UK New Nicotine Alliance

Registered charity in England and Wales – number 1160481

Mr Javed Khan OBE
Independent Review of Tobacco Policy

4th March 2022

Dear Mr Khan

We write on behalf of consumers of low-risk alternatives to cigarettes and in support of harm reduction as a critical strategy for future tobacco policy. Please find attached our submission to your review of tobacco policy in England. In summary, we make twenty proposals for your consideration.

1. Lift the EU-imposed ban on snus
2. Remove the 20mg/ml limit on the strength of nicotine e-liquid
3. Replace excessive and inappropriate warnings on vaping products
4. Replace excessive and inappropriate warnings on non-combustible tobacco products
5. Replace partial bans on vape advertising with controls on themes and placement
6. Replace blanket bans on advertising of low-risk tobacco products with controls
7. Limit plain packaging to combustibles but control themes on smoke-free packaging
8. Require NHS inserts in cigarette packs to encourage switching to smoke-free products
9. Allow commercial inserts in cigarette packs to promote smoke-free products
10. Amend the leaflet requirement in vaping products
11. Drive motivation to switch with improved risk communications
12. Eliminate pointless restrictions on tank and refill container sizes
13. Take a principled approach to flavoured smoke-free products
14. Introduce consumer protection regulation for modern oral nicotine pouches
15. Use fiscal policy to support the transition to smoke-free alternatives
16. Allow use of smoke-free products in public places
17. Impose well-designed age restrictions
18. Strengthen healthcare and public health system response
19. Allow prescribing of e-cigarettes on a trial basis and engage with vape shops
20. Use science and evidence to underpin the strategy

We would welcome a meeting with you to discuss these proposals. We confirm we have no conflicts of interest concerning the tobacco, nicotine or pharmaceutical industries.

Yours sincerely

Louise Ross
Chair
New Nicotine Alliance

Sarah Jakes
Trustee
New Nicotine Alliance

Clive Bates
Voluntary Public Health Adviser
New Nicotine Alliance

The Independent Review of the Government's Tobacco Policies
By Javed Khan OBE
Submission by the New Nicotine Alliance (UK)
Twenty policy proposals to address smoking and health disparities

Introduction

The New Nicotine Alliance is a non-profit charity representing the interests of current and future consumers of low-risk alternatives to cigarettes such as vaping products, nicotine pouches, smokeless tobacco, and heated tobacco products. These low-risk smoke-free alternatives to cigarettes provide a fast-acting and achievable pathway for many smokers who would otherwise be unable or unwilling to quit smoking or nicotine. This approach is known as tobacco harm reduction. Harm reduction is a widely used strategy in public health (for example, in illicit drugs, HIV, teenage pregnancy, and alcohol policy), but it has been underused as a tobacco policy strategy. We argue that in the next phase of tobacco policy, the government should go "all in" on tobacco harm reduction and maximise its potential.

In our view, large scale voluntary switching by smokers from cigarettes to low-risk alternatives is the game-changing strategy to meet the ambitious Smoke-free 2030 goal and address the pronounced health disparities caused by smoking. *We do not believe the government will come close to meeting the 2030 target without maximising the tobacco harm reduction opportunity.*

Our submission to the Independent Review highlights twenty policy measures that would help to expedite mass switching from smoked to smoke-free products.

These proposals build on two previous submissions to the Department of Health and Social Care.

- In October 2020, we wrote to the Department of Health and Social Care with a proposal to utilise post-Brexit regulatory flexibilities to contribute to levelling up and meeting the 2030 smoke-free goal.[1]
- In May 2021, we wrote to the Department of Health and Social Care with a range of proposals to meet the 2030 smoke-free goal and contribute to levelling up.[2]

This submission draws together and updates these proposals.

We have organised our submission into three main sections:

1. Problem definition – how we see the problem and opportunities
2. Strategy – the underpinning ideas for our proposed policy measures
3. Policy proposals – twenty policy initiatives to deliver the 2030 smoke-free target

We confirm we have no ties to any of the industries involved, and our engagement raises no issues under Article 5.3 of the Framework Convention on Tobacco Control. We are a charity registered in England, number 1160481.

1 Problem definition – outlining the challenge

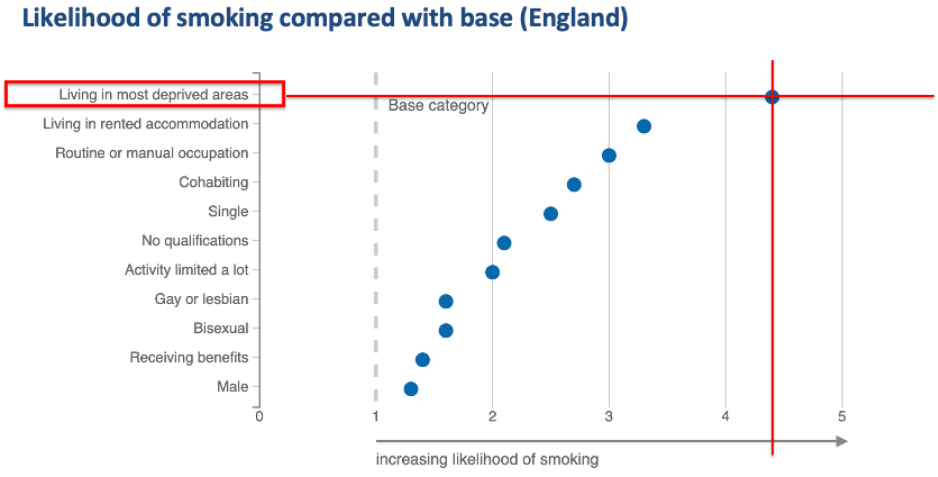
1.1 Health and wellbeing at the individual level

Smoking prematurely kills around 96,000 annually in the UK, more than obesity, alcohol, road accidents, drug misuse and HIV *combined*.[3] It is not just an end-of-life effect: smokers generally have worse health (34.4% report fair, bad or very bad health) than non-smokers (19.4%)[4].

