Tobacco harm reduction in England – England's Tobacco Control Plan

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England has adopted a broad-based comprehensive approach to tobacco control, adopting the main tools of established tobacco control: tobacco taxation; smokefree environments; advertising bans; standardised packaging; warnings and risk communications; support for smokers wishing to quit and some product regulation. However, what is different and interesting in England is the very positive approach taken to vaping and its role as a harm reduction approach in tobacco control. Harm reduction is recognised as integral to tobacco control in the WHO Framework Convention on Tobacco Control:[1]

> „1(d) ‚tobacco control' means a range of supply, demand and **harm reduction strategies** that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke;" (emphasis added)

England is rightly seen as one of the world's most progressive backers of tobacco harm reduction. The approach covers law and regulation, taxation, communications, research and service provision. There is a broad consensus in favour of tobacco harm reduction among the main agencies and non-governmental organisations, including key players like Public Health England, Cancer Research UK, the Royal College of Physicians, Action on Smoking and Health and a group of credible academics.

In 2017, the Department of Health (UK/England) released its tobacco control plan for England: *Towards a smoke-free generation: tobacco control plan for England*[2] and followed up with a delivery plan.[3] The embrace of vaping and other low-risk alternatives to smoking runs through the text. This is probably the first significant government policy paper anywhere that recognises and pursues the opportunities of tobacco harm reduction, rather than defining these technologies as a threat to be suppressed. For that, the Department of Health and its allies deserve considerable credit.

How did England's positive approach to vaping emerge?

The history is instructive, because it shows that decisions and leadership positions taken by consumers and by key individuals at decisive moments

changed the course of policy. There was not a single point at which the government in England decided to be pro-vaping.

In 2010, e-cigarettes became a visible political issue for the first time. The Medicines and Healthcare Products Regulatory Agency (MHRA) noticed the presence of nicotine products on the UK market that were growing in popularity but were not licensed as medicines. The MHRA recommended that the products should be regulated as medicines and those products without marketing authorisation (all e-cigarettes at the time) should be taken off market in 21 days. The MHRA went out to consult on the proposal,[4] receiving submissions from the usual medical and health organisation supporting the *de facto* ban. But something else happened: over 1,000 consumers wrote in explaining their personal experience with e-cigarettes and imploring the regulator not to remove them from the market. These personal and visceral accounts cut through and the proposal was shelved.

But it was shelved only until December 2012, when the European Commission brought out its proposal for a revision to the Tobacco Products Directive (TPD). At that time, the TPD in force had been agreed in 2001, and predated the emergence of vaping products.[5] The Commission proposed a single approach: regulate these products as medicines. For regulators, this was simple and elegant. Just adopt a regulatory framework and related institution that already exists – all achieved by neat cross reference between the new Tobacco Products Directive (nicknamed TPD-2) and the Medicines Directive.[6] A perfect solution, but only if you are a bureaucrat. For consumers and producers, it was a nightmare. The basic problem is that vaping products are not medicines, their users are not patients and the manufacturers do not make therapeutic claims. With one important exception, the manufacturers would be unable to bear the weighty burdens of a medicine regulation approval process. Nevertheless, the UK government decided in June 2013 that it would back the Commission's proposal and lined up with health organisations to back the medicalisation proposal.

As with the abortive attempt to impose medicine regulation in 2010, the proposed directive galvanised consumers and pro-harm reduction public health experts into a massive and ultimately successful advocacy effort to defeat this measure in the European Parliament. This time, consumers from all over Europe wrote to their MEPs and explained their personal experience and what these products had meant to them as they struggled with smoking. The personal experiences cut through all the false and misleading claims about the risks of vaping that had been put to the Parliament. On 8 October 2013, the European Parliament rejected medicine regulation and the legislature started an intense and secretive process of defining the measures that eventually became the framework for regulating vaping products at EU level, Article 20 of the revised Tobacco Products Directive.[7]

This began to change minds in England – the testimonies from consumers were so compelling and authentic that open-minded public health experts started to listen more carefully. A decisive turning point was the first 'E-cigarette Summit', which was held on 12th November 2013 at the prestigious Royal Society in London. This brought vapers and public health experts together to discuss the issues and look at the science, both what was known and what was then unknown, in a meeting ably chaired by the widely respected academic, Professor Ann McNeill. However, the E-cigarette Summit produced something more subtle and valuable as well: it generated empathy, humility and the ability on the part of experts to 'walk in their shoes' and to see the world as smokers and vapers see it. That moved the expert community into a place where they saw the opportunity as greater than the threat and started to think positively about the potential for thousands and maybe millions of smokers to switch from smoking to vaping.

