New Nicotine Alliance UK

Registered charity in England and Wales – number 1160481

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29 October 2020

Dear Ms Churchill and Ms Mirza

**Proposals for post-Brexit tobacco and nicotine policy reforms – taking back control and levelling up**

The New Nicotine Alliance represents consumers of low-risk alternatives to cigarettes such as vaping products, smokeless and heated tobacco products. As consumers, we have a direct interest in the regulation of these products and the personal and public health consequences of poor regulation.

We write to make ten proposals (see next page) for revisions to tobacco and nicotine policy that would promote both public health and personal and economic wellbeing. The opportunity arises because Brexit allows the UK the freedom to roll back and improve on policies derived from European Union legislation. The government has committed to review the key UK legislation by May 2021.[1]

**Overall concept**. The idea is to support the government's stated aim to go smoke-free or to make smoked tobacco "obsolete" by 2030. This is generally taken to mean reducing adult smoking prevalence to below 5%. The goal was raised in a July 2019 government consultation on its preventative approach to health in the following form.[2]

> *We are setting an ambition to go 'smoke-free' in England by 2030.*
>
> *This includes an ultimatum for industry to make smoked tobacco obsolete by 2030, with smokers quitting or moving to reduced-risk products like e-cigarettes. Further proposals for moving towards a smoke-free 2030 will be set out at a later date.*

We support this goal and agree that smokers should be strongly encouraged to move to low-risk alternatives to smoking – these include e-cigarettes, heated tobacco products, smokeless tobacco and novel oral nicotine products such as pouches. These products, beyond any reasonable doubt, offer deep reductions in risk to a smoker who switches from cigarettes to any of these products. The NHS already promotes switching from smoking to vaping through its public health campaigns and messaging.[3] This

1 Minister for Public Health, Parliamentary answer, Tobacco: Packaging. 13 February 2020 [link]

2 Cabinet Office & Department of Health and Social Care: Advancing our health: prevention in the 2020s. July 2019. [link]

3 NHS, Using e-cigarettes to stop smoking [link]

proposal would deepen that approach and extend it to the full range of low-risk products. Parliament has also been supportive of the concept of tobacco harm reduction.[4]

However, the effectiveness of this approach is currently held back by poorly designed and counterproductive European Union legislation. This creates disincentives and barriers to switching and has the effect of protecting the cigarette trade and implicitly promoting smoking.

To assist the government's smoke-free-by-2030 agenda, we recommend the following ten reforms to UK tobacco and nicotine policy.

1. Lift the ban on oral tobacco (snus) and properly regulate all smokeless tobacco
2. Raise the limit on nicotine concentration in vaping liquids to allow vaping products to compete more effectively with cigarettes
3. Replace bans on advertising of vaping products on TV, radio, internet and in publications with controls on themes and placement
4. Replace blanket bans on advertising of low-risk tobacco products with controls on themes and placement
5. Replace excessive and inappropriate warnings on vaping products with risk communications that encourage smokers to try switching
6. Replace excessive and inappropriate warnings on non-combustible tobacco products
7. Allow and enable candid communication of relative risk to consumers
8. Adopt a fresh approach to pack inserts for both vaping products and cigarettes to encourage switching to lower risk products
9. Remove wasteful restrictions on vaping product tank and e-liquid container size that have no discernible purpose
10. Recognise and regulate novel oral nicotine products

These proposed reforms would be a step towards creating a coherent risk-based framework for all nicotine products. A focus on risk means the most important factor for policymakers is whether the product involves inhalation of products of combustion, not whether it is or is not a tobacco product.

These reforms become possible on 1 January 2021 at the end of the transition period following the UK departure from the European Union once critical EU directives no longer apply.

The UK, and England in particular, have taken an effective and pragmatic approach to tobacco policy that is world-leading in our view. However, there is a clear case that EU legislation holds back British public health policy. Our ten proposed measures support the Prime Minister's 'levelling up' agenda and will help many disadvantaged groups. The proposals align well with the government's existing tobacco policy aims and promote established conservative values of personal responsibility and individual autonomy. The proposals do not require additional public spending and may create savings to the NHS and other public bodies. It is possible that they would reduce tobacco excise revenue, but the benefits would greatly outweigh the costs.

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4 House of Commons Committee on Science and Technology, Report on e-cigarettes, 17 August 2018 [link]

In the attached briefing, we set out the case for the ten proposed reforms following a short overview of the arguments about health, levelling up, personal cost, economics, tobacco policy and youth vaping.

We hope these ideas will help to inform the government's approach to preventing ill-health and meeting the smoke-free 2030 goal and that they will be included as options for further consultation as the government develops its Smokefree 2030 agenda. Brexit means Britain can take back control and these reforms show how an independent policy could lead to better health and wellbeing while contributing the levelling-up agenda at a low cost.

We would welcome the opportunity to discuss these ideas with you and to provide more information. Please let us know if a meeting is possible.

Because of wider interest in post-Brexit regulatory freedoms and the levelling-up agenda, we are copying this letter widely.

Yours sincerely

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Chair
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**Copied to:**
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**About the New Nicotine Alliance:** The New Nicotine Alliance was founded as a registered charity (1160481) in 2015 to advance public understanding and awareness of ways to reduce the harms associated with cigarette smoking. We take a consumer-interest, scientific and public health perspective and wish to encourage a mature public discussion about the opportunities and risks of encouraging safer nicotine products to address the health, welfare and other harms associated with smoking.

**Disclosure:** The New Nicotine Alliance is completely independent of commercial interests in relevant industries (e-cigarettes, tobacco, pharmaceutical companies, etc). It operates on a small budget and not-for-profit basis and is free from commercial bias. Our policies and statements are evidence-based, with a clear focus on the health of consumers and the wider public.

# Briefing: post-Brexit reform of EU-derived tobacco and vaping regulation

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# 1 Introduction and context

## 1.1 The health argument

Smoking prematurely kills around 96,000 annually in the UK, more than obesity, alcohol, road accidents, drug misuse and HIV *combined*.[5] Lifelong smokers are likely to lose on average around 10 years of life through cancer, heart disease or respiratory conditions. It is not just an end-of-life effect: smokers generally have worse health (34.4% report fair, bad or very bad health) compared non-smokers (19.4%)[6]. The overwhelming cause of disease and death from smoking is inhalation of *smoke*, the hot smouldering particles (tar) and toxic gases arising from the combustion of tobacco leaf.