Nicotine is the primary reason 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. Though not harmless, they are *much less harmful* – with likely risk reductions of one to two orders of magnitude. When smokers completely switch 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, in drugs, alcohol and HIV. This concept should be systematically extended to tobacco-related harms and the UK approach to the Smoke-free 2030 ambition and, through UK international advocacy, to the SDG goals as they relate to non-communicable diseases.

1.2 Health disparities at the population level

Even in 2022, around one in seven adults in England still smokes, and smokers are overrepresented in deprived communities, in sub-populations with low income, poor education and employment status, and among those with various forms of disadvantage, such as mental health problems, homelessness, prison experience, and substance use. See graphic below:



Source: ONS Smoking inequalities, England 2016 [link]

Across a wide range of measures, there are strong disadvantage gradients in smoking prevalence.

- 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)

1.3 Impact on household finances

Being a smoker is a costly 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 £11.15 per pack) would spend £4,070 per year, of which £3,269 or about 80% is tax. For comparative purposes, the Jobseeker's Allowance is £74.70 per week, or £3,884 annually.[5] Vaping provides an opportunity to switch to much lower cost vaping products. Depending on the choice of products, estimates suggest the cost of regular smoking is 5-15 times higher than vaping. It follows that substantial savings to the household budget are possible by switching from smoking to vaping.[6] Improving the options to switch to lower-cost products may also reduce the pressures that lead to illicit trade or switching to other smoking products (e.g., from cigarettes to hand-rolling) to save money.

1.4 National economic arguments

Reducing smoking by switching to low-risk products will reduce receipts of tobacco excise duty. However, the government is not indifferent to the health, life expectancy and productivity improvements 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.[7] The same assessment estimated loss of tobacco duty and net loss of VAT associated with quitting smoking at a present value of £11,000[8] - suggesting that the benefits are more than six times as great as the lost tax to the exchequer, a highly positive benefit-cost ratio.

1.5 Adolescent vaping and smoking

Much of the political and public health concern surrounding alternatives to smoking 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 – notably adult smokers and current or potential adolescent smokers.

- The respective risks must be considered carefully – vaping is a youth risk behaviour, but it is a low or distant risk compared to behaviours like smoking, heavy drinking, illicit drugs, teenage pregnancy or distracted driving. For tobacco policy, the youth focus should be on adolescent *smoking*.
- Vaping among young people in Britain remains low despite the popularity of vaping with adults. In the 16-18 age group, 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.[9] For these young people, vaping may be a beneficial diversion from smoking.[10] [11]
- The effect of adults who switch from smoking to vaping is to reduce the role-modelling impact of parents, siblings or other significant adults in young people's lives. British research shows that: "*parental and sibling smoking is a strong and significant determinant of the risk of smoking uptake by children and young people and, as such, is a major and entirely avoidable health risk*."[12]
- 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]*".[13]
- 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 turn triggers youthful curiosity - one of the main drivers of youth uptake.

2 Strategy – how to approach an ambitious smoke-free objective

In this section, we set out the main concepts that underline our twenty specific proposals set out in section 0 below.

2.1 Traditional tobacco control will not deliver the smoke-free 2030 goal

The smoking toolkit study shows smoking prevalence in England fell from 21.4% to 14.8% between 2010 and 2020 - a decline of less than one-third (31%). To meet the 2030 5% target, the decline between 2020 and 2030 would need to be approximately two-thirds (a 66% reduction) - *twice the ambition*. This challenge is also compounded by the concentration of the residual smoking population in disadvantaged population groups, where smoking is deeply entrenched. We do not believe a package of strengthened traditional tobacco control measures will come close to meeting the smoke-free 2030 goal. Tobacco control policy has consisted of years of high taxes, plain packaging, smoking bans, marketing bans, gruesome graphic warnings, visceral public campaigns, age restrictions and "denormalisation". This has been backed by extensive engagement in smoking cessation through the NHS and local authorities. Yet, the effect has been to leave one in seven adults still smoking but concentrated in the poorest and most disadvantaged sub-populations.

2.2 Maximal tobacco harm reduction is the only way to meet the 2030 goal

In our view, the key strategy for attaining smoke-free status, especially in individuals and communities where smoking is deeply entrenched, is switching from high-risk smoked products to low-risk smoke-free products. The reason is simple: this is a more straightforward pathway to follow for many smokers because it does not demand the user gives up nicotine or many of the sensory or behavioural aspects of smoking. Yet switching is likely to reduce health risk by 95% or more. Switching from cigarette smoking to these new products provides three main benefits: (1) an improvement in long-term health outlook and life expectancy; (2) a rapid improvement in wellbeing and fitness; and (3) substantial household budget savings due to the high cost of cigarettes.

