

Comments on the  
Draft Control of Tobacco and Electronic Delivery Systems Bill 2018

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# Comments on the Draft Control of Tobacco and Electronic Delivery Systems Bill 2018

## Summary

We welcome the opportunity to comment on the Draft Control of Tobacco and Electronic Delivery Systems Bill 2018<sup>1</sup>. To summarise our advice:

- The draft Bill does not sufficiently differentiate between nicotine products of very widely differing risk to health. It does not embrace the definition of ‘tobacco control’ used in the WHO FCTC, which includes ‘harm reduction’. As these products are rising in importance, this is a significant weakness in a major Bill that should set direction for several years.
- We are concerned the draft Bill will cause harm to health by obstructing smokers switching from high risk combustible products (cigarettes) to low-risk non-combustible products (including vaping, heated products and smokeless tobacco). These switches should be encouraged.
- There is a substantial body of evidence that electronic nicotine delivery systems (ENDS) and other low-risk products are helping smokers to quit. This could help countries meet targets for reducing non-communicable diseases more rapidly and at minimal cost to government.
- Many countries are now revising their approach to new technologies that compete with cigarettes, most recently New Zealand and Canada. Countries like the UK have adopted ‘risk proportionate’, which is championed by the Royal College of Physicians and Public Health England. It would be disappointing if South Africa adopted a backward-looking tobacco control Bill just as other countries were modernising their approach.
- We are concerned that the draft Bill would protect the cigarette trade and favour the incumbent tobacco industry. The draft Bill would erect barriers to entry to innovative low-risk products and by make access to lower risk products more difficult, less appealing and more expensive.
- The Bill presents an opportunity for South Africa to lead in tobacco policy, to influence low and middle income countries, especially in Africa, and to lead thinking in WHO. But this will require a different approach to that used in the current draft Bill. We have made a range of suggestions for text amendment in Section 2, but the most important step is to redefine the strategic policy intent to exploit the opportunities of tobacco harm reduction rather than treat them as a threat.
- In Section 1 of this submission, we provide some context and a brief introduction to the concept of tobacco harm reduction.
- In Section 2, we set out proposals for amending the Bill. We commence this section with a suggested change in strategic intent as this would underpin proposed text changes.
- In Section 3, we provide five insights into tobacco harm reduction policy drawn from the 2016 report of the Royal College of Physicians. We hope the Ministry finds these insights persuasive and useful as it develops this legislation.

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<sup>1</sup> The Draft Control of Tobacco and Electronic Delivery Systems Bill 2018 ([Gazette 41617, 9 May](#)) Invitation to comment, Ministry of Health, Republic of South Africa, 9 May 2018 [\[link\]](#)

# 1 Introduction

## 1.1 Policy goal: tackling disease and premature death

Addressing the burden of disease caused by tobacco use, primarily smoking, remains the among the most important public health challenges today. In 2015, smoking prevalence in South Africa was 31.4 percent among men aged over 15 and 6.5 percent among women. 6.3 million people are smoking daily, and 42,000 South Africans die prematurely each year as a result<sup>2</sup>. All nations of the World Health Assembly have committed to tackle the disease burden of tobacco. It is important to emphasise that the primary goal of policy is to reduce harm, disease and death, as deeply and quickly as possible.

Under agreements made to reduce non-communicable diseases (NCDs), the nations of the World Health Assembly, including South Africa, committed to reduce smoking prevalence by 30 percent in relative terms by 2025, compared to 2010<sup>3</sup>. However, the World Health Organisation's most recent assessment of progress and likely outcomes<sup>4</sup> suggests that South Africa would not meet this target, with a decline in smoking prevalence from 19.4 percent to 16.5 percent between 2010 and 2025 – a relative decline of just 15 percent, or half the ambition agreed at the WHA. The WHO's assessment is consistent with similarly pessimistic analysis of a larger set of countries by independent academics writing in *The Lancet*<sup>5</sup>, which found that South Africa has a probability of between five and 50 percent of making the NCD target for smoking.