Nicotine is the most important reason why people smoke, but nicotine itself is not the cause of the disease burden. All the low-risk products share a common characteristic – they do not involve combustion and there is no smoke to inhale. They do, however, provide nicotine and can satisfy smokers who would not otherwise wish to quit or would find it hard to quit. They are *much less harmful* – with likely risk reductions of one to two orders of magnitude – though not harmless. When a smoker completely switches from smoking to a low-risk product, they avoid nearly all the incremental health risks of continued smoking. This allows for 'harm reduction', a well-established concept in public health policy, for example with drugs, alcohol and HIV. This concept should be systematically extended to tobacco-related harms and the UK approach to the 2030 smokefree ambition and, through UK international advocacy, to the SDG goals as they relate to non-communicable diseases.

## 1.2 The levelling up argument

Smoking is very unevenly distributed and therefore the health and economic burdens of smoking also fall unevenly. The five NHS Clinical Commissioning Groups with the highest smoking prevalence are in highly disadvantaged areas, with the most extreme case, Corby, having smoking prevalence twice the national average and more than four times the CCG with the lowest level, Rushcliffe.[7]

| NHS Clinical Commissioning Group | Smoking prevalence |
|---|---|
| 1. Corby | 27.5% |
| 2. Blackpool | 23.4% |
| 3. Great Yarmouth and Waveney | 22.5% |
| 4. Hull | 22.2% |
| 5. North East Lincolnshire | 22.2% |
| England | 13.9% |

Smoking is also concentrated in sub-populations with various forms of disadvantage. For example:

- unemployed (smoking prevalence 26.4%) compared to employed (14.5%);
- manual or routine occupation (23.2%) compared to managerial and professional (9.3%);
- no educational qualifications (28.3%) compared to degree level (7.8%);
- serious mental illness (40.5%) compared to all adults (16.5% in 2014-15)

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5 For a summary of health impacts, see Action on Smoking and Health factsheet: Smoking Statistics, April 2020 [link]

6 Data in this section from: ONS, Adult Smoking habits in the UK: 2019. [link] except mental health data: GP Patient Surveys 2014-15 cited at: Public Health England, Health Matters, Smoking and Mental Health, 26 February 2020 [link].

7 ONS, Adult smoking habits in Great Britain, 2019 edition, 7 July 2020. [link] Table 5. Full table for all CCGs here: Google sheet

Tackling smoking in deprived populations has proved challenging, and it demands more creative public health approaches. Tobacco harm reduction aims to engage humanely with people facing disadvantage, rather than expecting they will just comply with ever more punitive and coercive incentives to quit.

### 1.3 The personal cost argument

Being a smoker is a very expensive undertaking in the UK. Excise duties and VAT account for around 70-80% of the pack price. For example, someone who smokes 20 budget tax-paid cigarettes per day (e.g. Mayfair bought at Tesco for £10.30 per pack) would spend £3,759 per year, of which £2,979 or about 80% is tax. For comparative purposes, the Jobseeker's Allowance is £74.35 per week, or £3,866 annually.[8]

Vaping provides an opportunity to switch to much lower cost vaping products. Depending on choice of products, estimates suggest the cost of regular smoking is 5-15 times higher than vaping, and therefore great savings to the household budget are possible by switching from smoking to vaping.[9] The tax on cigarettes is painfully high for many smokers and sharply regressive, given the concentration of smoking in poorer populations. As a result, a substantial illicit trade in cigarettes has developed. Encouraging switching to much lower cost and legally-sold alternatives would help to tackle the black market.

### 1.4 The economic argument

Reducing smoking by switching to low-risk products will reduce the collection of tobacco excise duty. However, the government is not indifferent to the health, life-expectancy and productivity improvements arising from stopping smoking. In its 2016 impact assessment for the Tobacco Products Directive, the Department of Health estimated the average discounted value for the benefit of quitting smoking to be £72,000 per successful quit.[10] The same assessment estimated loss of tobacco duty and net loss of VAT associated with quitting smoking at a present value of £11,000[11] - suggesting that the benefits are more than six times as great as the lost tax to the exchequer. In addition, smoking cessation has economic welfare and health benefits sharply skewed to poorer groups.

### 1.5 The tobacco policy argument

The tobacco harm-reduction approach is complementary and not an alternative or antagonistic to the government's tobacco policy. This is because the thrust of tobacco policy (tax, packaging, marketing bans, smoking bans, publicity campaigns, stop-smoking support) is focussed on encouraging smokers, often with quite painful incentives, to quit smoking. The availability of low-risk consumer products *increases the options to quit smoking.* It provides new pathways to quit for those who do not want to stop using nicotine or find it difficult to stop. It does this without diminishing any of the existing options such as counselling or medication. It works through market forces, relying on private sector innovation and, importantly, the free choices of consumers to protect their own health and wellbeing on their own

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8 From Gov.UK, Jobseeker's Allowance [link] 8 October 2020. The figure of £74.35 is for individuals over aged 25 or over.

9 See various estimates available online. **Techround**, Compare the cost of smoking and vaping. "*The cost of vaping per year is £273.95 compared to £3,796 for smoking cigarettes*". [link] **Vapemate**, Vaping versus smoking – costs: "*Vape prices are less than what it would cost you to buy one month's worth of cigarettes! "* [link] **Totally Wicked**, Is vaping cheaper than smoking? "*The average 20 a day smoker will spend up to £10.60 a day! That means each year they are forking out around £3,869. When you make the switch to vaping the average annual cost … is just £633.60*". [link]

10 Department of Health (England). Impact Assessment for Tobacco Products Directive (TPD), April 2016 – paragraph 76 and Annex A. On average, each additional non-smoker will gain 1.2 life years (discounted). Each life-year gained is valued at £60,000 based upon studies of what members of the public are on average willing to spend to reduce their own mortality risk, or to improve their own health outcomes. [link]

11 Department of Health (England). Impact Assessment for Tobacco Products Directive (TPD), April 2016. Annex A page 72. [link]

initiative and at their own expense. On the supply side, it represents development of a pro-health technology industry and establishes a pathway for traditional tobacco companies, the proverbial 'merchants of death', to reduce the huge negative societal impact of the cigarette trade by migrating their business towards non-combustible products.

