

Response to Independent Review of Smokefree 2030 policies

March 2022

Executive summary

- 1. This submission by British American Tobacco UK (BAT UK) responds to the *Independent Review of Smokefree* 2030 policies.
- 2. BAT UK is a member of the British American Tobacco group (BAT) of companies and is responsible for the importation, distribution and sale of tobacco products, vapour products and tobacco-free oral nicotine products in the UK.
- 3. BAT UK is at the forefront of the development and sale of products that provide an alternative to smoking without burning tobacco. We were the first tobacco manufacturer to launch a vapour product in the UK market back in 2013 and are currently the UK's leading vapour company by sales and share.
- 4. We believe our business focused on these products is making a significant contribution to the UK economy. According to an Oxford Economics report (2021)¹, BAT's direct, indirect, induced and retail operations linked to alternative nicotine products contributed £360 million to UK GDP and supported 7,100 jobs across the UK in 2019.
- 5. Of this, investments in research and development (R&D) at the company's global R&D facility in Southampton accounted for £210 million, which is equivalent to approximately 2% of all R&D investments in the South East of England. BAT was the UK's seventh largest patent applicant to the Patent Cooperation Treaty in 2019, filing more than 170 patent applications relating to new alternative nicotine products.
- 6. Of 2,240 UK-based employees at BAT, 320 are highly skilled specialists working specifically on alternative nicotine products at our company's global R&D facility in Southampton, providing significant employment opportunities in the surrounding area. BAT UK also operates 50 specialist vape retail stores across the country, which employ 220 people.
- 7. Greater consumer choice is at the heart of our strategy, but its effects require amplification from sensible regulations that allow adult consumers to access alternative choices, as well as from public health bodies and the media to drive informed consumer decision making.
- 8. We acknowledge the government's ambition to go 'smoke-free' by 2030. We believe that the key to achieving this ambition is the continued evolution of a range of smoke-free alternative nicotine products which are less risky than traditional combustible tobacco products allowing people to quit smoking. We welcome government's continued inclusion of these products as a core part of its strategy for achieving its smoke-free ambition.

¹ The economic and R&D impact of BAT's alternative nicotine products business, Oxford Economics, 2021

Background

- 1. The UK is an excellent example of where significant public health gains have materialised because of smokefree alternative nicotine products being incorporated into a tobacco control strategy. Major reports have been published by Public Health England (PHE) and the Royal College of Physicians, among others, highlighting the reduced-risk potential of vapour products. This, combined with a progressive approach to regulation and the inclusion of vapour products in several public health cessation programs, has encouraged the vaping category to grow and people to quit smoking.
- 2. Smoking rates in England have dropped by around 5% over the last 5 years to a record low of 13.9% arguably one of the biggest factors driving this reduction has been smokers switching to vaping products.² A large and growing body of UK research has found vapour products to be significantly less risky than smoking and highly effective at helping smokers to quit:
 - a. A study by Queen Mary University, supported by Cancer Research UK, found vaping to be twice as effective as traditional nicotine replacement treatments in helping smokers quit³.
 - b. A study led by University College London, funded by Cancer Research UK found that as the use of vaping products in quit attempts went up from 2011 onwards, so did the success rate of quitting, leading the study to estimate that over 50,000 people could quit each year by using vaping products⁴.
- 3. Through the Tobacco and Related Product Regulation review and following Brexit, the UK has an opportunity to enhance vaping regulation to help accelerate switching from smoking, improve consumer safety, enhance product standards, close regulatory loopholes and to ensure proper compliance with, and enforcement of, existing regulations.
- 4. While the UK's supportive approach to vaping has led to record low smoking rates, more must be done to strengthen consumer safety in the category and encourage more smokers to switch and, ultimately, improve public health and becoming smoke-free by 2030.
- 5. There are 3.6 million vapers in the UK. Of these 1.8 million are ex-smokers, with the remaining being smokers who also vape⁵. The number of smokers switching to vaping has stagnated recently as consumer confidence has been shaken, largely driven by misleading media articles, junk science and concerns over product quality standards, particularly the ingredients used in e-liquids. 53% of smokers believe that vaping is as harmful, or more harmful, than smoking⁶.
- 6. There are still an estimated 6.9 million smokers in the UK. A recent Cancer Research UK report found that at current quit rates, England will not reach its smoke-free target until 2037. To meet the target, quit rates would need to increase by some 40% over the next 10 years⁷.
- 7. Data from Stop Smoking services in England couldn't be clearer about the value of vaping as part of the offer to smokers. The 2021 Public Health England vaping evidence review found:
 - Between April 2019 and March 2020, 221,678 quit dates were set with a stop smoking service and 114,153 (51%) of these led to self-reported quits 4 weeks after the quit date.
 - A vaping product was used in 5.2% of quit attempts. This was either using the vaping product alone, at the same time, or following use of a licensed medication.
 - Consistent with findings in our previous reports, the highest quit rates (74%) were seen when the quit attempt involved people using a licensed medicine and a vaping product one after another.
 - Quit rates were similar for people using a vaping product and licensed medication at the same time (60.0%), a vaping product alone (59.7%) and varenicline alone (59.4%).