2.3 Smoke-free policy must have the support of those most affected

There has been sustained public support for smoking-reduction policies. However, policymakers should pay particular attention to those most affected by policies to achieve the Smoke-free 2030 ambition and be mindful of the effects on those who continue to smoke (still 2-3 million people even if the policy succeeds). It is essential that ministers carefully consider the *policy-induced harms* of imposing measures like taxes, restrictions and campaigns that may make people who smoke feel stigmatised. As far as possible, the 2030 target should be achieved *with the consent of those affected*, using all available insights and levers to convince those most reluctant to stop smoking, but without causing them significant harm. That suggests a different approach to the traditional toolkit of tobacco control will be needed to reach the hardest-to-reach fairly and proportionately. A central premise of our proposals is that ambitious public health targets should, as far as possible, be met with measures that rely on the consent and informed choices of those affected. The measures we propose should appeal to hearts and minds rather than making smokers feel alienated and punished.

2.4 The importance of Brexit and risk-proportionate regulation

To meet the target, address health disparities and realise tangible benefits in deprived communities, we believe the government will need to go "all in" on tobacco harm reduction. The UK exit from the European Union provides many opportunities for better, pro-health regulation that would be obstructed by the relevant European Union directives. Some of the agenda we propose below involves some smart *deregulation* that we recognise some stakeholders may find uncomfortable. The purpose of such deregulation is to allow smoke-free alternatives to compete effectively with the deeply entrenched incumbent cigarette trade. We do not favour a *laissez-faire* approach to nicotine regulation: we stress "risk-proportionate regulation" – the idea that restrictions and burdens on commercial freedoms should be proportionate to risk and should not foreclose opportunities. Following Brexit, the UK is free to remove or modernise a range of excessive regulatory restrictions on smoke-free products that, in practice, function to protect the cigarette trade.

2.5 The danger of over-cautious consensus positions and significant public spending

We are concerned that consensus positions of tobacco control and medical organisations reflect the measures they find agreeable, not necessarily what will work or be sufficient to meet the goal. [14] The challenge for the review is to identify what will work and challenge the stakeholders who reject such measures to articulate the justification for their opposition. While we understand the history of tobacco and smoking, we are concerned that the anti-tobacco reflex is too indiscriminate and indifferent to promising harm reduction options. *We stress that the critical distinction in tobacco and nicotine policy is not between tobacco and non-tobacco products but between combustible and non-combustible products*. We call for certain tobacco products – such as heated tobacco and snus – to be treated similarly to non-tobacco products such as e-cigarettes and nicotine pouches. This distinction is logical because *combustion* causes most of the harm. However, it does mean including non-combustible tobacco products in the harm reduction portfolio if the government is serious about meeting its 2030 Smoke-free objective.

We are also concerned about proposals that rely heavily on assumptions of substantial additional public expenditure or novel and untried taxation policies to raise funds for a specific cause like tobacco policy. The danger is that such funds will not be forthcoming in an environment where the Treasury is retrenching the public finances after the unconventional measures taken during the pandemic. Our proposals rely primarily on consumers making pro-health choices on their own initiative and at their own expense in a supportive regulatory and communications environment that encourages switching from high-risk to low-risk nicotine products.

3 Policy - twenty proposals to address smoking and health disparities

We propose the following package to address the opportunities to reduce the individual and population health, welfare and economic burdens of smoking.

3.1 Lift the EU-imposed ban on snus

The government should lift the European Union ban on snus (oral tobacco). The lowest smoking rate in Europe (7%) is in Sweden, where many nicotine users use snus, a form of smokeless tobacco. In Norway, daily smoking among young women (age 16-24) reached 1% in 2019 and remained at that level in 2021. This was a fall from 17% to 1% prevalence over just ten years as almost all nicotine use in this age group has migrated to snus.[15] This is already a true "smoke-free generation", and it has been achieved very quickly and by consent rather than by force. The most recent Global Burden of Disease (GBD) study found no excess mortality, oral cancer, ischemic heart disease or stroke risk for smokeless tobacco users in Sweden and Norway,[16] and the 2016 GBD concluded: "*for snus or snuff, we did not find sufficient evidence of an RR greater than one for any health outcomes*".

However, despite no discernible health risk, the EU Tobacco Products Directive bans snus[17] though allows cigarettes to be ubiquitously available. 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, and therefore lifting the ban would not be divergent with the rules of the EU internal market. The 2021 Eurobarometer survey shows Sweden has a smoking prevalence of 7% compared to the EU average of 23%.[18] This is because many nicotine users consume snus instead of smoking. As a result, Sweden has by far the lowest levels of cancer and heart disease in men and clearly attributable to the use of snus by men as an alternative to smoking.[19] [20]

There is an obvious case for lifting the ban, including the harm reduction benefits, negligible health impacts, and the availability of chewing tobacco and cigarettes. That case has been made repeatedly to the European Commission and others.[21] The Swedish government has an appropriate regulatory regime for oral tobacco (snus), which could be adopted or adapted for the UK.[22] Smokeless tobacco intended for *chewing* is already legal in the UK, and it is absurd for policymakers to allow or ban a tobacco product depending on what the user does with it once inside their mouth. Chewing tobacco use is widely prevalent in UK South Asian communities.[23] Yet these smokeless products are often high in carcinogens and are currently barely regulated. The UK could develop a regulatory scheme for all smokeless tobacco based on technical advice from WHO's expert 'TobReg' committee in 2008.[24]

To maximise the potential of tobacco harm reduction, it is essential to have a diverse range of smoke-free options that provide for different tastes, different points in a transition to smoke-free status, and use in different settings. Even if the interest in snus turns out to be limited (we cannot know this while it is banned), *there is no reason to stop any smoker from choosing snus as an alternative to smoking.* The snus ban has no basis in science, policy or ethics and is essentially a violation of consumer rights.