The Royal College of Physicians eloquently explained the interaction between restrictive vaping policy and the risk of increased or prolonging smoking.[12]

> However, if [a risk averse and precautionary] approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult. (Section 12.10 page 187)

EU legislation is not "getting this balance right". Given that the risks of smoking are likely to be at least twenty times those of vaping, then sound policy must be focussed on the danger that restrictive vaping policies will lead to increases in smoking compared to the alternative.

### 1.6 The concern about adolescent vaping

Much of the political and public health concern surrounding vaping is driven by fear of youth uptake of vaping. Policymakers need to place these concerns in context and avoid interventions that will significantly increase risks for other at-risk groups – notably adult smokers and adolescent smokers or would-be smokers.

- The respective risks need to be considered carefully – vaping is a youth risk behaviour, but it is a low and/or distant risk compared to other behaviours like smoking, heavy drinking, illicit drugs, teenage pregnancy or distracted driving. Also, the health risks to middle-aged adult smokers are high and near-term. Restrictive policies that aim to protect young people from relatively minor risks could cause serious harms to adults.
- Use among young people in Britain is relatively low, despite of the popularity of vaping with adults. In the age group 16-18, just 2.5% used e-cigarettes more than once a week and 6.5% less than weekly. Teenage vapers, especially the more frequent vapers, were concentrated among teenage smokers or former smokers.[13] For these young adolescents, vaping may be a beneficial diversion from smoking.
- Despite much higher prevalence of adolescent vaping in the United States driving rhetoric about a 'teen vaping epidemic', British experts analysing American data have found most vaping is infrequent and frequent vapers are far more likely to be current or former tobacco users. They conclude: *We find a gaping chasm between the vision of an epidemic of e-cigarette use threatening to engulf a new generation in nicotine addiction and the reality of the evidence contained in the [US data]*.[14]
- The approach adopted in Britain has been successful – position these products as adult alternatives to smoking, control marketing themes and placement, and avoid generating excessive public concern among adults, which in turns triggers youthful curiosity - one of main drivers of youth uptake.

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[12] Tobacco Working Group. Royal College of Physicians (London) Nicotine without smoke: tobacco harm reduction 28 April 2016 [link]

[13] Action on Smoking and Health, Use of e-cigarettes among young people in Great Britain, June 2019. Based on ASH Smokefree GB Youth Survey. [link] *Figure 3: Use of e-cigarettes by age, GB youth*, and *Figure 2: Use of e-cigarettes by tobacco smoking status*.

[14] Jarvis M, Jackson S, West R, Brown J. Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey 2017-2019 reveal about high school e-cigarette use in the USA? *Qeios*. 2020 Sep 2; [link]

## 2 Regulation of tobacco and nicotine products: relevant European Union legislation

There are three main European Union directives that govern important aspects of UK tobacco policy until 1 January 2021.

### 2.1 Tobacco Products Directive 2014 (TPD)

This directive is supposed to facilitate the functioning of the single market by harmonising regulation in relation to tradeable goods with a high level of health protection.[15] This is implemented in the UK through a statutory instrument.[16] However, it became a vehicle for interest group lobbying and political grandstanding, and resulted in several arbitrary and counterproductive policies that should now be removed from UK legislation.

### 2.2 Tobacco Advertising Directive 2003 (TAD)

This directive bans 'cross-border' advertising, sponsorship and promotion of all tobacco products – meaning any advertising or promotion capable of crossing a border (radio, internet, publications etc).[17] This is extended to all tobacco advertising, e.g. including billboards, in UK primary legislation.[18] Advertising of vaping products, which are not classified as tobacco products, is covered by Article 20 of the TPD.

### 2.3 Tobacco Excise Directive 2011 (TED)

This directive sets the framework for harmonising definitions and reporting excise duties at the EU level and sets minimum rates for different types of duty.[19]

## 3 Recommended post-Brexit reforms for e-cigarettes and oral nicotine products

### 3.1 Lift the ban on oral tobacco and properly regulate all smokeless tobacco

The TPD bans oral tobacco, a form of smokeless tobacco known as 'snus'.[20] This product has been highly successful in reducing smoking to low levels in Scandinavia, notably in Sweden and Norway. Both countries are exempt from the EU-wide ban even though both are part of the European Economic Area. The 2017 Eurobarometer survey shows Sweden has a smoking prevalence of 7% compared to the EU average of 26% and UK prevalence of 17%.[21] This is because many nicotine users consume snus instead of smoking. This has provided significant health benefits, with Sweden showing the lowest levels of cancer

15 Tobacco Products Directive, 40/14/EU, 3 April 2014 [link]

16 Tobacco and Related Products Regulations 2016 SI 2016/507 [link] and The Standardised Packaging of Tobacco Products Regulations, 2015, SI 2015/829 [link]. The latter implements Article 13 of the TPD as well as UK policy on standardized packaging

17 Tobacco Advertising Directive 2003/30/EC May 2003 [link] Note: TV advertising is banned under the 1989 'Television Without Frontiers' Directive 89/552/EEC [link].

18 Tobacco Advertising and Promotion Act 2002 [link]

19 Tobacco Excise Directive 2011/64/EU, [link]

20 Tobacco Products Directive Article 17. SI 2016/507 Regulation 17 [link]

21 European Commission, Attitudes of Europeans to cigarettes and e-cigarettes, Eurobarometer 458. 2017. [link]

and heart disease in men in Europe by some distance and clearly attributable to use of snus by men as an alternative to smoking.[22]

Despite the obvious case for legalising this product made repeatedly to the European Commission and others,[23] in 2017 the Commission defended the ban before the European Court of Justice. The case was brought by a snus manufacturer and joined by independent consumer groups making an argument based on the right to health.[24] The Court regrettably but inevitably sided with maintaining the discretionary powers of European institutions regardless of the public health arguments, rights of consumers and EU regulatory principles. The ban was upheld.[25]

Standing back from the health and legal arguments, it is undeniably *absurd* that EU regulation depends on what the user does with the smokeless product once it is placed in their mouth. The product is banned if it is merely placed in the mouth, but if they chew it, the product is legal.[26]