- ⁴ <u>https://www.ucl.ac.uk/news/2019/oct/e-cigarettes-may-help-over-50000-smokers-quit-england-each-year</u>
- ^sUse-of-e-cigarettes-vapes-among-adults-in-Great-Britain-2021.pdf (ash.org.uk)
- ⁶ Vaping in England: 2021 evidence update summary GOV.UK (www.gov.uk)
- ⁷https://www.cancerresearchuk.org/sites/default/files/cancer research uk smoking prevalence projections february 2020 final.pdf

²https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbritain/2019
³ When combined with behavioural support; https://www.qmul.ac.uk/media/news/2019/smd/e-cigarettes-more-effective-than-nicotine-replacement-therapies-finds-major-uk-clinical-trial.html

Recommended regulatory reforms to improve consumer confidence in reduced risk products and to help achieve a smoke-free 2030

The current regulations have created an environment where vapour products are widely available for smokers looking to switch from combustible tobacco products. However, more needs to be done to make smokers aware of vapour products and other tobacco-free nicotine alternatives, address consumer misperceptions regarding their reduced risk compared to combustible cigarettes and increased enforcement and removal of illegal vaping products from the UK market.

- 1. Regulate non-nicotine-containing e-liquids intended for mixture with a nicotine-containing concentrate and used in open system tank devices, in line with the existing TRPR regulations for pre-mixed nicotine-containing e-liquids:
 - 1.1. 'Short-fill' or 'shake n vape' is the term used to describe a self-mixed e-liquid used for vaping. It is created by the user adding pure nicotine liquid (or 'shots') to a propylene glycol / vegetable glycerine (PG/VG) liquid (typically sold in bottle sizes ranging anywhere from 50ml to 1 litre). This 'short-fill' e-liquid mixture is then poured into the tank of an open system vaping device.
 - 1.2. Non-nicotine containing e-liquids are not regulated by the TRPR they were an unforeseen product and therefore do not have to comply with the same requirements as nicotine containing liquid for pre-market notification, health warnings, ingredients restrictions, emissions testing, toxicological risk assessments or the 10ml bottle size limit. Consequently, a loophole in the law has materialised, giving rise to a large and growing e-liquid short-fill market in the UK (estimated at around 23%⁸ of those who use 'open' system devices/bottles).
 - 1.3. Public Health England and the parliamentary Science and Technology Committee⁹ have both urged that non-nicotine containing e-liquids be regulated in line with nicotine containing liquids.
 - 1.4. To ensure consumer safety and prevent accidents associated with the self-mixing of vaping e-liquids, all non-nicotine e-liquids (i.e., short-fills) for sale in the UK intended to be used with nicotine containing e-liquids and open system vapour devices should be regulated in line with the existing regulations for nicotine containing liquids as specified in the TRPR.

2. Maintain the current 10ml e-liquid bottle size to ensure child safety:

2.1. This size of bottle is both proportionate for meeting adult consumer needs, while mitigating against the risk of accidental ingestion of nicotine liquid should a young child accidentally open the bottle. E-liquid bottles are typically carried on persons (i.e., in bags, handbags, pockets etc.), meaning they are more accessible to young children than other household items/liquids which contain poisonous substances (i.e., such as cleaning fluids, bleach etc), which tend to be stored in cupboards out of reach of children.