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

3.2 Remove the 20mg/ml limit on the strength of nicotine e-liquid

The government should raise the European Union limit on nicotine concentration in vaping liquids to allow vaping products to compete more effectively with cigarettes. This change is necessary to provide a satisfying alternative to smoking in a compact format. The limit is arbitrary and based on a nonsensical quantity (nicotine liquid strength) and does not do what it was supposed to do - set a level playing field for competition between smoking and vaping. The Tobacco Products Directive limits nicotine concentrations in e-liquids to 20mg/ml (about 2% nicotine concentration)[25]. The 20mg/ml limit in EU Tobacco Products Directive (20)(3)(b) should be lifted, and the limit should default to that built into UK Poisons Act, in which nicotine solutions with less than 7.5% nicotine are exempt from classification as poisons. This legacy European Union rule provides no benefits or consumer protections but provides unjustified regulatory protection to cigarettes on sale in the UK based on faulty reasoning.

Products with stronger liquids available in the United States, such as the Juul pod, have 59mg/ml liquids (~5% nicotine). These have proven highly successful in the US market but are locked out of the EU. Yet these products have been effective at helping smokers to switch to vaping as an alternative to smoking,[26] and the limited products available in the UK under EU restrictions appear less effective.[27]

With this limit on vaping technology in place, cigarettes can deliver a higher peak of blood-nicotine than many vaping products – therefore leaving the most dangerous product with a considerable advantage in the marketplace.[28] 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'[29] and is 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 a lesser quantity of whiskey. Though whiskey is 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.[30]

The misunderstanding was pointed out to the Commission when the legislation was crafted, including by several of those whose science the Commission cited to justify its approach.[31] [32] [33] The 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 deters more dependent smokers from switching in the first place. It makes 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 while combatting the craving for a smoked cigarette, a common feature of the quitting process. In 2016, at the time of implementation of the TPD, Action on Smoking and Health estimated that 250,000 vapers were using

e-liquids stronger than the EU's newly imposed limit.[34] Why should regulators make it more difficult for those who want higher nicotine strengths to quit smoking?

2. **Creates a barrier to better, easier-to-use devices**. It works against more compact devices that use low volumes of liquid at a higher strength, which do not require refilling or complicated configuration. Yet these easy-to-use and convenient devices are often valued by smokers, particularly in the early stages of switching 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 smokers 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 means 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 deliberately *increase* them through regulation.
5. **Promoting a black market.** It promotes a black market in the products that are banned. These are either 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 also encourages users to mix their own liquids from a nicotine base liquid, typically 7.2% nicotine or even near-pure nicotine, in conditions of unknown cleanliness – a dangerous substance and procedure.
6. **Favouring the cigarette trade**. The nicotine delivery of cigarettes *to the user* is not significantly limited by the nicotine *yield* limits[35]. Most smokers can compensate and self-titrate to achieve the nicotine dose they want. This effect has been well documented for several decades.[36] [37] However, the 20mg/ml limit is a significant constraint for the e-cigarette category.

The 20mg/ml limit should be removed and not replaced. Longstanding UK poisons legislation applies to nicotine solutions exceeding 7.5% nicotine,[38] and this is a sufficient limit for health and safety purposes.

3.3 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 more prominent, bolder, more visceral and more graphic. However, the European Union Tobacco Products Directive carelessly and without evidence applies this philosophy to vaping products,[39] with the danger that users will find the warnings off-putting or an implicit exaggeration of risk. This is because they look like the warnings applied to cigarettes, at least before 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*".[40] Researchers at London South Bank University found evidence that these warnings deter smokers from switching from smoking to vaping.[41]

> …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:

> 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 smokers to try it. Replace warnings on all smoke-free nicotine products with more sophisticated risk communications. Statements of the following form could be tested and developed for use on non-combustible tobacco or nicotine products.

- "*Switching completely from conventional cigarettes to this product significantly reduces your body's exposure to harmful chemicals.*"
- *No [tobacco][nicotine] product is safe, but this product presents substantially lower risks to health than cigarettes.*
- *Any [Tobacco][Nicotine] product can be addictive, but this product presents substantially lower risks to your health than smoking.*

These statements are designed to replace the current mandatory warnings on non-combustible tobacco products. They could be supplemented by broader risk communications described in section 3.11 below.

The existing warning regime for vaping products should be overhauled and replaced by risk communications that reflect substantially reduced risk relative to cigarettes to encourage switching.

3.4 Replace excessive and inappropriate warnings on non-combustible tobacco products

The European Union Tobacco Products Directive applies counterproductive warnings to low-risk tobacco products, including smokeless tobacco, oral tobacco products (though these are currently banned in the UK) and heated tobacco products.[42] 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 helpful context or guidance to consumers.

The same approach should be adopted for these products as for vaping products. The critical 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 cigarettes to encourage switching.

