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Tobacco Control Plan 2016
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Dear Alette

Assessing and mitigating unintended consequences of policies for vapour technologies and other low risk alternatives to smoking

We welcome the Department's openness to the views of consumers and for the opportunity to share our insights at the roundtable on 16 March 2016. With a view to continuing the engagement, please find this contribution to development of the Tobacco Control Plan, due later this year. In this submission we would like to focus on the concern that policies directed at vapour products or other low-risk alternatives to smoking may do more harm than good. There is a clear danger that policies that bear down on vapour products work against reducing smoking and in effect contribute to the avoidable toll of smoking-related disease and premature death.

We would like to make seven observations and propose seven recommendations in response.

Observation 1: current e-cigarette policy is likely to cause harm through unintended consequences

Because e-cigarettes are substitutes for smoking and their uptake driven by consumer appeal, there is a risk that e-cigarette policy will have harmful unintended consequences. The Royal College of Physicians explains[1]:

> *A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg 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.* (12.10)

[1] Royal College of Physicians, ***Nicotine without smoke: tobacco harm reduction,*** London 28 April 2016 [link]

This also explains why it is important to be guided by evidence of costs, benefits or risks and not to take unduly cautious action if there is no real evidence of a material problem, or if intervention would have very little benefit. We should note that the RCP found no evidence of gateway effects, renormalisation, reducing quitting, rather that "*e-cigarettes appear to be effective when used by smokers as an aid to quitting smoking*." The RCP also did not find significant risks to users: "*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*"

The government should therefore be focussed less on a "*risk averse precautionary approach*", and more on avoiding unintended consequences of regulation that "*causes harm by perpetuating smoking."*

We were pleased by the acknowledgement of the potential for unintended consequences in the recently published Impact Assessment[2] for the Tobacco Products Directive. Several specific concerns are drawn out, though not quantified, in the assessment. For example:

> 117. [...] 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. [...]
>
> 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.

Against these potential costs or risks, only the most trivial benefits were proposed for e-cigarettes (paragraphs 80-83 in the Impact Assessment), essentially improvements to problems that are not significant to start with (like poisonings or non-smoker uptake). Even these benefits have the potential to be overwhelmed by black market side-effects.

The Impact Assessment conceals a very negative assessment of e-cigarette policy within a much larger, though optimistic assessment of the overall impact of the TPD2. If the costs and benefits of the e-cigarette policies *alone* had been evaluated independently of the rest of the directive, the balance of costs and benefits would be strongly negative and the risks would be flashing red.

Recommendation 1. We recommend a more comprehensive approach to mapping and assessing unintended consequences of e-cigarette policy to cover all policy proposals either in place or under evaluation in future, taking account of EU and WHO initiatives. At Appendix 1, we give an overview of some of the possible unintended consequences associated with various policy options. The government should document and assess the risks, and then decide which require closer monitoring, evaluation and further research.

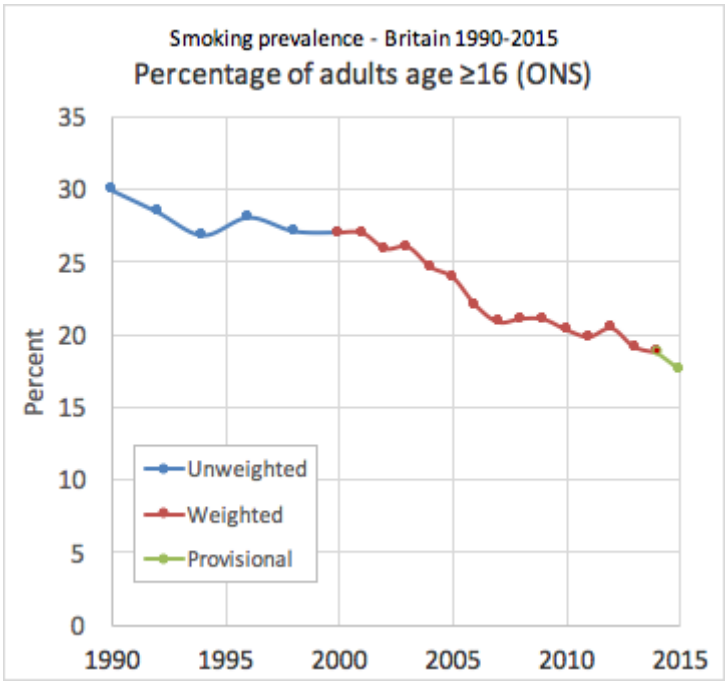
[2] Department of Health, MHRA, Tobacco Products Directive, Impact Assessment,18 April 2016. [link]