3. Increase and ring-fence funding to strengthen capacity to support enforcement and removal of illegal vaping products including an expanded programme of pre-market notification investigations and in-market vigilance:

- 3.1. Non-compliance with vigilance, reporting, labelling, ingredients, and online advertising requirements is evident in the UK market. According to various new articles, approx. 133,000 illegal vapour products have been seized from retail outlets in the UK by Trading Standards in the last 5 months. The evidence of the availability of sub-standard products, demonstrates that the existing penalties regime is not sufficient to deter illegal behaviour and non-compliance by some manufacturers and retailers.
- 3.2. This is exacerbated by an under-funded, under-quipped and light-touch approach to enforcement of the regulations, which is not fit for purpose. Ring-fencing and increased funding should be made available for Trading Standards to create their own vapour product enforcement team supported by MHRA. Border Force should be given powers to seize and detain illegal vapour products from being imported into the UK. Finally, by introducing a duty stamp to be put on all legal and compliant vapour products and e-

⁸ <u>Use-of-e-cigarettes-vapes-among-adults-in-Great-Britain-2020.pdf (ash.org.uk)</u>

⁹ https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/505/50502.htm

liquids for sale in the UK will ensure manufacturers are registered and accountable to regulations providing much needed oversight and control on an ever-growing vapour market.

- 3.3. As a priority an enhanced oversight of information submitted as part of pre-market notifications to MHRA, including toxicological risk assessments; spot-checks of compliance with device and e-liquid quality and safety standards (including emissions).
- 3.4. Further measures should also be taken to ensure that existing price promotion restrictions across all online platforms and websites should be properly and fully enforced. Swift enforcement action should be taken to remove illegal content from online retailers who do not follow the law. As an alternative, if it is not possible to prevent this illegal behaviour through the ASA process, the government should expressly regulate through the TRPR to prohibit these activities.

4. Strengthen quality requirements for e-liquid ingredients and extend the list of prohibited e-liquid ingredients (i.e., the negative list):

4.1. Nicotine and the major components of the e-liquid (glycerol and propylene glycol, potentially water, ethanol, and other diluents) should be of pharmaceutical grade purity. All other ingredients (including flavours) should be of a purity grade suitable for use in food. A toxicological risk assessment to determine whether the concentration of an ingredient is considered sufficiently safe, considering the foreseeable consumer use of the e-liquid, should be performed, with the results included in the Technical File held by the producer, available for inspection by authorities.

5. Maintain the current 20mg/ml maximum nicotine limit:

5.1. According to ASH, only 2% of adults using a vapour product in the UK use a nicotine strength of over 20mg/ml. 24% use a strength between 13-20mg/ml, while the vast majority use between 1-12mg/ml¹⁰. Given the current nicotine limits on combustible tobacco products in the UK, coupled with local dynamics and usage patterns across the UK vaping market, the existing 20 mg/ml limit provides an appropriate and commensurate nicotine level for vapour products to provide a satisfactory alternative for most smokers.

6. Tighter guidelines should be introduced for e-liquid container packaging and labelling:

6.1. The use of brand or product names that replicate, imitate, or associate themselves with well-known nonvaping brands or other products, that are particularly popular with under 18s, should be prohibited. The use of cartoons, cartoon characters and fictional characters popular with, or related to, youth culture, should be prohibited. Use of flavour names or descriptors that are particularly associated with youth culture, reminiscent of confectionary disproportionally appealing to youth, misleading, linked to illegal or dangerous substances, sexually inappropriate or have unsubstantiated claims, should be prohibited.

7. Introduce a bespoke regulatory framework for tobacco-free oral nicotine pouches:

- 7.1. As it stands today, tobacco-free oral nicotine pouches are subject to general consumer safety legislation, rather than being specifically regulated under the TRPR, as this product category was not widely established in 2016. PHE (2021) recently stated that "as other non-tobacco nicotine products, such as nicotine pouches, emerge in England it seems appropriate to review regulations for these products at the same time." The most straightforward way to do this would be to update the TRPR and add a chapter(s) specifically for these products. Such provisions should reflect the reduced risk potential of these products compared to other tobacco and smoke free alternatives.
- 7.2. Pre-market notification should be required, as should robust product quality, ingredients and manufacturing standards, including a maximum nicotine limit of 20mg per pouch in line with recently published British Standards Institution document PAS 8877:2022. Appropriate packaging and labelling requirements should be mandatory, including a text warning that the product contains nicotine, and the products should not be made available to those aged under 18.
- 7.3. The sale of products should be permitted in all retail outlets except for those aimed at minors; and advertising and promotion of products should be allowed if they are directed to adults only.
- 7.4. Tobacco-free oral nicotine pouches have an important role to play alongside vapour products in providing smokers with an alternative to tobacco.

 $^{^{10}\} https://ash.org.uk/wp-content/uploads/2020/10/Use-of-e-cigarettes-vapes-among-adults-in-Great-Britain-2020.pdf$