3.5 Replace partial bans on vape advertising with controls on themes and placement

For vaping products, the European Union's Tobacco Products Directive strongly restricts advertising and promotion – prohibiting advertising in publications and the press, all 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 smoke-free tobacco brands). Advertising bans work against the 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 because it presents a rival proposition to smokers and attempts to draw them away from smoking. However, unlike public sector anti-smoking advertising, it does this without public spending and competitive-selection pressure favouring effective advertising. There is some evidence that advertising low-risk products does promote switching and that bans on such advertising would be counterproductive.[43] [44] [45]

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.[46]

> 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 was only done for the UK implementing regulations. As such, it came two years after the Tobacco Products Directive was irrevocably finalised in closed meetings in Brussels in 2014, and there was no flexibility to change the implementing regulations. Therefore, the impact assessment did not inform the UK government's position in negotiating the TPD itself – a clear process flaw that can now be rectified retrospectively.

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. These codes provide a good framework for responsible advertising of all smoke-free alternatives to cigarettes, which has been successful where applied. The Committee of Advertising Practice summarises these as follows:[47]

- Ensure your ads are socially responsible
- Don't target, feature or appeal to children
- Don't confuse e-cigarettes with tobacco products
- Don't make medicinal claims and take care with health claims
- Ensure you don't mislead about product ingredients or where they may be used

Control over themes and placement would be similar to the approach used for alcohol, arguably a significantly more dangerous consumer product than e-cigarettes, and especially for young people. This was the approach used for e-cigarette advertising until the European Union ban was implemented. 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. The government 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)

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

For low-risk tobacco products (smokeless, oral and heated tobacco products), the European Union Tobacco Advertising Directive (TAD) and UK legislation combine to ban almost all advertising and promotion for tobacco products.[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 that includes advertising for cigarettes but also safer alternatives to cigarettes that are also tobacco products – such as snus and heated tobacco products. This legislation now looks counterproductive and protective of the incumbent cigarette trade.

The conceptual arguments made above apply equally to low-risk tobacco products as well as to vaping products. The critical 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.

We have listed this separately to the proposal to liberalise vaping advertising (above) because it involves a different and more difficult legislative path (amending primary legislation).

The blanket 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 should recommend appropriate controls – comparable to alcohol or e-cigarettes.

3.7 Limit plain packaging to combustibles but control themes on smoke-free packaging

The UK has an established policy of plain standardised packaging for cigarettes. We do not wish to relitigate the arguments for and against that measure. However, it should not be applied to non-combustible products. There is no case for applying a standardised packaging mandate to smoke-free products as packaging is integral to the product's appeal and the experience of visiting a vape shop or online retailer. Where the product is a much safer alternative to cigarettes, there should be a presumption of freedom to design packaging as the manufacturer or vendor sees fit, circumscribed by controls on themes. The government should apply the same thematic principles in the CAP codes (see 3.3 and 3.6 above) to branding and packaging, including flavour descriptors. This should operate through a complaint-driven system. The justification for plain standardised packaging rests on the great harm caused by cigarettes and other smoking products. This justification does not apply to smoke-free products.

Plain packaging is inappropriate for smoke-free products and conveys excessive risk. The pack surface should be treated as a marketing space and treated the same way as advertising for smoke-free products, with control of themes and age-targeting.

3.8 Require NHS inserts in cigarette packs to encourage switching to smoke-free products

This measure would require the inclusion of a pack insert in cigarette packs that promoted smoking cessation and switching to vaping. The information would be generic rather than brand-specific and framed as "a message from the NHS", drawing on messages already available on the NHS website.[50] This concept of an information insert already exists for vaping products and is a requirement of the European Union Tobacco Products Directive Article 20(4)(a).

A direct communication from the NHS to smokers via cigarette packs would potentially reach millions who would not see such messages on websites and would function as 'brief advice' from a trusted source.

3.9 Allow commercial inserts in cigarette packs to promote smoke-free products

This measure would allow cigarette companies to place inserts in cigarette packs with commercial promotions to switch from smoking to smoke-free products - this may include promotional material, coupons, or sign-up for marketing contact. Note that these promotions would be, by definition, targeted at smokers. This measure captures and capitalises on a competitive driver for tobacco companies to transition to low-risk products and retain market share as the consumers shift to non-combustible products. This measure would be *in addition* to any public health mandated messaging described in the previous section.

Allowing tobacco companies to promote smoke-free alternatives to their own customers would tap into tobacco companies' marketing incentives to switch smokers to their own alternatives to smoking and create a benign competitive dynamic.

3.10 Amend the leaflet requirement in vaping products

The European Union Tobacco Products Directive requires an information leaflet to be included in the packaging on e-liquids, with the specification of information to be provided on the leaflet (including, for example, contraindications, warnings for specific risk groups, possible adverse effects; addictiveness and toxicity).[51] However, the specified information provides little value to users that cannot be delivered in another way. It is fundamentally misleading because it does not allow for comparisons of health risks with cigarettes. No equivalent communication is required in cigarette packs.

The government should remove these pointless and potentially misleading EU requirements for an information leaflet by deleting Regulation 37(2). The content and themes of a leaflet could reinforce the harm reduction message and affirm the choice of vaping over smoking, building user confidence in switching to vaping. Around one-third of British vapers are dual users (making ongoing use of both smoked and smoke-free products). A pack insert could be used to encourage the transition from dual-use to exclusive smoke-free status. Again, a health message branded with the NHS could be included, suggesting it is shared with friends, relatives, and workmates.