The Swedish government has an appropriate regulatory regime for oral tobacco (snus), which could be adopted or adapted for the UK.[27] Smokeless tobacco intended for *chewing* is already legal in the UK and widely prevalent in South Asian communities.[28] Yet these smokeless tobacco products are often high in carcinogens and currently barely regulated – this is an example of where the EU fails to meet a legitimate need. The UK could develop a regulatory scheme based on technical advice from WHO's expert 'TobReg' committee, which set out proposals for regulating smokeless tobacco in 2008.[29] The government has indicated that it is open-minded about using post-Brexit freedoms to liberalise snus.[30]

*The ban on oral tobacco is wholly unjustified and should be lifted. Oral tobacco should be treated like any other smokeless tobacco or as it is regulated in Sweden. The UK should introduce a framework for regulation of all smokeless tobacco products.*

### 3.2 Raise the limit on nicotine concentration in vaping liquids

The TPD limits nicotine concentrations in e-liquids to 20mg/ml (about 2% nicotine concentration)[31]. This functions as a regulatory protection to the cigarette trade by making e-cigarettes less pharmacologically effective as alternatives to smoking, and therefore makes it harder for smokers to use this option to quit.

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22 Ramström L, Borland R, Wikmans T. Patterns of Smoking and Snus Use in Sweden: Implications for Public Health. Int J Environ Res Public Health. Multidisciplinary Digital Publishing Institute (MDPI); 2016 Nov 9;13(11). [link]
Ramström L, Wikmans T. Mortality attributable to tobacco among men in Sweden and other European countries: an analysis of data in a WHO report. *Tob Induc Dis*. 2014 Jan;12(1):14. [link]

23 Letter from 18 experts in tobacco and nicotine to EU Commissioner for Better Regulation, Frans Timmermans, 1 June 2017 [link]

24 New Nicotine Alliance, NNA's legal case: snus and the right to health, 7 July 2017 [link]

25 Info Curia case law. Case 151/17. Swedish Match vs Secretary of State for Health. 22 November 2018 [link]

26 Definition of 'oral tobacco' - Tobacco Products Directive Article 2(8) "'*tobacco for oral use' means all tobacco products for oral use, except those intended to be inhaled or chewed*". Chewing tobacco is not banned under the directive.

27 See Government of Sweden, Regulations amending the Swedish National Food Agency's Regulations on moist snuff (snus) and chewing tobacco (LIVSFS 2012:6). Notification of national regulations to the EU. 19 November 2015 [link]

28 Longman JM, Pritchard C, McNeill A, Csikar J, Croucher RE. Accessibility of chewing tobacco products in England. *J Public Health*. 2010 Sep 1;32(3):372–8. [link]

29 WHO Study Group on Tobacco Product Regulation Report on the Scientific Basis of Tobacco Product Regulation, WHO Technical Report Series, no. 951, 2008 [link]

30 Minister for Public Health. Parliamentary answer: Oral Tobacco, 3 June 2020. [link]

31 Tobacco Products Directive Article 20(3)(b) and SI 2016/507 Regulation 36(4) [link]

It makes no sense as an internal market 'level playing field' measure. Products with stronger liquids available in the United States, such as the Juul pod, have 59mg/ml liquids (~5% nicotine). These have proven extremely successful in the US market but are locked out of the EU. Yet these products have been highly effective at helping smokers to switch to vaping as an alternative to smoking[32] and the limited products available in the UK under EU restrictions appear less effective.[33]

With this limit on vaping technology in place, cigarettes are able to deliver a higher peak of blood-nicotine than vaping products – therefore leaving the most dangerous product with a considerable advantage in the marketplace.[34] The supposedly level playing field was tilted in favour of cigarettes by the Directive.

However, in recital 38 of the TPD, a roughly appropriate goal is specified:

> This concentration [20mg/ml] allows for a delivery of nicotine that is *comparable to the permitted dose of nicotine derived from a standard cigarette* during the time needed to smoke such a cigarette. (emphasis added)

While the expressed goal of parity is broadly reasonable, the problem is that the TPD uses a nonsensical measure to calibrate a "comparable dose" – the strength of the liquid. This is based on a misunderstanding of how people consume nicotine. This is a well understood process known as 'self-titration'[35] and is in similar in some ways to a comparison between beer and whiskey. For a given level of alcohol consumption, people drink a larger quantity of beer and lower quantity of whiskey. Though typically ten times stronger than beer, consumption of beer is not a barrier to intoxication – the level of alcohol consumption and quantity of alcohol beverage consumed depends on the *drinker* not the drink.[36]

The misunderstanding was pointed out to the Commission at the time the legislation was crafted, including by several of those whose science the Commission cited to justify its approach.[37] [38] [39] The

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[32] The main source of research is manufacturer Juul Labs Inc. It has undertaken research to support its pre-market tobacco application to the US Food and Drug Administration. Goldenson NI. Le G, Auguston EM. Switching Away from Cigarettes Among Adult Smokers who Purchased the JUUL System: 12-Month Follow-Up Results from Two Large Longitudinal Studies, Poster 3rd Scientific Summit on Tobacco Harm Reduction 2020 September 25, 2020. Juul Labs Inc. [link]

[33] The main source of research is manufacturer Juul Labs Inc. Shiffman S, Goldenson NI, Ding Y, Prakash S, Hatcher C. Auguston EM. Differences in Rates of Adult Smokers Switching Away from Smoking Using JUUL System Products, Across Jurisdictions with Different Maximum Nicotine Concentrations (North America and the United Kingdom), Poster 3rd Scientific Summit on Tobacco Harm Reduction 2020, 25 September 2020 Juul Labs Inc [link]

[34] The main source of research is manufacturer Juul Labs Inc. Goldenson NI, Fearon I, Buchhalter AR, Henningfield JE. Nicotine Pharmacokinetic and Subjective Effect Assessment of the JUUL System with Three Nicotine Concentrations Relative to Combustible Cigarettes in Adult Smokers, poster 3rd Scientific Summit on Tobacco Harm Reduction 2020, Juul Labs Inc. 25 Septemebre 2020 [link]

[35] Dawkins LE, Kimber CF, Doig M, Feyerabend C, Corcoran O. Self-titration by experienced e-cigarette users: blood nicotine delivery and subjective effects. Psychopharmacology (Berl). 2016 Aug 1;233(15–16):2933–41. [link]

[36] It would make no sense to control alcohol consumption by limiting the strength of, say, whiskey to be the same as beer. The difference between drinking and vaping is that more compact vaping devices constrain the volume flow due both energy required to create aerosol and due to the puffing effort required to consume a higher volume of weaker liquid – analogous to drinking beer through a fine straw.