Through its experience in fighting battles over the future of vaping between 2010 and 2014, the consumer movement strengthened and built its own consumer organisation, the New Nicotine Alliance.[8]

While consumers were fighting a very public and inspiring battle for the control over what was for them a life-or-death technology, there were also interesting developments at the highest levels in the UK government. In 2009, Number 10 Downing Street had set up a 'Behavioural Insights Team', which quickly became known as the 'Nudge Unit' after the famous book by Richard Thaler and Cass Sunstein. The concept was to promote 'good' behaviours (stopping smoking, making sensible pension provision, conserving energy) by using 'nudges', or subtle changes to the 'choice architecture' – the way choices are presented to citizens. As early as 2010, the Nudge Unit started to raise the prospects of e-cigarettes as a clever and cost-effective way of reducing the burden of smoking-related disease on the National Health Service and securing policy goals by encouraging people to take responsibility for their own health on their own initiative and at their own expense. For modern policy makers, this is an ideal goal, involving the state as an enabler, rather using its coercive powers to force behaviour change. The idea received the backing of the UK's most senior civil servant, Sir Jeremy Heywood, the Cabinet Secretary[9] and eventually the then Prime Minister David Cameron.[10] There was therefore backing for policy innovation in the UK government at the very highest level.

Further developments included the successful introduction of vaping as an option at one of the Stop Smoking Services. Louise Ross, the manager of the smoking cessations service in Leicester, understood smokers and could really see this working. She became (and remains) a vocal champion of harm reduction but backed by her direct personal front-line public health work.

This convinced many that there was an opportunity to revitalise these services with something that many smokers actually wanted to try. The UK's National Centre for Smoking Cessation and Training went on to produce guidance on the role of e-cigarettes for professional smoking cessation services.[11] The guide was produced with support and involvement of vapers and is an excellent resource for anyone professionally engaged in smoking cessation.

As the consensus started to build in 2014, the lead advocacy organisation, Action on Smoking and Health (ASH), came around to the consumer perspective on public health grounds, and its chief executive, Deborah Arnott, became a champion using her formidable diplomatic skills to build a coalition behind the idea. Cancer Research UK, the main cancer charity in the UK, was also in the process of re-evaluating its position, and again a courageous individual, Professor Linda Bauld, took the intellectual lead and brought Britain's large health charity into recognising the role for e-cigarettes in cancer prevention. Data supports Cancer Research UK in taking this stance: one study showed the cancer potency of 15 key carcinogens was 250 times lower (0.4%) in e-cigarette aerosol compared to cigarette smoke.[12] Cancer Research UK recognised the opportunity for a novel strategy for addressing the single most important cause of cancer in the UK and embraced the tobacco harm reduction concept. Other major organisations joined to form a consensus position to align with a statement of high-level principles.[13] The organisations included: Public Health England; Action on Smoking and Health; Association of Directors of Public Health; British Lung Foundation; Cancer Research UK; Faculty of Public Health; Fresh North East; Healthier Fu-tures; Public Health Action (PHA); Royal College of Physicians; Royal Society for Public Health; UK Centre for Tobacco and Alcohol Studies; UK Health Forum.