Messaging leaflets included in smoke-free product packaging should be amended or adopted to provide NHS reinforcement of positive health choices, to consolidate user choices made to switch and promote migration from dual-use to exclusive use of smoke-free products.

3.11 Drive motivation to switch with improved risk communications

The government should take a more assertive 'information environment' that stresses the benefits of going smoke-free and challenges misinformation and confusion about alternatives like e-cigarettes. Clear direction-setting from ministers, senior officials like the Chief Medical Officer (CMO) and trusted public figures would reassure users about migration from smoking to smoke-free.

Approve a range of accessible risk communications statements that commercial actors can use for any product category that can beneficially displace smoking, such as e-cigarettes, heated tobacco products, oral nicotine or snus. These would be generic and provide digested risk information supported by scientific assessment. This approach was proposed in Canada and then withdrawn. For e-cigarettes, Canada proposed the following:

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.

A similar set of messages, the circumstances in which they could be used, and by whom could be defined for England.

The government or other trusted source should define a set of generic risk communication talking points that can be used to differentiate high-risk smoking products from much lower risk smoke-free products.

3.12 Eliminate pointless restrictions on tank and refill container sizes

The European Union Tobacco Products Directive limits the size of vaping product tanks to 2 millilitres and refill containers to 10 millilitres.[52] 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.[53] Limiting the size of the container to some 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.[54]

The problem with smaller containers and tank sizes is that, for obvious physical reasons, 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 insistence in EU Tobacco Products Directive on small container sizes. It is a form of pointless regulatory harassment of vapers, and no one has been able to identify any public health or other benefits.

The tank and container size limits 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, as appropriate, warnings and remedial information.

3.13 Take a principled approach to flavoured smoke-free products

Flavours are integral to the appeal of low-risk alternatives to cigarettes. Cigarettes provide intense flavour sensations via the chemicals in tobacco smoke, many of which are harmful. The smoke-free alternatives, by contrast, generally add flavour agents to provide a good sensory experience for users, and these can be controlled more easily than smoke chemistry. Many consumers emphasise their exit from smoking is maintained by preferring non-tobacco flavours in smoke-free products. Regulation of flavours should proceed with great care for unintended consequences (driving people back to smoking or inhibiting switching). Any regulation of flavours should be based on the following:

- Impose controls on *chemical agents* that pose a material risk to health (e.g. carcinogenic, mutagenic, reprotoxic) where the justification is based on consumer protection.
- Impose controls on *flavour descriptors and brand names* that are irresponsible or inappropriate. Such controls should be based on the same criteria used to assess whether *advertising* is appropriate in the Committee of Advertising Practice codes.
- There should be no attempt to control the available sensory experience (i.e., the feel of using a flavour product) to 'protect' a sub-population like adolescents. The sensory experience should be a matter of consumer choice and is essential in sustaining competition and maximising switching.

The only controls on flavouring agents in smoke-free products should be based on any chemical hazard and consumer protection, not deterring use.

3.14 Introduce consumer protection regulation for modern oral nicotine pouches

Develop a consumer-orientated regulatory framework for modern oral nicotine pouches focusing on consumer choice, safety and predictability. At this stage, we can suggest design principles for regulations rather than specific regulatory limits. These principles include:

- Consumer choice and support for innovation should be the primary concern: regulation should not make these products less attractive or otherwise less competitive compared to cigarettes or tobacco-based snus, at least without a justification.
- There is a default limit of 7.5% nicotine concentration by weight built into The Control of Poisons and Explosives Precursors Regulations 2015 (Regulation 5, Schedule Part 2). Any other limits, for example, limits to the concentration or total mass of nicotine should be justified on consumer protection grounds.

- On 21 January 2021, New Nicotine Alliance wrote to the Minister for Public Health proposing that the Committee on Toxicology should examine this issue.

> We are also of the opinion that to formulate good regulation of these products, the government would benefit from a toxicological study - as previously conducted by the Committee on Toxicity (COT) towards vaping products and heated tobacco – to create an evidence base which can inform policymakers fully before any debate on how beneficial regulation can be achieved. We would respectfully request that the COT be approached by your office with a view to placing these products on their agenda for future review.

- Add appropriate risk communication information and safety information to packaging.
- Place the same limits on marketing these products as on vaping products.

Establish a proportionate regulatory regime for nicotine pouches and other non-tobacco oral nicotine products based on consumer welfare and protection.

3.15 Use fiscal policy to support the transition to smoke-free alternatives

Smoke-free products function as *economic substitutes* for cigarettes. If the cost of vaping increases relative to smoking, the demand for cigarettes will increase and progress towards the smoke-free goal will falter. Evidence for substitution comes from analyses of the effects of measures to control e-cigarette use. Evidence suggests e-liquid flavour bans,[55] e-cigarette advertising bans,[56] and access restrictions[57] may *increase* cigarette smoking. WHO also argues: [58]

> ENDS/ENNDS and cigarettes are substitutes – higher cigarette prices are associated with increased ENDS/ENNDS sales

It follows that the opposite is also true – that higher e-cigarette prices would be associated with increased smoking. Empirical and market data also support this.[59 60 61 62 63 64 65 66 67] To draw on a couple of specifics:

Abouk and colleagues (2021) studied the impact of ENDS taxes on youth tobacco use, concluding:[68]

> … we estimate sizable positive cigarette cross-tax elasticities, suggesting economic substitution between cigarettes and e-cigarettes for youth. These substitution effects are particularly large for frequent cigarette smoking. We conclude that the unintended effects of ENDS taxation may considerably undercut or even outweigh any public health gains.