Observation 2: these impacts are potentially large compared to other costs and the overall e-cigarette policy impact is highly sensitive to these effects

On the basis used to estimate the benefits of reduced smoking prevalence in the Impact Assessment (a value of £72,000 per successful quit) these negative effects could be very large compared to the costs that were quantified in the Impact Assessment. For example, a reduction of just 200 smokers per year quitting with e-cigarettes because of these effects would give an undiscounted detriment of (200 x £72,000 x 10 years) = £144 million - slightly more than the £140 million cost of the directive that was quantified.

Given that the ONS reports that there are now 2.2 million vapers of which 850,000 are ex-smokers, and a further 720,000 ex-smokers were vapers at some point and now use neither, it is easy to envisage very large costs emerging from very small variations in these numbers - plausibly far larger than 200 per year. For example, if a total of 50,000 fewer ex-smokers arising from the negative effects of the TPD, that would represent a social cost detriment of £3.6 billion.

We believe the net cost/benefit balance of e-cigarette policy will be dominated by the effect e-cigarettes have on smoking uptake and quitting, and that this should be the major concern of the Department of Health in formulating the next Tobacco Control Plan as it applies to e-cigarettes. It is worth noting that smoking has fallen most rapidly since the emergence of e-cigarettes[3].



Though we cannot say that e-cigarettes caused the recent decline, it should be a reason to be concerned about with changing the current light touch proportionate regulatory regime.

[3] Office for National Statistics, Opinions and Lifestyle Survey, General Lifestyle Survey and General Household Survey. [link] (note 2015 provisional data from the 2015 e-cigarette survey)

These effects are significant and may be a cause of avoidable death and disease in British citizens. For that reason, they should be the focus of intense scrutiny and evaluation.

Recommendation 2. We recommend that the government sets up a mechanism to monitor and assess potential unintended consequences and reports on these as it reports on the tobacco control plan. The Department should convene a seminar and commission methodological research to work out how best to detect and evaluate the potential unintended consequences. While we have ideas on this, we would prefer the Department to approach the issue systematically and to engage a wider range of expertise.

Observation 3: U.S. research is already showing these effects are real

It is not merely common sense that supposedly 'tough' policies on *harm reduction* may be a cause of *harm*. The first examples of policy evaluation are now emerging from the United States. For example the following papers suggest negative effects from e-cigarette policies.

- Friedman AS. How does Electronic Cigarette Access affect Adolescent Smoking? *J Health Econ* Published Online First: October 2015. [pubmed]
- Pesko MF, Hughes JM, Faisal FS. The influence of electronic cigarette age purchasing restrictions on adolescent tobacco and marijuana use. *Prev Med (Baltim)*, February 2016 [pubmed]
- Tuchman A. Advertising and Demand for Addictive Goods: The Effects of E-Cigarette Advertising, Stanford University, (working paper) September 2015 [link]

This is important research because small changes in the impact of vaping on smoking will greatly outweigh any residual health effects that arise from vapour products themselves. Yet, our impression is that the bulk of research funding is focussed on identifying problems with e-cigarettes, not on identifying problems with e-cigarette *policies*.

Recommendation 3: the government should work with research councils, charities and other funding bodies to develop a research-based policy evaluation programme that would provide evidence to inform policy implementation and revision.

Observation 4: the emergence of black markets will indicate policy failure

The emergence of significant black market trade in nicotine liquids, more DIY production, or changes in commercial or consumer behaviour to circumvent regulation is a sign of policy failure. This is a sign that consumers do not regard the policies as in their interests or that they regard policies that are ostensibly for the greater good or protection of others to be excessive and unjustified.

Black markets can play a valuable role in helping people to avoid harms that arise from badly constructed policies and should not automatically be seen as a bad thing in themselves, but as a pragmatic consumer response to bad policy. In this sense black markets function as a kind of warning signal of policy failure and can relay useful information to policy makers considering reforms. Black markets come with a range of risks too - criminalisation of the supply chain, uncertain product quality and risks associated with changed consumer behaviours. But these should be understood as consequences of poor

policies that create black markets, rather than black markets *per se*. We would far rather have a well functioning legitimate market, than see users turning to black markets or risky practices to retain their preferred alternative to smoking.