In another decisive development, one of the key players in ASH, Martin Dockrell, was seconded to Public Health England to lead its tobacco control programme. Dockrell set about commissioning in-depth evidence reviews, which give the basis for policy in England in the years to come. This included an initial assessment in 2014, and then the ground-breaking report in 2015 in which PHE said that vaping was likely to be at least 95% lower risk than smoking.[14] PHE continues to publish high quality evidence reviews commissioned from the UK expert community.[15]

The Royal College of Physicians is justly famous for its 1961 report *Tobacco and Health*, in which it set out in detail the known risks of smoking as they were understood at the time. That report and its equivalent from the US Surgeon General a year later altered the course of public health and started the concept of tobacco control. In 2016, it released a significant new report, *Nicotine without smoke: tobacco harm reduction*.[16] This report confirmed the scientific basis to be positive about vaping, despite the residual unknowns. In particular, the RCP

endorsed the low risk estimates of PHE, with the following carefully constructed formulation:

> „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." (Section 5.5 page 87)

This statement recognises uncertainty in both directions ("unlikely to exceed", "may be substantially lower") so it is providing an anchor for relative risk perceptions but without being a single point estimate. The idea was to help physicians, consumers and the public more generally to to get a feel for the consensus expert view of the relative risk of smoking and vaping. Although both PHE and RCP have been criticised for these estimates, it is normal practice to use numbers to communicate risk or to simplify complex science in order for people to have a sense of risk. We do this for example with Body Mass Index or alcohol consumption guidelines. There were even claims the tobacco industry might be involved in these numbers somehow, but this was completely untrue – it was the judgement of the RCP's Tobacco Working Group and PHE's expert consultants, none of whom had links to the industry or any sort.

The Royal College of Physicians also gave an important piece of policy advice which is taken more seriously in England than anywhere else. It concerns the risks of bad policy choices making the situations worse:

> „A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, e.g. exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks.
> However, if this 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)

Government officials in England were the first to really recognise the issues raised by the Royal College of Physicians. In its regulatory impact assessment for the TPD-2[17], the government noted the potential for harmful unintended consequences:

„207. There is a risk that due to the potential price increase and reduction of choice of e-cigarettes, people will choose to switch back to smoking, thus harming their health. This possibility is considered in the sensitivity analysis.
208. There is a risk that a black market will develop with potentially harmful e-cigarette products, due to consumers no longer having the same degree of choice in the legal market."

Academic groups also played a significant, and probably decisive, role in consolidating support for vaping as a tobacco harm reduction for England. Researchers at Kings College London, University College London, Queen Mary College London, South Bank University and University of Nottingham produced high quality research and data. In particular the group, at UCL adapted the monthly smoking toolkit survey to measure the uptake and use of e-cigarettes giving a high-resolution picture of the use of e-cigarettes in England. The academic leaders in England also share an intellectual heritage that originates from Professor Michael Russell, who died in 2009. Professor Russell memorably coined one of the great catch phrases of tobacco harm reduction as early as 1976: *People smoke for the nicotine but die from the tar*.[18]

England's targets are focussed on smoking

The single most important aspect of England's approach to tobacco control is the overriding focus on *smoking*. This is because the purpose of tobacco control is to reduce premature death and serious disease, and smoking – the inhalation of the products of combustion of dried and cured tobacco leaf – is by far the dominant cause of disease and premature death. It is important therefore to recognise what is *not* the priority. The policy does not give primacy to reducing nicotine use or reducing all tobacco use. This is important because there are potential trade-offs to be made between objectives – for example, if it was possible to reduce smoking by using safer forms of nicotine the goal of reducing smoking would prevail over the goal of reducing nicotine use.

This is reflected in the goals of the tobacco control plan, which are to:

„– reduce the number of 15-year olds who regularly smoke from 8% to 3% or less
– reduce smoking among adults in England from 15.5% to 12% or less
– reduce the inequality gap in smoking prevalence, between those in routine and manual occupations and the general population
– reduce the prevalence of smoking in pregnancy from 10.5% to 6% or less
The aim is to achieve these objectives by the end of 2022."

The focus on *smoking*, rather than on nicotine, tobacco use or other goals is appropriate from a public health perspective, because it is the smoke that causes the harm and this gives clarity to the policy framework. The way the targets are specified does not, therefore, preclude the use of reduced-risk tobacco and nicotine products to achieve the smoking-related targets. This idea is explicitly endorsed in support of tobacco harm reduction.