Pesko and Warman (2017) studied the effects of prices on youth transitions in the US National Youth Tobacco Use Survey from 2011 to 2015 and concluded:[63]

> We find that higher e-cigarette cartridge prices reduce e-cigarette use and increase current cigarette consumption, especially for males and for older teenagers. Our results suggest that on average e-cigarettes reduce youth smoking.

Pesko and colleagues (2020) examined adult tobacco use and price data and concluded:[69]

> Similarly, we find that higher e-cigarette tax rates increase traditional cigarette use and reduce e-cigarette use. Cross-tax effects imply that the products are economic substitutes. Our results suggest that a proposed national e-cigarette tax of $1.65 per millilitre of vaping liquid would raise the proportion of adults who smoke cigarettes daily by approximately one percentage point, translating to 2.5 million extra adult daily smokers compared to the counterfactual of not having the tax.

The fact that ENDS and cigarettes are economic substitutes should be a central consideration in ENDS tax policy because this is the mechanism by which ENDS taxation is likely to do more harm than good. In an excellent example of a synthesis of the literature for decision-makers, Associate Professor Michael Pesko of Georgia State University and colleagues wrote to members of the US Congress setting out evidence-based concerns about the likely perverse consequences of ENDS taxation – i.e., more smoking. The letter summarised the evidence by estimating the effect of the proposed Federal ENDS tax, which would approximately equate taxes on cigarettes and ENDS, as follows[70]

- *Simulating the current bill's e-cigarette tax on teen tobacco use indicates that this policy would reduce teen e-cigarette use by 2.7 percentage points, but that 2 in 3 teens who do not use e-cigarettes due to the tax would smoke cigarettes instead (study A). This would result in approximately a half-million extra teenage smokers overall. This finding that teens substitute to cigarettes in response to e-cigarette taxes has also been documented using National Youth Tobacco Survey data (study B).*
- *The tax would raise the number of daily adult cigarette smokers by 2.5 million nationally and reduce adult e-cigarette users by a similar number (study C).*
- *For every e-cigarette pod eliminated by an e-cigarette tax, more than 5.5 extra packs of cigarettes are sold instead (study D).*
- *For every three pregnant women that do not use e-cigarettes due to an e-cigarette tax, one smokes cigarettes instead (study E).*

The economic arguments for switching to smoke-free products are powerful influences on switching incentives and are particularly important to low-income smokers. Switching can be welfare-enhancing both from a health and wellbeing perspective but also through its effect on the household budget.

To support the smoke-free goal, HM Treasury should announce a tax policy intention not to impose any excise duties on non-combustible nicotine products before 2030 or until the smoke-free goal has been reached.

Harmonise VAT rules for vaping (and other smoke-free products) products and over the counter NRT products on the basis that vaping is proven to be a more effective smoking cessation aid.[71] At present, NRT products attract the reduced VAT rate under 2008 provisions for smoking cessation aids.

If the government insists on taxing non-combustible tobacco products, it should establish a risk-proportionate element in tax design. It should do this by announcing that the highest level of tax on a non-combustible tobacco product will not exceed an equivalent of one-third of the lowest level of taxation on combustible tobacco products.

The government should not tax smoke-free alternatives to cigarettes to maximise the economic incentive to switch. Where taxes are applied, for example, to heated tobacco products, it should be a policy objective to maintain a pronounced differential in prices for smoked and smoke-free products.

3.16 Allow use of smoke-free products in public places

The government should maintain the *status quo*. The government should only intervene to limit the use of smoke-free products in enclosed spaces if there is a clear risk to the health or safety of bystanders, not to try to modify the behaviour of users. There is no compelling evidence of material risks to bystanders from exposure to vape or heated tobacco aerosol. The decisions on policy in enclosed spaces should, as now, continue to be made by owners or managers of premises. The government's appropriate role is to provide guidance on the risks and benefits of different approaches so that owners or managers can make informed decisions. The guidance published by Public Health England in 2016 (*Use of e-cigarettes in public places and workplaces: Advice to inform evidence-based policymaking*)[72] is an excellent example of appropriate government action in this area. An update to this guidance would be welcome and could include tailored advice for different settings – pubs, hotels, transport, stadiums etc.

The government should maintain its policy of relying on owners and managers of premises to determine policy on indoor use of non-combustible products, focusing on providing guidance to inform policy.

3.17 Impose well-designed age restrictions

Limit sales to people aged 18 and over. Vaping and other smoke-free products are for adult nicotine users and should be available for sale to people aged 18 or above. This should apply even if there are changes in age restrictions for combustible tobacco. *Possession* should never be an offence.

Allow parents, guardians or carers to supply smoke-free products by proxy. Harm reduction should not have to wait until 18. Adolescent underage smokers are disproportionately from disadvantaged backgrounds (for example, users of Child and Adolescent Mental Health Services, Looked After Children and those in the youth criminal justice system). For many adolescents, a switch from smoking to vaping may be highly positive (not something to prevent by law). Smoke-free products should be available as a harm-reduction alternative to cigarettes at any age with the permission of a parent, guardian or carer, who should be exempt from restrictions on proxy purchasing for smoke-free alternatives to smoking. This requires an amendment to Section 91 of the Children and Families Act 2014 to create an exemption or a defence for parents, guardians or carers supplying smoke-free products by proxy in the interests of the person under the age of 18. In Leicester City, a scheme to help young people in care to stop smoking saw vaping as the only successful method of getting young clients to stop smoking. NRT had no appeal to these young people.