[37] Farsalinos K. The European Commission has misinterpreted my scientific research on nicotine in e-cigarettes, 10 Jan 2014 [link]

[38] Etter, JF and 14 experts, Scientific Errors in the Tobacco Products Directive, A letter sent by scientists to the European Union. 17 January 2014. [link]

[39] Dawkins LE. Please Do Not Distort My Words To Justify Your Policy, 13 January 2014. [link]

critics' evidence-based arguments were ignored and the Directive proceeded unchanged, cementing in an advantage to the cigarette trade. The 20mg/ml limit causes at least six problems:

1. **Creates a barrier to stopping smoking**. It will deter more dependent smokers from switching in the first place. It will make the transition from smoking to vaping harder, especially in the crucial early stages while the user is learning how to obtain a satisfactory dose of nicotine.
2. **Creates a barrier to better easier-to-use devices**. It works against more compact devices that use low volumes of liquid at higher strength, which do not require refilling or complicated configuring that do not form a barrier to vaping enthusiasts but may deter ordinary smokers. Yet these easy-to-use and convenient devices are often valued by smokers, particularly in the early stages of trying to switch from smoking to e-cigarette use.
3. **Creates a barrier to future innovation**. It is also a barrier to new product designs that would use stronger liquids to provide future consumers with better or cheaper products more able to compete with cigarettes and to reach smokers who do not currently find e-cigarettes satisfying.
4. **Higher consumption of liquid and greater toxic exposure.** It will mean some users are forced to consume greater quantities of weaker liquids using higher powered devices with potentially greater toxicant exposure. While these elevated risks remain very low compared to smoking, there is no justification to *increase* them using regulation.
5. **Promoting a black market.** It will promote a black market in the products that are banned. These will either be legally produced products imported illegally, or more dangerously, products made for the black market or counterfeit products of uncertain quality with unknown ingredients, contaminants and risks. It will also encourage users to mix their own liquids from near-pure nicotine in conditions of unknown cleanliness – a dangerous substance and procedure.
6. **Favouring the cigarette trade**. The nicotine delivery of cigarette *to the user* is not significantly limited by the nicotine yield limits[40], as most smokers can compensate and self-titrate to achieve the nicotine dose they want. This effect has been well documented for several decades.[41] [42] The 20mg/ml limit is, however, a significant constraint for the e-cigarette category.

*The 20mg/ml limited should be removed and not replaced. Longstanding UK poisons legislation applies to nicotine solutions exceeding 7.5% nicotine[43] and this is a sufficient limit for health and safety purposes*.

### 3.3 Replace bans on advertising of vaping products with controls on themes and placement

For vaping products, the TPD strongly restricts advertising and promotion – prohibiting advertising in publications and the press, broadcast media and internet-based services. The policy and public health problem is that advertising bans favour incumbent products – in this case cigarettes – at the expense of market entrants (the less well-known vaping and smokefree tobacco brands). Advertising bans work

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40 Cigarettes in the EU and U are limited to 'nicotine yields' of 1.0mg. This quantity is the nicotine trapped in a filter when the cigarette is smoked by a machine to a pre-determined smoking regime. This is different to the *content* of a cigarette, which is typically 12-20mg/gram of tobacco or about 8-14mg per stick.

41 Benowttz NL, Hall SM, Herning RI, Jacob P, Jones RT, Osman AL. Smokers of Low-Yield Cigarettes Do Not Consume Less Nicotine. *N Engl J Med*. 1983 Jul 21;309(3):139–42. [link]

42 Russell MAH, Jarvis M, Iyer R, Feyerabend C. Relation of nicotine yield of cigarettes to blood nicotine concentrations in smokers. Br Med J. 1980 Apr 5;280(6219):972–6. [link]

43 The Poisons Act, 1972 and Poison List and Poisons Rules as amended. [link] See Health and Safety Executive, Active Substances subject to Poisons Law: The UK has left the EU, new rules from January 2021. [link]

against diffusion of innovation and the building of confidence in new brands and ideas. The advertising of the low-risk product alternatives to cigarettes should be understood as "anti-smoking" advertising in the sense that it presents a rival proposition to smokers. However, unlike public sector anti-smoking advertising, it does this without public spending and with competitive-selection pressure that will favour advertising that is effective. There is some evidence that advertising of low-risk products does promote switching and that bans on such advertising would be counterproductive.[44] [45] [46]

For example, Dave et al (2019) conclude for the United States:

> Our results indicate that a policy banning TV advertising of e-cigs would have reduced the number of smokers who quit in the recent past by approximately 3%.

This should be no surprise: it was highlighted as a risk in the government's 2016 Impact Assessment for the UK implementing legislation for the TPD.[47]

> There may also be potential negative health implications if the restrictions on advertising reduce the number of consumers switching from tobacco products to e-cigarettes. Survey evidence suggests that the vast majority of e-cigarette users are current or ex-smokers, with use by never smokers negligible.

Regrettably, the impact assessment came two years after the Tobacco Products Directive was irrevocably finalised in closed meetings in Brussels in 2014. The impact assessment, therefore, did not inform the UK government's position in the negotiation of the TPD – a clear process flaw that can now be rectified.

The appropriate and proportionate approach to controlling advertising of lower risk tobacco products is to place limits on content, targeting, timing and placement, rather than an outright ban. This would be similar to the approach used for alcohol, arguably a significantly more dangerous consumer product than e-cigarettes. It was the approach used for e-cigarette advertising until the European Union ban was implemented, and it remains the approach for e-cigarette advertising not covered by the EU ban – i.e. for fixed advertising such as billboards. This is in the form of two codes set down by the Committee on Advertising Practice (CAP), covering broadcast and non-broadcast advertising.[48] These codes are then managed and enforced by the UK Advertising Standards Authority. We should simply return to this system for *all* advertising of vaping products in all media, whether or not prohibited by the EU.