Data and monitoring

England has excellent data resources monitoring levels of smoking, vaping and other forms of nicotine use. There is also good data on behaviours – for example intention and attempts to quit smoking – and on beliefs and attitudes. Three main sources stand out:

- The Office of National Statistics and Public Health England collaborate and include smoking and vaping questions in the major household surveys and provides headline prevalence figures and local-level data.[19]
- The Smoking Toolkit Survey, Smoking in England, measures a range of smoking, vaping and quitting behaviours and is conducted monthly by academics at University College London.[20]
- Action on Smoking and Health with YouGov provides annual surveys of use, behaviours, risk perceptions and attitudes.[21]

Current data from the authoritative ONS surveys show very positive progress in the direction of smoking and vaping trends:

- UK adult (≥ age 18) smoking prevalence fell from 20% in 2011 to 14.7% in 2018
- Number of smokers 2018 = 7.2 million

Vaping prevalence is measured in a different survey (Opinion and Lifestyle Survey) which covers 16,000 households in Great Britain (GB = England, Scotland, Wales but not Northern Ireland) and adults ≥ age 16.

- Vaping prevalence reached 6.3% in 2018 a rise from 3.7% in 2014 and very low levels in 2011
- Number of vapers in 2018 = 3.2 million

Vaping has become a large-scale phenomenon relative to smoking and appears to be having significant downward pressure on smoking rates. In England, we are witnessing tobacco harm reduction in action and starting to benefit from a public health win.

Evidence-based support for tobacco harm reduction

In the tobacco control plan, the government explicitly commits to an evidence-based approach and argues that this leads directly to endorsement of tobacco harm reduction.

> **„4. Backing evidence-based innovations to support quitting**
> We are committed to evidence-based policy making, so we aim to:
> – Help people to quit smoking by permitting innovative technologies that minimise the risk of harm.
> – Maximise the availability of safer alternatives to smoking.
> The best thing a smoker can do for their health is to quit smoking. However, the evidence is increasingly clear that e-cigarettes are significantly less harmful to health than smoking tobacco. The government will seek to support consumers in stopping smoking and adopting the use of less harmful nicotine products."

This embraces the opportunity of new technologies instead of defining them as threat. However, the position is not unconditional: it is contingent on foundations in supporting evidence and monitoring the marketplace for adverse effects.

> „The Department of Health] will, based on the evidence reviews undertaken by [Public Health England], review policy and regulation of nicotine delivery systems to provide an environment that facilitates smokers taking action to improve their health and the health of those around them, whilst minimising any risk of new nicotine addiction in children.
> [The Department of Health] will monitor the impact of regulation and policy on e-cigarettes and novel tobacco products in England, including evidence on safety, uptake, health impact and effectiveness of these products as smoking cessation aids to inform our actions on regulating their use."

As well as looking for problems or benefits arising from the products, this will also include assessment of the policies. This means the government will also monitor for *harmful unintended consequences of regulation* and respond accordingly.

To this end, Public Health England will update its evidence reports on e-cigarettes and other novel nicotine delivery systems annually until the end of the Parliament in 2022 and will include within quit smoking campaigns messages about the relative safety of e-cigarettes.

Evidence updates (see 2015 version) that cut through the detached academic activism and media clickbait about vaping are playing an important role in responsible government policy.

Indoor vaping – let property owners decide policy

There is no robust evidence of material harm from secondhand vapour. The vapour is much less toxic than cigarette smoke and there is no 'sidestream' vapour released from the device while not in use by the users. Cigarettes burn continuously at the tip releasing smoke even when not in use.

It is not just an absence of evidence of harm: the evidence that is available suggests the possibility of material harm from second-hand vapour would be minimal – whereas second hand cigarette smoke, especially the smoke generated when a user is holding a lit cigarette, has been associated with cancer and heart disease in bystanders. For example, one study estimated lifetime cancer risk from passive vaping compared to passive smoking.[22] The difference was of the order of 10,000 times i.e. negligible:

> „ECLR [Excess Lifetime Cancer Risk] for passive smokers is 5 orders of magnitude higher than the passive vaper."