Age restrictions should be designed to prevent unsupervised youth uptake but not to prevent or penalise responsible adults from helping young people divert from smoking. There is no reason why harm reduction should only start at age 18.

3.18 Strengthen healthcare and public health system response

Adapt the GMS contract to more strongly incentivise GPs to increase smoke-free status in the populations they serve. General practitioners should lead NHS efforts to achieve smoke-free status by whatever means work, including recommending the full range of non-combustible, harm-reduction

alternatives to smoking (e-cigarettes, heated tobacco products, oral pouches, and snus). To engage GPs, they must have access to quality actionable advice and information backed by compelling incentives. While there are many excellent GPs and other patient-facing health professionals, the overall picture is still mixed. This is not surprising given the influence of misleading news coverage, ideologically motivated health organisations, and unscrupulous academics. Achieving sustained smoke-free status should be well rewarded in the NHS General Medical Services (GMS) contract Quality and Outcomes Framework (QOF). This incentive system should be rationalised to focus on the outcome - smoke-free status - to encourage innovation in achieving this. The National Centre for Smoking Cessation and Training should develop advice for healthcare providers on integrating tobacco harm reduction into smoking cessation activity.

Take the opportunity of hospital admissions as a point of intervention to encourage sustained smoke-free status. Hospitals should encourage a switch to smoke-free alternatives for patients presenting with high dependence on smoking. This encouragement should extend to visitors as they are likely to form part of the community or family context for smoking. The announcement of a trial of this approach is very welcome, and we hope the government and NHS will act on the results if they show promise.

The government should provide local authorities with clear guidance about the comparative harms of combustible cigarettes and reduced-risk alternatives. Improved information will allow elected members and officials to make informed decisions when formulating and setting local policy. It will help encourage local government and Directors of Public Health to do everything in their power to contribute towards reducing smoking rates among their electorate.

- Continue government-backed campaigns like Stoptober with intensified messages about switching.
- Prioritise the updating of relevant publications by the National Centre for Smoking Cessation and Training.

The existing NHS incentive structures should be used to motivate general practice and hospitals to more assertively address smoking, including through brief interventions on tobacco harm reduction. Local authorities and Directors of Public Health should become more engaged.

3.19 Allow prescribing of e-cigarettes on a trial basis and engage with vape shops

We recommend NHS support for initial trial and transition to smoke-free status among disadvantaged groups. The public purse should not, as a general rule, pay for vaping or other smoke-free alternatives. These are consumer behaviours, and consumers should meet the costs. However, we do believe there is a role to support the initial conversion from smoking to vaping. Assistance at the point of conversion is especially important for low-income or other disadvantaged groups where initial outlay with uncertain results may be a significant barrier to trial. The most effective way to deliver this is an empirical question with trade-offs between simplicity, administrative cost, user choice and flexibility and may vary from situation to situation. We recommend a review of existing practice and rapid experimental trials.

There is a significant pool of expertise and insight in the vaping shops, combined with a non-clinical environment that may work better for some smokers. There is potential to make better connections between the healthcare system, public health and vape shops. Stop-smoking services and NHS providers should team up with the experts in vape shops to help consumers switch from smoking to vaping, where that is what they want to do. There are already excellent examples of mutual assistance and two-way

education between stop-smoking services and vape shops that provide experience to build on. There are two different models at work: smoking cessation aims to help a smoker achieve abstinence by managing withdrawal and craving. The consumer route seeks to replace one pleasurable habit with another but at vastly lower risk. The latter involves a different mindset and more in-depth product knowledge, which is more likely to be forthcoming in a vape shop than a smoking cessation clinic.

Given the implications for health, welfare and the healthcare system, there is a justification for time-limited support to help smokers switch from smoking to smoke-free. This is no different in principle to support for smoking cessation but offers a separate and additional pathway to reach smoke-free status.

3.20 Use science and evidence to underpin the strategy

The Department of Health and Social Care to continue the annual evidence assessments commissioned by Public Health England (now Office for Health Improvement and Disparities) and undertaken by experts at King's College London (2015-2022) and other high-trust institutions.

- Support a set of 'living reviews' of critical aspects of scientific knowledge concerning tobacco harm reduction, such as exposure biomarkers studies and other studies on product risk compared to smoking and absolute risk benchmarks. This would complement the living systematic reviews of e-cigarettes for smoking cessation undertaken by the Cochrane review team.
- Broker a new consensus statement from public health groups, updating the 2016 statement.[73] A revised and widely endorsed statement would provide further confidence for the public and professionals.
- Support a coordinating mechanism (a "priority-setting partnership") among research councils and foundations to survey the need for actionable evidence, taking account of the views of stakeholders and the at-risk populations.
- Publish an annual joint statement on the Smoke-free 2030 goal by the CMO and Minister for public health. This should provide an update on progress and advice to the public, media and health professionals on how to respond.

The Smoke-free 2030 agenda and its impact on smoking and health disparities should be built on a foundation of high-quality science and behavioural economics and be backed by robust monitoring and policy evaluation.

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