*The bans on the advertising and promotion of low-risk nicotine products should be replaced by controls on content and placement of advertising of the type already in place in the UK for e-cigarettes advertising that falls outside EU jurisdiction. This should include low risk tobacco products (see next section)*

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44 Tuchman AE. Advertising and demand for addictive goods: The effects of e-cigarette advertising. *Mark Sci*. 2019;38(6):994–1022. [link]

45 Pepper JK, Emery SL, Ribisl KM, Southwell BG, Brewer NT. Effects of advertisements on smokers' interest in trying e-cigarettes: The roles of product comparison and visual cues. *Tob Control*. 2014 Jul 1;23(Suppl 3):iii31–6. [link]

46 Dave D, Dench D, Grossman M, Kenkel DS, Saffer H. Does e-cigarette advertising encourage adult smokers to quit? *J Health Econ*. 2019 Feb;68:102227. [link]

47 Department of Health, Impact Assessment for Tobacco Products Directive (TPD), 18 April 2016 [link] See paragraph 177. The TPD was finalised in April 2014. The Impact Assessment applies to the 2016 implementing legislation SI 2016/507.

48 Committee on Advertising Practice (UK), UK Code of Broadcast Advertising: section 33. E-cigarettes [link]; UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code): section 22. E-cigarettes [link]

### 3.4 Replace blanket bans on advertising of low-risk tobacco products with controls

For low-risk tobacco products (smokeless, oral and heated tobacco products), the Tobacco Advertising Directive and UK legislation combine to ban almost all advertising and promotion.[49] The TAD applies a cross-border advertising ban to all forms of tobacco, regardless of risk. The UK Tobacco Advertising and Promotion Act extends the prohibition to cover almost all advertising. Together they create a blanket ban.

The conceptual arguments made above apply equally to low-risk tobacco products as well as to vaping products. The key distinction for policy purposes is not between tobacco and non-tobacco products, but between combustible and non-combustible products. European Union legislation has created a significant distortion and violation of the proportionality principle by lumping all tobacco products together even though there may be hundred-fold differences in risk between tobacco products.

*The bans on the advertising and promotion of tobacco products should be limited to smoking products. Low-risk tobacco products should be included in a similar regime to vaping products, with controls on content and placement. The Committee on Advertising Practice ran an excellent process to develop guidelines for e-cigarette advertising and it could be asked to do the same for low-risk tobacco products.*

### 3.5 Replace excessive and inappropriate warnings on vaping products

Warnings have played a significant role in alerting users to the dangers of smoking. Over time, these warnings have become larger, bolder, more visceral and more graphic. However, the TPD carelessly and without evidence applies this philosophy to vaping products,[50] with the danger that users will find the warnings off-putting or an implicit exaggeration of risk because they look like the warnings applied to cigarettes, at least prior to 2014, in terms of size and boldness. A stress on addiction in the warning also plays into confusion about nicotine and contributes to smokers' unwillingness to switch. The warning covers 30% of the pack and is in bold black and white: it reads: "*This product contains nicotine which is a highly addictive substance*."

In a survey for Action on Smoking and Health, the most common reason given by smokers for not trying e-cigarettes was "*I do not want to substitute one addiction for another*"[51] and researchers at London South Bank University found evidence that these warnings are deterring smokers from switching from smoking to vaping.[52]

> …the TPD e-cigarette health warning may reduce smokers' willingness to use and likelihood of purchasing an e-cigarette.

The same group also suggested the way ahead:

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49 Tobacco Advertising Directive 2003/33/EC [link] implemented as primary legislation in the UK by The Tobacco Advertising and Promotion Act 2002 [link]

50 Tobacco Products Directive Article 20(4)(b) and SI 2016/507 Regulation 37(4) [link].

51 Action on Smoking and Health / YouGov survey Use of e-cigarettes (vaporisers) among adults in Great Britain, September 2019 [link] See figure 5.

52 Cox S, Frings D, Ahmed R, Dawkins L. Messages matter: The Tobacco Products Directive nicotine addiction health warning versus an alternative relative risk message on smokers' willingness to use and purchase an electronic cigarette. *Addict Behav Reports*. 2018 Dec 1;8:136–9. [link]

> Messages conveying reduced harm or indeed, no message at all, may be more effective in encouraging smokers to switch to these lower risk products.

These stark warnings should be scaled back in size and boldness to more proportionately reflect risk. But crucially, the underlying concept should shift from *deterrence warnings* to *risk communication*, in which the much lower risk of the product is communicated to users along with encouragement for smoker to try it. The choice of message requires research and evaluation among target audiences. Such a warning could read: "*No product is completely safe but use of this product is much less harmful than smoking".*

*The existing warning regime for vaping products should be overhauled and replaced by risk communications that reflect greatly low-risk relative to cigarette with a view to encouraging switching.*

### 3.6 Replace excessive and inappropriate warnings on non-combustible tobacco products

The TPD also applies counterproductive warnings to low-risk tobacco products, including smokeless tobacco, oral tobacco products (though these are banned in the UK) and heated tobacco products.[53] The warnings cover 30% of the two largest surfaces of the pack in bold black and white, and state: "*This tobacco product damages your health and is addictive*". Again, this provides no useful context or guidance to consumers. The same approach should be adopted for these products as for vaping products. The key distinction is not between non-tobacco and tobacco, but between combustible and non-combustible products.

*The existing warning regime for smokeless and heated tobacco products should be overhauled and replaced by risk communications that reflect greatly reduced-risk relative to cigarette with a view to encouraging switching.*

### 3.7 Allow candid communication of relative risk to consumers

The TPD prohibits any claims on packaging that "*suggests that a particular tobacco product is less harmful than others*". It also applies this part of the TPD to vaping products, making it impossible to suggest that any product covered by the directive is less harmful than any other.[54] This runs directly counter to reality. There are huge differences in risk between smoking and non-combustible tobacco and nicotine products. Given that a reduction in risk is one of the more compelling arguments to switch, deliberately preventing direct communication of this information with smokers obviously compromises principles of informed consumer choice and autonomy.