Even if there are traces of hazardous agents in e-cigarette vapour, they are present at such low concentrations in exhaled vapour that they pose no meaningful risk to bystanders when compared to occupational exposure limit values (a benchmark of acceptable risk).[23]

The primary issue with vaping is one of *nuisance* rather than a material health threat. Excessive restrictions on where people can vape is a potential source of unintended consequences: if smokers are trying to switch from smoking to vaping, it would raise the chance of distraction or relapse.

In the absence of material risk to the health of bystanders, there is a very weak justification for a mandated regulatory approach in which a general prohibition would override the preferred approaches of property owners and managers. Consider the following approaches to vaping:

1. A bar wants to have a vape night every Thursday
2. A bar wants to dedicate one room where vaping is permitted
3. A corrections facility that is smoke-free wants to support inmates to manage nicotine withdrawal and related tensions by allowing them to vape
4. In a town with three bars, one decides it will cater for vapers, two decide they will not allow vaping
5. A bar manager decides on balance that his/her vaping customers prefer it and his/her other clientele are not that bothered – he'd do better by allowing it
6. A hotel wants to allow vaping in a few rooms and in its bar, but not in its restaurant
7. An office workplace decides to allow vaping breaks near the coffee machine to save on wasted smoking break time and encourage smokers to quit by switching
8. A care home wants to allow an indoor vaping area to encourage its smoking elderly residents to switch during the coming winter
9. A vape shop is trying to help people switch from smoking and wants to demo products in the shop
10. Vaping might be permitted in railway stations or airport terminals, but not on trains and aircraft
11. Many shops, public buildings and places catering for children decide not to allow vaping at all

Figure 1: hypothetical examples of 'bottom up' vaping policies

The argument is that there is no good rationale to override these reasonable decisions with a blanket prohibition when there is no plausible material risk to bystanders. The absence of a legislated ban does not create a 'right to vape' but it makes the vaping policy in any space a matter for the owner or manager rather than for government or legislature.

Public Health England has produced guidance for employers and organisations looking to introduce policies around e-cigarettes and vaping in public and recommend such policies to be evidence-based.[24] PHE recommends that e-cigarette use is not covered by smokefree legislation and should not routinely be included in the requirements of an organisation's smokefree policy. Action on Smoking and Health (UK) produced a set of structured questions to guide employers through vaping policy options.[25]

PHE will support local areas looking to implement local smokefree policies differentiating the levels of harm caused by existing tobacco products including e-cigarettes and other novel products.

This recognises that decisions on vaping policy should rest with owners and managers of properties and steers them not to include vaping in organisational smoke-free policies by default. This implicitly acknowledges that there is no justification (for example, material harm to bystanders or workers) to override the preferences of property owners with blanket vape-free laws. This is an ethically robust position to take.

Marketing restrictions on vaping products

The United Kingdom is bound by the European Union Tobacco Products Directive and its restrictions on the advertising, promotion and sponsorship of vaping devices and e-liquids (these are detailed Article 20(5) of Directive 40/14/EU).[26] These provisions essentially ban advertising in any medium capable of crossing a border – TV, radio, internet, publications etc. The Directive does not have jurisdiction over advertising that is fixed within a member state – billboards, point-of-sale, etc. The UK abides by the directive, but England has taken a more permissive approach to the advertising that is not covered by the Directive. Heated tobacco products are classified as tobacco products and all advertising of these products is banned by default because it is covered by the legislation designed to eliminate advertising of cigarettes.

The starting point for policy makers is to be clear on what the policy is supposed to achieve – what is the risk it is supposed to address. Advertising of cigarettes is largely banned in the EU because smoking kills 700,000 EU citizens annually, and advertising is thought to increase the appeal of this product and therefore potentially mean more people smoke, smoke more, smoke for longer or don't quit as soon as they might. Many activists have simply argued for applying the same measures to vaping products as to tobacco products. However, the basic justification – death and disease caused by smoking is just not valid for e-cigarettes.