Recommendation 4: UK government should monitor black market development and changing supply chain and consumer workarounds with a view to amending the underlying policy drivers of black market activity, if appropriate. The purpose should not be to crackdown on users protecting their health and welfare, or to extend the 'war on drugs' philosophy to nicotine, but to learn from the market reactions to distortions created by badly designed regulation.

Observation 5: current European Union policy on low risk nicotine products is unsatisfactory and needs reform before it has even been implemented

The essence of the European Union policy on e-cigarettes was negotiated in a few political meetings and in secrecy in October to December 2013. None of the usual disciplines of policy making were followed: consultation, evidence-based options appraisal, impact assessment or scrutiny by national parliaments. We believe that Article 20 of the Directive should be regarded, at best, as a temporary stop-gap measure. This thinking would be at least consistent with the way it was made.

Considering that vapour products were barely known and even less understood at the time the Directive was conceived, it is no surprise that the TPD2 is unfit for purpose for regulating what is, in reality, an emerging, rapidly evolving and disruptive technology. We already know much more about these products, the health effects, the potential risks and benefits than were known in 2012 and 2013. However, the UK government encouraged and endorsed a form of regulation, an EU directive, that is notoriously hard to adapt and develop in response to changing technology, new knowledge and better understanding. At the time, the UK government, European Commission and Council favoured compulsory regulation of these products as medicines[4], an approach the Royal College of Physicians refers to in 2016 as the:

> *... proposal to regulate all nicotine products as medicines, which to date has proved to operate against public health interest and has, in any case, been subject to successful legal challenges in other EU member states.* (10.6)

Fortunately, consumers lobbied the European Parliament to reject this approach and the worst damage from ill-advised UK policy was averted. The weaknesses in the policy that followed and the likelihood that it will do little more than protect the cigarette trade has been well documented[5] [6] [7] and we do not wish to repeat that analysis here. However we do believe we need to move to a better and more flexible and proportionate policy framework for new nicotine products as soon as possible.

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[4] European Council, Council General Approach. 21 June 2013.

[5] Snowdon CJ. E-cigarettes and Article 20 of the Tobacco Products Directive. European Policy Information Center (EPICENTER), September 2015. [link]

[6] Counterfactual: What is wrong with the Tobacco Products Directive for vapour products? May 2015 [link]

[7] Counterfactual: Treatment of e-cigarettes is disproportionate and much worse than cigarettes, 22 February 2016 [link]

The TPD2 Article 28 review process[8] requires a report on the directive no later than May 2021, and a new directive may take a further 4-5 years after that come into effect. This is far too slow. This timetable cannot possibly suit such a rapidly evolving technology and rapidly advancing understanding of both benefits of the product and potential costs of policies. Work on a new European policy framework should begin this year, not wait for 2021.

There is no case in science, ethics or law for denying smokers access to snus (Article 17). Sweden has smoking prevalence of 11% compared to the EU average of 26%, according to the most recent Eurobarometer survey[9]. There is no doubt that snus has had the effect of reducing smoking related disease and premature death in Sweden[10] which, for example, has the lowest rates of lung cancer in Europe. At the time the snus ban was being reaffirmed, did anyone in the European Council or Commission ask: "*given the evidence from Sweden, might there be unintended consequences from banning snus in the rest of Europe?"*. This is where we believe UK officials should intervene in future.

Recommendation 5: UK should press for innovation in European Union policy that is more rapid than currently envisaged. Options include expediting the report on the directive (or the part of that that deals with low risk nicotine products - articles 17, 19, 20) or defining a new directive for these products. The latter route may be faster and more flexible given it would be narrower in scope. If the current Article 20 is recognised as an interim measure, then the case for a new directive for new nicotine technologies is clear. There should be an evaluation of the potential unintended consequences of the snus ban in countries other than Sweden, and its potential to add to the options that British smokers have to quit smoking - the UK should champion rigorous policy appraisal in this area, not just follow the prohibitionist herd.

Observation 6: the lawfulness of the TPD2 Article 20 remains in question

The TPD2 is based on harmonising member state laws to promote free movement of goods with a high level of health protection. If Article 20 does not, *in reality*, achieve those two ends it is unlawful under the EU treaties and should be withdrawn.

It appears that in the Totally Wicked case the Advocate General accepted many assertions about the value of the directive from member states and the Commission. However, these assertions may not in fact be true and may be challenged by new knowledge. Monitoring for unintended consequences for health is also monitoring for the lawfulness of Article 20 of the Directive. It does not require a court challenge for Ministers to be obliged to act lawfully and to be proactive when they have reason to believe the legislation is not lawful, even at EU level. If the Totally Wicked challenge is even partly successful, that should provide an opportunity to revisit Article 20.

