cancel registration for products which they no longer sell.

**Responsible person** – Manufacturers are required to provide a 'responsible person' who can serve as a point of contact and accountability for notified products. However, this system is not sufficiently robust and must be strengthened to ensure that the responsible person is UK-based and is accountable for the products registered in their name.

**Market surveillance** – Pre- and post-market testing is limited by the capacity and resources of the MHRA and its powers. The competent authority must have the powers and resources to carry out pre- and post-market surveillance to ensure products are compliant.

### **Products in scope**

If you have any evidence on the market for the products in scope, please provide it here, specifying which product or products you are referring to. (Optional, maximum 500 words)

#### Heated tobacco

- Findings from the ASH/YouGov Smokefree GB survey show that 3.3% of adults (1.7 million people) have tried heated tobacco products (HTPs), rising to 5% of 18-24 year olds and 6% of 25-39 year olds. Smokers are also more likely to have tried HTPs (14%). Less than 1% (0.7%) of all adults currently use HTPs (400,000 people).<sup>73</sup>
- Current use of heated tobacco has been unchanged since 2017. The proportion
  of adults who have used it in the past but have now stopped has increased
  significantly, from 0.9% in 2017 to 2.6% in 2025.
- Awareness of HTPs is increasing. In 2025, 28% of adults were aware of heated tobacco, compared to 9% in 2017 and 19% in 2024. Awareness is higher among people who smoke (50%). Awareness is also higher in younger adults (18-24 37%, 25-39 36%) compared to those aged 40 and over (23%).
- Among 11–17-year-olds, awareness of heated tobacco has risen from 7.1% in 2022 to 24% in 2025. 0.7% of 11-17 year olds currently use heated tobacco, while 2.7% have tried it.

#### **Nicotine pouches**

- Findings from the 2025 ASH/YouGov Smokefree GB survey show that around 1.1% of adults currently use nicotine pouches, while 6% have tried them. 74 Use of nicotine pouches is on the rise, particularly among younger adults. Between 2023 and 2025, current use among 18 to 34-year-olds increased from 1.2% to 2.6%, compared to just 0.2% among adults over 55. Young men (aged under 40) are nearly three times more likely to use nicotine pouches than women, with 3.5% of men reporting use compared to 1.2% of women. Awareness of these products is increasing. In 2025, 56% of adults were aware of them, compared to 45% in 2023.
- Data from the Smoking Toolkit Study found that nicotine pouch use among 16-24 year olds increased from 0.7% in January 2022 to 4% in March 2025, with no change in those aged 35+.<sup>75</sup>

 According to the ASH survey, nearly 4% (3.8%) of 11-17 year olds say they've tried nicotine pouches, which amounts to approximately 210,000 children. Awareness of nicotine pouches has increased among children 11-17, rising from 38% in 2024 to 43% in 2025.

#### Information requirements

The bill specifies that the regulations may require the following information as part of a product's registration:

- the reasons for an ingredient's inclusion in the product
- images (for example, an image of the product or its label or packaging)
- information relevant to any risks or suspected risks to human health or safety posed by the product
- information about substances released into the body of a person using the product or about the emissions released by the product
- information about the producer's operations
- information about any individual nominated by the producer in accordance with regulations under clause 97 (responsible person)

If there is any other information not listed above that should be required before a product can be registered, please outline it here and explain why this is the case. (Optional, maximum 500 words)

Companies registering vaping products should be required to provide details of which Producer Compliance Scheme they have signed up to for recycling. If a manufacturer fails to provide this information then the registration should be rejected.

#### **Product standards and testing requirements**

Please provide evidence on existing testing regimes and their effectiveness and any testing standards which are used in relation to the products in scope. (Optional, maximum 500 words)

Currently there is no consistency across testing regimes used by various labs who test vaping products. Emissions files provided to MHRA refer to various different units such as ug/puff and ng/mg as well as different testing methods such as GC-FID and ICP-MS which is confusing and makes comparison difficult. The regulations should specify what testing is required and how it should be carried out.

DHSC should provide an approved list of ISO-accredited testing labs in the UK or EU which are suitable for manufacturer testing. Any product testing carried out at labs not on this list should be considered invalid. This is essential to ensure that results from toxicology testing can be easily verified.

Please provide evidence on the most effective point in a product's route to market for testing to be conducted. For example, before registration. (Optional, maximum 500 words)

Testing should be carried out before products are brought to market to ensure that they are compliant and to verify the information provided by manufacturers. However, ongoing market surveillance will be necessary to identify any emerging issues and ensure that the products supplied to consumers match those which are supplied for pre-registration testing.