These justifications for bans or restrictions on cigarette advertising cannot simply be applied to e-cigarette advertising or to any reduced risk product. As alternatives to smoking, e-cigarettes function as a form of stop-smoking technology. Advertising for e-cigarettes is a form of anti-smoking advertising. A ban on e-cigarette advertising might therefore be damaging to public health by erecting barriers to entry to a new and disruptive technology (vaping products) in a market dominated a harmful and entrenched incumbent (cigarettes). Again, it

is essential for policymakers to adopt an open-minded approach to unintended consequence of what superficially seem like positive policies.

The UK's approach to e-cigarette advertising was that adopted by the UK Committee on Advertising Practice (CAP) in 2014. The starting point is that conventional "legal, honest, decent, truthful" standards should apply, as they do to all advertising. That is in itself a significant protection. The CAP also produced useful guidelines on e-cigarette advertising that provide a reasonable balance of interest between protection of minors and promotion of new low-risk products to smokers. The framework is somewhat similar to the controls on alcohol advertising[27] controlling aspects of content and placement, but not imposing outright bans.

The CAP has recently consulted on allowing certain health claims to be permitted – a highly positive development. This draws a distinction between therapeutic claims (e.g. helps to stop smoking) and health claims (e.g. vaping greatly reduces exposure to carbon monoxide) and allows truthful and evidence based statements to be made in advertising.[28]

If the regulation of e-cigarette advertising had purely been a UK matter, then it is likely England would have a workable and proportionate system. Unfortunately, through the Tobacco Products Directive the EU all forms of advertising capable of crossing a border are banned outright.

Risk-proportionate taxation of nicotine products

The UK has one of the highest tobacco tax regimes in Europe and the wider world. In September 2019, a pack of 20 Marlboro cigarettes sells for around £11.50 (€13.00). Of this, £3.12 is the pre-tax price and £8.38 is the tax, the excise duty plus value added tax. Approximately, 73% of the price is tax. Budget cigarettes are cheaper but carry a higher burden of tax.

There are strong reasons not to tax reduced-risk alternative smoke-free nicotine products at all. This would reflect their value in supporting smoking cessation and addressing ethnic and socio-economic health inequalities. In the UK, over-the-counter nicotine replacement therapy (NRT) even attracts a tax subsidy, a reduced rate of value added tax (VAT), for its perceived value in reducing smoking.[29]

High and regressive tobacco taxation that falls disproportionately on poor or marginalised ethnic groups presents formidable ethical challenges. For users,

the obvious mitigating response has been to seek out illicit untaxed supply or down-trading to tobacco products that attract lower duties (typically, hand-rolling tobacco or "budget" brands). However, it is important to have as many *lawful* options as possible to mitigate the unfairness implicit in tobacco taxation – that includes facilitating low-cost pathways to switch from smoking to low risk alternatives. For that reason, we recommend a system of risk-proportionate taxation is implemented, as advocated by Chaloupka, Sweanor and Warner.[30]

So far, the UK has stuck loosely to the principles of risk proportionate taxation, though there is still room for improvement. The current rates of tobacco duty

- Nicotine replacement therapy sold over the counter attracts a tax subsidy – NRT attracts a reduced rate of VAT – 5% compared to the standard 20%. The evidence to support a tax discount for NRT sold over the counter is very weak.
- Non-pharmaceutical, non-tobacco oral nicotine products (for example, Zyn) attract no excise duty, but the full 20% rate of VAT is applied. These products are rising in popularity in many markets, but are not yet significant in the UK.
- E-cigarettes attract no excise duty, but the full 20% rate of VAT is applied. Depending on the approach taken, vaping can be as much as 90% cheaper than smoking. Economic factors are understood to be a major driver of switching and can provide a significant economic benefit to poor households – they may be important in addressing health and welfare inequalities.
- Heated tobacco products attract both excise duty and VAT. However, a separate category has been defined for heated tobacco products, so this allows for risk-based differentiation in future. The excise duty is currently at set the same level as hand-rolling tobacco on a weight basis: £234.65 per kg (September 2019). But because relatively small amounts of tobacco is used in the heated tobacco consumables, the price of heated products like iQOS is about half that of the equivalent cigarettes.
- Chewing tobacco attracts a lower excise duty than cigarettes or heated tobacco, £125.20 per kg. However, the main issue with smokeless tobacco is that oral tobacco (snus) is banned throughout the European Union, with the exception of Sweden. This is despite the low levels of smoking and smoking-related disease in Sweden that is attributable to snus.