A 2018 expert assessment for Public Health England concludes:[55]

> Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are

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53 Tobacco Products Directive Article 12 and 9.4. SI 2016/507 regulation 10 [link]

54 Tobacco Products Directive Article 13(1)(b). Though it refers to 'tobacco products', this element of Article 13 is applied to vaping products by Article 20(4)(b)(ii) of the TPD. In the UK it is applied by the Standardised Packaging of Tobacco Products Regulations 2015 SI 2015/829 [link]

55 McNeill A, Brose LS, Calder R, Bauld L & Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England. 6 February 2018 [link] [Press release]

> encouraged to make the switch from smoking to vaping. It should be noted that this does not mean e-cigarettes are safe.

In 2016, the Royal College of Physicians concluded in a detailed assessment:[56]

> Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products and may well be substantially lower than this figure.

These expert insights are potential life-saving information for smokers, yet EU legislation prevents consumers having access to this knowledge through the packaging of the products or commercial communications, which are more accessible than expert reports.

There is good evidence that heated tobacco products and smokeless tobacco are also far less risky than cigarettes – again, because there is no combustion, and therefore no inhalation of products of combustion. The US regulator, the Food and Drug Administration, has recently approved "modified risk" claims for a heated tobacco product and a snus product.[57]

We do not recommend a *laissez faire* approach to claims or a system as cumbersome and expensive as the FDA's. The appropriate approach is the same as for warnings and risk communication: the government should specify a range of generic category-wide statements that can be used in advertising, promotion and packaging to communicate relative risk to users and potential users. Such statements would be available to use with notified products meeting agreed standards and not presenting novel risks. This approach was proposed, though not so far implemented, by Health Canada. The risk communication messages proposed by Health Canada were as follows:

1. If you are a smoker, switching completely to vaping is a much less harmful option.
2. While vaping products emit toxic substances, the amount is significantly lower than in tobacco smoke.
3. By switching completely to vaping products, smokers are exposed to a small fraction of the 7,000 chemicals found in tobacco smoke.
4. Switching completely from combustible tobacco cigarettes to e-cigarettes significantly reduces users' exposure to numerous toxic and cancer-causing substances.
5. Completely replacing your cigarette with a vaping product will significantly reduce your exposure to numerous toxic and cancer-causing substances.
6. Switching completely from smoking to e-cigarettes will reduce harms to your health.
7. Completely replacing your cigarette with an e-cigarette will reduce harms to your health.

The choice of messaging should be developed and tested for comprehension and relevance to the British market. Research on similar messages to emphasize the differences in risk between combustible

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[56] Tobacco Advisory Group of the Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016 [link] (Section 5.5 page 87)

[57] Food and Drug Administration (US). Modified Risk Orders [link]. See Technical Project Lead reports Swedish Match General Snus, 22 October 2019 [link] and Philip Morris International iQOS heated tobacco product, 7 July 2020 [link]

products and non-combustible products should be conducted for other non-combustible tobacco products.

*The government should lift the EU ban on candid communication with smokers about low-risk alternatives and provide manufacturers with vetted and evidence-based statements they can use on packaging and in advertising and promotion.*

### 3.8 Adopt a rational approach to pack inserts for both vaping products and cigarettes

The TPD requires an information leaflet to be included in the packaging on e-liquids, with specification of information to be provided on the leaflet (including, for example, contra-indications, warnings for specific risk groups, possible adverse effects; addictiveness and toxicity).[58] However, the information specified provides little of value to users that cannot be provided in some other way and is fundamentally misleading because it does not allow for comparisons of health risks with cigarettes. Again, it is an example of a pointless bureaucratic burden with no public health rationale. Worse, no such leaflet is required in cigarette packets. It is another example of the TPD placing a burden on the safer product, e-cigarettes, but not on the incumbent and far more dangerous product, cigarettes.

On the other hand, a promising and highly targeted strategy would be to use pack inserts *in cigarettes* to encourage smokers to try vaping or low-risk nicotine products. This could be a commercial decision by a tobacco company to encourage its consumers to switch to lower risk products or a government mandated message proposing a switch to low-risk products. The former is *prevented* by the TPD.[59] This would involve placing promotional inserts within cigarette packs recommending trial of vaping products or non-combustible tobacco products and offering inducements to smokers to switch. It may also involve risk communication (see above).

*The UK should remove the requirement for a packaging leaflet in vaping products, and instead specify mandatory information that must be included in the packaging. The UK should make amendments to domestic regulations to allow commercial incentive and/or mandate public information inserts in cigarette packs that encourage smokers to switch to approved low-risk products. This could also provide agreed relative risk information as proposed above.*

### 3.9 Remove wasteful restrictions on vaping product tank and e-liquid container size

The TPD limits the size of vaping product tanks to 2 millilitres and refill containers to 10 millilitres.[60] It is difficult to establish any reliable origin or rationale for this measure – and in practice there is none. Recitals 40-42 of the TPD reflect a reasonable approach to risk arising from containers of liquids that could be toxic if ingested: use well-engineered and child resistant containers; warn of the hazard; and provide information on what to do if the liquid is swallowed. This is the usual approach for managing hazardous substances in the home, for example, cleaning fluids, medicines and fuels – and there are international standards for child-resistant containers.[61] Limiting the size of the container to some

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58 Tobacco Products Directive, Article 20(4)(a) and SI 2016/507 Regulation 37 [link]

59 Tobacco Products Directive Article 13(a) and The Standardised Packaging of Tobacco Products Regulations, 2015 SI 2015/829 Regulation 10 (3a), (4), (5) [link]. The application of the EU Directive to low-risk *tobacco* products is clear but for non-tobacco e-cigarettes the Directive is somewhat ambiguous. The UK regulations unambiguously apply to both.

60 Tobacco Products Directive Article 20(3)(a) and SI 2016/507 regulation 36(2)(3) [link]

61 ISO 8317:2015 Child-resistant packaging -- Requirements and testing procedures for reclosable packages [link] and related standards, 55.020 - Packaging and distribution of goods in general [link]

notionally sub-lethal dose is not an approach widely used for hazardous products and not mentioned in the recitals to the TPD. Nicotine ingestion is rarely lethal, partly because it triggers vomiting, and it is not as toxic as widely assumed.[62]

The problem with smaller containers and tank sizes is that, for obvious physical reason, these generate more refilling activity, entail a greater likelihood of running out of liquid, more chance of spillage, and create more waste. It is made more difficult by the EU TPD insistence on small container sizes. It is a form of pointless regulatory harassment of vapers and for no public health or other policy benefit that we are aware of.