## Responsible person

Please provide evidence of existing schemes where a 'responsible person' can be nominated to submit information on behalf of an organisation, and their effectiveness. Please also provide any information relating to rules around who is allowed to submit information. (Optional, maximum 500 words)

Manufacturers must be required to designate a responsible person for each product registered. This person must be based in the UK and be accountable for the products registered in their name. They must be able to provide the documents required, within a reasonable time, and be responsible for recording any Yellow Card issues and taking recall action if necessary. Checks will be necessary to ensure that manufacturers provide a valid responsible person. The competent authority must have the power to withhold registration of products from manufacturers who have not listed a responsible person who meets these requirements.

### Notification scheme fees

What fees should be charged for registration and testing of a product? You may refer to the fee regimes for the existing notification systems as a basis. Please provide rationale and any supporting evidence. (Optional, maximum 500 words)

The fee regime for tobacco products should be based on the following objectives:

- (1) Ensuring fees are sufficient to fund a comprehensive registration scheme. The current fee level for notifying tobacco products is insufficient for funding the current notification system and will need to be significantly increased. This should cover the administration of the scheme, pre- and post-market testing, enforcement activity, and activity to improve compliance in the sector.
- (2) Ensuring that fee levels are consistent across all combustible tobacco products. Currently, rolling tobacco is significantly cheaper for manufacturers to notify as is not subject to the annual testing fee of £1,000 (which only applies to cigarettes). The fees for cigarettes, rolling tobacco and all other tobacco products should be equalised to reduce the profitability of non-cigarette tobacco products which are already taxed at a lower rate than factory made cigarettes.

(3) Ensuring that fee levels sufficiently reflect the uniquely lethal nature of tobacco. There is a justifiable cost they should meet for the safe running of the market. Tobacco is a uniquely lethal product which kills 2 in 3 long term users and costs England around £43.7bn a year in public service costs, increased social security spending, and lost economic productivity. Tobacco manufacturers make excessive profits, with Imperial Tobacco making an estimated 70% profit margin on tobacco products in 2021, compared to an average of 10% for UK manufacturing. The fees for registering tobacco products should be increased to reflect the lethality of tobacco to consumers, the financial burden tobacco consumption places on the UK economy and public services, and the excessive profitability of manufacturers. Fees for registering tobacco products should be higher than fees for vaping products to reflect the reduced risk from vaping compared to smoking.

The fee regime for vaping and other non-medicinal nicotine products should be based on the following objectives:

- (1) Ensuring fees are sufficient to fund a comprehensive registration scheme. Fee levels should be sufficient to fund the administration of the registration scheme, including market surveillance and enforcement activity. However, it will be important to keep the fees at a level that does not deter smaller vape retailers from entering the market. This would risk concentrating the market in the hands of a small number of large companies, particularly tobacco manufacturers who use their monopoly status in the tobacco market to manipulate prices and maximise their profits.
- (2) Incentivising manufacturers to keep the registration list up to date. A registration fee should be applied for every individual product registered under the new system, along with the introduction of an annual fee. If a manufacturer fails to renew the fee annually, then the registration for the relevant product should be removed. This will ensure that manufacturers have an incentive to cancel registration for products which they no longer sell in the UK. Currently, manufacturers have no incentive to remove products from the MHRA register, meaning that thousands of products which are no longer on the UK market are still notified with the MHRA.

#### **Enforcement**

How effective or ineffective is the current enforcement regime for ensuring that only notified products are sold in Great Britain and Northern Ireland? (Optional)

Somewhat ineffective

Please provide any evidence to support your view and any recommendations on how enforcement could be improved in the future. For example, on things like sale of unregistered products. (Optional, maximum 500 words)

Registered products must comply with all relevant product regulation and be removed from the register if they are not. The offence of sale or supply of unregistered products should sit with the retailer as well as the producer. Currently, only the producer can currently be prosecuted for non-notification of products. This would incentivise retailers to ensure that they are only selling legal, registered products.

Please provide any additional evidence or views on future registration powers, providing a clear rationale for any views that you offer. (Optional, maximum 500 words)

Future labelling rules should require each product's unique registration number to be printed on its packaging. This would let enforcement officers and others in the supply chain quickly verify a product's status without relying on product names, which are often very similar.

For vaping products, the government should maintain the existing XML notification method to minimise any new system build requirements. The existing EU data dictionary should be maintained and updated to reflect GB or UK specific changes. Maintain the ECID and GBID format to enable the competent authority to continue to work with European member states when required to identify non-compliant products and carry out seizures/recalls as needed.

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