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[8] Directive 2014/40/EU Article 28 states:

> The Commission shall pay special attention to: [...](g) "market developments concerning electronic cigarettes and refill containers considering, amongst others, information collected in accordance with Article 20, including on the initiation of consumption such products by young people and non-smokers and the impact of such products on cessation efforts as well as measures taken by Member States regarding flavours"

[9] European Commission, *Special Eurobarometer* 429, Attitudes of Europeans towards tobacco, May 2015 [link]

[10] Ramström L, Wikmans T. Mortality attributable to tobacco among men in Sweden and other European countries: an analysis of data in a WHO report. *Tob Induc Dis* 2014;12:14. [link]

Recommendation 6: obtain and publish legal advice on UK's obligations and options if it becomes clear the TPD Article 20 is not promoting free movement of goods or a high level of health protection as the TPD2, and its implementation in other member states, applies to e-cigarettes, snus or novel tobacco products. UK government should insist that the European Commission and other member states assess unintended consequences arising from the TPD2 and respond appropriately to the findings.

Observation 7: the UK is embedded in European and global tobacco policy and should promote good harm reduction practice universally

The UK government participates in international tobacco policy as a member of the European Council and state party to the WHO Framework Convention on Tobacco Control. WHO and EU policies have an effect in the UK, and affect British businesses as they trade in Europe and internationally. UK should have three policy objectives internationally:

1. To prevent bad policies being introduced in the UK
2. To improve the policy environment for British businesses, British citizens and British travellers elsewhere in Europe and internationally
3. To promote good policy and practice, and British expertise, in other countries

We do not think it is acceptable to approach our international engagement passively and with a 'can we live with this?' philosophy. There are EU member states that are gold-plating the directive in a way that is likely to be harmful to both health and to free movement of goods (the ostensible purpose of the TPD), for example banning flavours or internet distance selling. We do not believe the UK should be indifferent to this.

The WHO Framework Convention on Tobacco Control (article 1) explicitly endorses 'harm reduction' strategies in tobacco control[11]:

> *(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)

Yet communications from from COP-6 endorsed prohibition and mandatory medicine regulation without the slightest regard for unintended consequences, and in doing so gave authority to policies that may be immensely harmful to health.

Recommendation 7: the UK government should be proactive in promoting its increasingly positive and evidence-based approach to tobacco harm reduction internationally, building on the work of PHE[12] and the NCSCT[13], and the academic and professional understanding in the UK, notably through the Royal College of Physicians[14]. We would like to see the UK lead discussions of unintended consequences and a pro-harm reduction approach at FCTC COP-7 and in the European Council. The UK should not agree to, for example, language that allows prohibition or mandatory medical classification of e-cigarettes, even if it does not

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[11] WHO Framework Convention on Tobacco Control, Article 1(d), 2003 [link]

[12] McNeill A, Brose LS, Calder R, *et al.* E-cigarettes: An Evidence Update. A Report Commissioned by Public Health England. London: 2015. [link]

[13] National Centre for Smoking Cessation and Training, Electronic cigarettes: A briefing for stop smoking services, 2016 [link]

[14] Royal College of Physicians, *Nicotine without smoke: tobacco harm reduction*, London 28 April 2016 [link]

require it. It would send a valuable signal to UK stakeholders and internationally to name the forthcoming plan, *The Tobacco Control and Harm Reduction Plan 2016*.

We are grateful for the opportunity to raise these observations and recommendations with the Department and would welcome a meeting to discuss these issues and any other areas in which the Department would like the views of new nicotine consumers.

Yours sincerely

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On behalf of New Nicotine Alliance

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The New Nicotine Alliance advocates for consumer interests in new nicotine technologies and is completely independent of commercial interests in the relevant industries (e-cigarettes, tobacco, pharmaceutical companies, etc).

Clive Bates is Director of Counterfactual, which is a sustainability consulting and advocacy practice. He is an Associate of the New Nicotine Alliance. He has no competing interests with respect to any relevant industries.