The UK New Nicotine Alliance of consumers has advanced a powerful case to adopt risk-proportional taxation.[31] The NNA sets out key principles it want to see adopted by the government.

1. **The tax regime has implications for human life**. Given cigarettes and smoke-free alternatives are substitute products there will be positive price cross-elasticities between smoking and smoke-free products. A significant

tax on smoke-free products will cause a relative increase in the demand for combustibles – and will, therefore, cause more smoking. The default excise rate should be zero, proceeding with caution if higher rates are proposed.

2. **Setting the level: the highest level applied to any smoke-free product should be substantially lower that the lowest rate applied to any combustible product**. Maintain a significant differential between the cost of being a smoke-free product user and a smoker to maintain an incentive to switch and to avoid developing a black market or encouraging home-made production.
3. **Recognise cost burdens of tax administration**. Vaping is likely to have at least a 95% lower risk than smoking. If excise duties were set proportionate to risk relative to smoking to create a proportionate deterrent, then the tax yield for e-cigarettes would be so low it would not be worth the cost of collecting. The only way to make a non-zero tax viable is to tax smoke-free *disproportionately* to risk, thereby imposing a disproportionate deterrent to users switching.
4. **Comparison with NRT – therapeutic value**. Smoke-free products in fact produce a *net health benefit* by reducing smoking. From an economic and tax perspective, such products should be viewed more like over-the-counter medicines. Some jurisdictions apply a reduced sales tax to nicotine replacement therapy – a tax *subsidy* – to reflect its positive public health value.

It is argued that because tax-take is falling from cigarettes as people switch or quit, then excise duty should be applied to alternative products to compensate. This does not have an economic rationale, even if superficially appealing politically. Tax should be raised from the least distorting and most efficient tax base available: there is no reason why cigarette excise losses should not be recovered from taxes on, for example, carbon dioxide, fuel charges, removal of tax subsidies or by cutting spending that is less cost-effective than reducing smoking.

Innovation and heated tobacco products

The Tobacco Control Plan recognises the potential value of innovation. This is an important feature of tobacco policy, because many jurisdictions have erected substantial barriers or even outright prohibitions of products like e-cigarettes or heated tobacco products.

> „In addition there has been the development and very recent introduction of novel tobacco products that claim to reduce the harm of smoking. We welcome innovation that will reduce the harms caused by smoking and will evaluate whether products such as novel tobacco products have a role to play in reducing the risk of harm to smokers."

The UK has an open mind to innovation that could reach more people with a product they find acceptable and pleasurable. However, the UK has not shown that it has a fully open mind about tobacco harm reduction: it supported the ban on oral tobacco (Swedish snus) despite extensive evidence that snus is responsible for Sweden's anomalously low rate of smoking (5% daily smoking in Sweden compared to an average of 24% in the European Union).[32]

Medicalisation and treatment using e-cigarettes

Though there was a battle over medicalisation of e-cigarettes in 2010 and 2013, the UK government still sees this as an important route to market that is allowed under the Tobacco Products Directive.

> „The Medicines and Healthcare products Regulatory Agency (MHRA) will ensure that the route to medicinal regulation for e-cigarette products is fit for purpose so that a range of safe and effective products can potentially be made available for NHS prescription.
> [Public Health England] will provide evidence-based guidance for health professionals to support them in advising smokers who want to use e-cigarettes or other nicotine delivery systems to quit."

The tension over medicalisation is no longer there as long as it is available as a parallel track and not a mandatory pathway. Products with a medical marketing authorisation may be more readily used in healthcare settings or even prescribed as treatment options. It is possible that they could also have product specifications and marketing approaches that would not be permitted under the Tobacco Products Directive, for example higher nicotine strength than the 2% limit imposed by the Directive.

The key issue here is the need for a positive approach by health and medical professionals – what they say needs to be realistic and patient-focussed. England already has good officially-blessed guidance on e-cigarettes for health professionals and it will be very helpful to have this routinely updated. Simplifying the medical licensing option is of lesser importance, but could provide some benefits within healthcare settings, but only as long as it remains *an option*.