*The limits on tank and container size serve no purpose and should be eliminated. The market should determine appropriate container sizes for consumers. Regulators should stick to specifying child resistant features and appropriate warning and remedial information.*

### 3.10 Recognise and regulate novel oral nicotine products

Relatively novels forms of non-tobacco, non—combustible nicotine products are gaining welcome traction in the marketplace. These oral nicotine products such as pouches, films, lozenges and gums have a potentially important role to play in encouraging and supporting smokers to quit smoking and appear to offer a very low risk profile. To meet the 2030 target, the government should support the widest possible range of low-risk products: different smokers will use different products at different point in the journey to smokefree and at different times and in different situations. This is an area where product standards could be applied for consumer safety purposes (e.g. a limit of total nicotine content and standards for ingredients and contaminants). Marketing restrictions consistent with those applied to vaping products would also be justified.

*Establish a light-touch regulatory framework for oral nicotine products, recognising that their acceptability and appeal to consumers is integral to their public health effect.*

## 4 Create a coherent framework for all nicotine products

The EU directives provide an incoherent basis for regulating low-risk nicotine products. The UK now can fix those weaknesses to build a principled regulatory framework. At present, EU legislation draws arbitrary policy boundaries: including banning an entire category of low-risk tobacco products (snus) because it is sucked rather than chewed, conflating high-risk and low-risk tobacco products for policy purposes and missing out an important category completely: modern oral nicotine pouches and other non-tobacco oral nicotine products than include films, gums and lozenges are not covered. Aspects of the Directives are disproportionate or anti-proportionate, meaning higher burdens are applied to lower-risk products. There is also discrimination – meaning regulation favours the incumbent cigarette trade, for example the limits imposed on nicotine concentrations in e-liquids clearly discriminate against vaping products and in favour of cigarettes.

In this area, the UK should retain well-established regulatory principles that the EU has ignored in developing tobacco and nicotine policy – in particular, principles of proportionately and non-discrimination and an appropriate approach to the precautionary principle.

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[62] Mayer B. How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. *Arch Toxicol* 2014;88:5–7. doi:10.1007/s00204-013-1127-0 [link]

- **Proportionality**. Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.[63] In several cases, it is impossible to find a justification for the measure or its excessive intervention.
- **Non-discrimination or 'equal treatment'**. The principle of non-discrimination, as articulated by the Court of Justice should apply in European Union policymaking. It has been articulated as follows[64]:

  > *… the principle of equal treatment or non-discrimination requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified.*

- **Precautionary principle**. This principle is widely misapplied and misunderstood. It requires a careful consideration of "the benefits and costs of action or lack of action" – and therefore an assessment of likely perverse consequences of regulatory intervention.[65] In this case, that would mean regulation of safer alternatives that leads to more smoking.

In tobacco and nicotine policy, the EU does not follow these principles and as a result its policies and legislation are often arbitrary, ill-conceived and counterproductive. On leaving the European Union, the UK has the opportunity to re-engineer its framework for regulation of tobacco and nicotine to support its 2030 smoke-free goal and it would be effective to draw on these principles in a way that the European Union has not.

*We recommend that the UK orientate its policy to be 'risk-proportionate', and therefore to make the critical distinction in policymaking between combustible smoked products and non-combustible smoke-free products, not between tobacco and non-tobacco products. A new product category should be introduced to allow regulation of modern oral nicotine pouches and other non-tobacco oral product – thereby adding to the broad range of quality-assured products available to smokers to quit.*

## 5 Protecting the UK from adverse future EU legislative developments

European Union regulation in this area continues to develop and without UK representatives involved, it may take on a direction counter to UK national and public health interests. It is essential, therefore, that the government reserves the right to diverge from these directives from 1st January 2021, at least for England, Scotland and Wales.

### 5.1 Revision of the Tobacco Products Directive

*A further revision of the Tobacco Products Directive is possible in the next four years*. The European Commission is due to publish a report on the implementation of the TPD by 20 May 2021.[66] This report may then lead to a Commission proposal for a revision of the TPD. This may impose further unwarranted restrictions, for example on product design, ingredients and flavourings; place further limits on commercial freedoms; impose new packaging requirements; or impose an onerous approval process for certain products. It remains unclear how this process will evolve from 2021 to 2024 but given the Commission's approach to the review, it is unlikely that the TPD will move in the direction proposed in

63 Treaty on European Union Article 5.4. [link]

64 Case 304/01 Sept 2004 *Spain v European Commission* para 31

65 European Union, Communication (COM(2000) 1final) on the precautionary principle, 2000 – summary [link]

66 European Commission, Report on the Application of the Directive 2014/40/EU [link]

this briefing. It is more likely to become more burdensome and more restrictive towards low-risk products, and so even more protective of the cigarette trade and contrary to UK objectives.

### 5.2 Revision of the Tobacco Excise Directive

*A revision of the Tobacco Excise Directive is currently in progress*.[67] Our main concern is that the revision will apply non-zero minimum excise duty rates to low-risk tobacco and nicotine products. This would have the effect of attenuating the financial incentive to switch from smoking to a smoke-free product and so work against UK public health objectives. Any taxes should remain proportionate to risk[68], and in practice that means keeping excise on non-combustible products low or zero-rated.[69]

*In trade negotiations with the EU, the government should reserve the right to use its post-Brexit independence to diverge from the key EU directives on tobacco products, tobacco advertising and tobacco excise. There are pressing reasons, as detailed in this briefing, to do that without delay in 2021, but as these directives evolve, it is likely that the case for divergence will become more pressing, not less.*

67 European Commission, Revision of excise rule for tobacco [link]

68 Chaloupka FJ, Sweanor D, Warner KE. Differential Taxes for Differential Risks--Toward Reduced Harm from Nicotine-Yielding Products. New England Journal of Medicine 2015;373:594–7. [link]

69 New Nicotine Alliance. Revision of the Tobacco Excise Directive, Implications for low-risk nicotine products, December 2016 [link][full report - PDF]