Appendix 1: Mapping potential unintended consequences

Policy	Likely unintended consequence
Loss of product diversity	Consumers are unable to personalise the vaping experience or find products that they enjoy and find it less satisfactory, so continue to smoke or relapse
Restrictions on liquid strength	Smokers are unable to sustain a satisfactory nicotine experience during the first stages of switching or while they are learning to vape, so relapse to smoking or give up on vaping
Limits on container and tank size	The experience of vaping becomes more inconvenient and so less attractive. More filling operations are required and the likelihood of running out of liquid is increased.
Ban e-cigarette use in public places	Diminishes value proposition of e-cigarettes to users and 'denormalises' vaping, a much less risky option, and so diminishes the appeal of vaping relative to smoking, May promote relapse in existing vapers if they cannot maintain adequate nicotine levels or if they join smokers outside.
Restrictions on advertising, promotion and sponsorship	Reduces the ability of e-cigarette brands to compete with cigarettes (the market incumbent) and diminishes means to communicate the value proposition to smokers. May reduce means to communicate innovation or build trusted brands. If subjected to excessive control may become dull and sterile, diminishing appeal.
Bans on online sales	Because vaping options are highly diverse, user density still quite low, and technological evolution rapid, the internet-based business model is important to provide the greatest choice and convenience to users. If users are forced to purchase from 'bricks and mortar' outlets but do not have a specialist shop nearby they are likely to see their options limited and vaping relatively less attractive
Policy compliance burdens and other costs - leading to black markets	Black markets develop in response to restrictive or costly regulation or taxation. Black markets can to some extent compensate for poorly designed policy and they are likely to emerge as the TPD is implemented. However, they also cause harms through trade, transit and handling of high strength liquids, product quality, poor labelling, inferior packaging. They may exacerbate risks the policy is designed to mitigate.
Product design restrictions and requirements – testing and paperwork	There are numerous subtle trade-offs in product design between safety and appeal and cost. For example, the perfectly safe product that no-one wants to buy may be worse for health if it means more people smoke. Excessive design regulation can impose high costs, burdens and restrictions, slow innovation and drive good products and firms out of the market through 'regulatory barriers' to entry. Very high spec regulations will tend to favour high volume, low diversity commoditised products made by tobacco or pharmaceutical companies. Regulation can adversely reshape the market and reduce the pace of innovation.

Policy	Likely unintended consequence
Bans on flavours	All e-cigarettes and liquids are flavoured with something – and this forms a key part of the appeal. Many former smokers report switching to non-tobacco flavours as a way of moving permanently away from smoking. There is a significant risk that loss of broad flavour categories will cause relapse among e-cigarette users, fewer smokers switching, and development of DIY and black market flavours – which may be more dangerous.
Ban refillable systems	This idea has been proposed by tobacco companies for commercial and anti-competitive reasons. It means removing the 'open system' 2nd and 3rd generation products that increasingly dominate the market. Many vapers report these are more effective alternatives to smoking. Any (minor) risks of poisoning, dermal contact, DIY mixing etc have to be set against the likely black market response, and the substantial benefits arising from personalisation and huge extension to the diversity of products available.
Health warnings	Alarmist health warnings, even if technically correct, can be misleading and misunderstood by the public. This has always been the case with smokeless tobacco – warnings do not adequately communicate relative risk and, therefore, understate smoking risks or the advantage of switching. They may obscure much more important messages about relative risk compared to smoking that is not provided in official communications.
Ban sales to under-18s	There is near universal support for this policy. A US study [link] found that in areas where e-cigarette sales to under-18s had been banned the decline in smoking was slower than in areas where it was not banned. However, it is worth noting that NRT is made available to people over 12 years in some jurisdictions – because young smokers also need to quit. It should not be assumed that 'harm reduction' should start at 18.
Prohibit health or relative risks claims	This denies smokers real world truthful information about relative risk and may cause more smoking. It is uncontroversial that e-cigarettes are safer than smoking – the debate is over where in the range 95-100% less risky. This erects high and unnecessary regulatory barrier to truthful communication - and therefore obscures the most important consumer benefit from consumers. The authorities could address this by providing authoritative advice on relative risk - for example of the type provided by Public Health England or the Royal College of Physicians, which could be used in communication with consumers.
Raise taxes on e-cigarettes	This reduces the financial incentive to switch from smoking to vaping unless the tax on smoking is also increased. But these taxes if raised too far will tip users into other forms of unintended behaviour – accessing the black market, switching to rolling tobacco, or create cottage industries producing e-liquids in garages. It may also favour smoking cessation medications that are less effective on average, such as NRT[15] (which in the UK actually receives an unjustified VAT discount)

[15] Brown J, Beard E, Kotz D, *et al.* Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. *Addiction* 2014;109:1531–40 [link]