Advice to healthcare professionals and to users

There is now recognition among tobacco control professionals and public sector practitioners that e-cigarettes can be used constructively to reduce harm. For example, in Britain the National Centre for Smoking Cessation and Training and Public Health England, the government's public health agency, have developed evidence-based guidance and training for health and smoking cessation professionals.[33] [34] It provides a clear and measured assessment of the state of science and best practice. This is a summary of the advice given to UK health professionals by the National Centre For Smoking Cessation and Training and Public Health England:

"**Recommendations for practice**

1. Be open to e-cigarette use in people keen to try them; especially in those who have tried and failed to stop smoking using licensed stop smoking medicines.
2. Provide advice on e-cigarettes that includes:
   - E-cigarettes provide nicotine in a form that is much safer than smoking.
   - Some people find e-cigarettes helpful for quitting, cutting down their nicotine intake and/or managing temporary abstinence.
   - There is a wide range of e-cigarettes and people may need to try various types, flavours and nicotine dosages before they find a product that they like.
   - E-cigarette use is not like smoking and people may need to experiment and learn to use them effectively (e.g. longer 'drags' may be required and a number of short puffs may be needed initially to activate the vaporiser and improve nicotine delivery). They may also need to recognise when atomisers need replacing.
   - People previously using e-cigarettes while smoking (e.g. to reduce the number of cigarettes that they smoke) may need to consider changing devices and/or nicotine concentrations when making a quit attempt.
   - Although some health risks from e-cigarette use may yet emerge, these are likely, at worst, to be a small fraction of the risks of smoking. This is because e-cigarette vapour does not contain the products of combustion (burning) that cause lung and heart disease, and cancer."

The National Health Service, which is widely respected in the UK, has also taken up the cause and provides pragmatic advice and factual information to smokers looking to quit. The NHS has incorporated vaping as a harm reduction strategy in its "Live Well" advice and "One You" campaign.

Public Health England has also built vaping into 'Stoptober', the annual government-backed stop-smoking campaign. Stoptober embraced e-cigarettes in

October 2017 and became the first government backed smoking cessation campaign to advertise the idea of vaping to quit smoking on television.

This is a balanced and open-minded approach and reflects an emerging consensus on how to exploit the opportunities of e-cigarettes, while containing any risks. More examples of innovative public sector initiative are available via a page devoted to England on the Counterfactual website.[35]

Brexit and UK tobacco policy

The government believes that some aspects of its policy could be improved and that the constraints imposed by the EU Tobacco Products Directive were removed.

> „Over the course of this Tobacco Control Plan, the government will review where the UK's exit from the EU offers us opportunities to re-appraise current regulation to ensure this continues to protect the nation's health. We will look to identify where we can sensibly deregulate without harming public health or where EU regulations limit our ability to deal with tobacco.
> In particular, the government will assess recent legislation such as the Tobacco Products Directive, including as it applies to e-cigarettes, and consider where the UK's exit provides opportunity to alter the legislative provisions to provide for improved health outcomes within the UK context."

This might give the opportunity, for example, to lift some EU-imposed restrictions that have no support in evidence. For example, bans on advertising, limits on nicotine strengths, excessive warnings, and limits on tank and container size.[36 37]

A more pessimistic view of Brexit and vaping is possible, depending on the precise form of Brexit that the UK takes. For example, it is possible that the UK will remain in a lengthy transitional period or measures necessary to secure an open border between Ireland and the UK in Northern Ireland (the 'backstop') will mean that the UK stays in close regulatory alignment with single market regulation. That would likely include the Tobacco Products Directive. However, in doing so the UK would also become a 'policy-taker' and be excluded from negotiations and voting on new measures. The UK could therefore find itself complying with a new version of the Tobacco Products Directive in the mid-2020s having had little say in its development. It is likely that losing the UK voice at the table will be disadvantageous to vapers and smokers across the European Union. The EU will lose a champion of the rational and pragmatic harm reduction approach, increasing the relative weight of abstinence-only ideological perspectives in the decision-making.

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