For this reason, renewed efforts and a refreshed policy delivered through new legislation is to be welcomed. However, we do not believe the Bill as drafted will deliver the full

## 1.2 Enhanced tobacco control measures should include tobacco harm reduction

The main argument that we make in this submission is that if the policy focus is to on reducing harm, then the policy needs to embrace the concept of “tobacco harm reduction”. This means using policy and legislation to exploit the very wide range of risks (one to three orders of magnitude) associated with different forms of nicotine product, and incentivising users to switch from the highest risk products (cigarettes) to those that do not involve any combustion – ENDS, smokeless and heated tobacco products and variations on nicotine replacement therapy. The WHO Framework Convention on Tobacco Control provides a definition of tobacco control that includes tobacco harm reduction<sup>6</sup>:

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)

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<sup>2</sup> American Cancer Society, Vital Strategies, *South Africa fact sheet*, Tobacco Atlas [\[link\]](#)

<sup>3</sup> World Health Assembly Resolution 66/8 Draft comprehensive global monitoring framework and targets for the prevention and control of non-communicable diseases, March 2013 [\[link\]](#)

<sup>4</sup> World Health Organisation, WHO global report on trends in prevalence of tobacco smoking 2015. [\[link\]](#)

<sup>5</sup> Bilano V, Gilmour S, Moffiet T, d’Espaignet ET, Stevens GA, Commar A, et al. Global trends and projections for tobacco use, 1990-2025: an analysis of smoking indicators from the WHO Comprehensive Information Systems for Tobacco Control. *Lancet* (London, England). Elsevier; 2015 Mar 14;385(9972):966–76. [\[link\]](#)

<sup>6</sup> WHO Framework Convention on Tobacco Control, Article 1 (Definitions), Geneva, 2003 [\[link\]](#)

The key strategy available to reduce smoking and smoking-related NCDs over the short timescale to 2025-30 is *tobacco harm reduction*. The harm reduction strategy more generally involves substituting a high-risk product or behaviour with a low-risk product or behaviour. It is a well-established strategy in many areas of public health, for example in intravenous drug use and HIV prevention. To put it bluntly, we do not try to help people avoid HIV by telling them to stop having sex, but by ensuring they access condoms when they do have sex. The concept of harm reduction is already well understood in South Africa in the context of HIV/AIDS – our proposal is that this concept should be adopted in response to the tobacco epidemic. This is not an alternative to established tobacco control, but complementary and mutually reinforcing. There is more we can do to reduce disease burdens through tobacco control by *also* adopting tobacco harm reduction strategies for people who continue to use nicotine.

### 1.3 What is tobacco harm reduction?

Tobacco harm reduction starts from the insight that the vast majority of harm done by tobacco use is done by *smoke* – the products of combustion arising from burning tobacco leaf. The nicotine is not the main or even an important harmful agent in tobacco use, but it is the reason why people use tobacco, mostly as smokers. This has been known since at least the 1970s<sup>7</sup>:

*People smoke for the nicotine, but they die from the tar.*

So the opportunity for a rapid win for health is to eliminate the tar (the smoke residues) for people who continue to use nicotine by choice or because they are dependent. Tobacco harm reduction involves the use of non-combustible products such as vaping products like e-cigarettes, heated tobacco products, or smokeless tobacco made to high purity standards – so called Alternative Nicotine Delivery Systems (ANDS) – shown in four categories below.



Most of these products have risen to prominence rapidly since 2010, and their rise has coincided with rapid declines in smoking in the UK and US among *both adults and adolescents*.

<sup>7</sup> Russell MJ. Low-tar medium nicotine cigarettes: a new approach to safer smoking. *BMJ* 1976;1:1430–3. [\[link\]](#)

The science and policy issues are discussed in more depth in Section 3, which draws on five statements from the UK Royal College of Physicians' major 2016 report: *Nicotine without the smoke: tobacco harm reduction*<sup>8</sup>. The Royal College endorses the use of e-cigarette to reduce smoking:

*The Royal College of Physicians' new report, 'Nicotine without smoke: tobacco harm reduction', has concluded that e-cigarettes are likely to be beneficial to UK public health. Smokers can therefore be reassured and encouraged to use them, and the public can be reassured that e-cigarettes are much safer than smoking.*

This is a conclusion supported by the largest UK public health agency, Public Health England<sup>9</sup>, which has recently shown its support by advertising switching to e-cigarettes on national prime-time television.

Independent American experts have reviewed the evidence in detail and have called for a fundamental change in the public health approach to nicotine, giving primary to reducing NCDs and stressing the value of harm minimisation approaches:<sup>10</sup>

*A reframing of societal nicotine use through the lens of harm minimization is an extraordinary opportunity to enhance the impact of tobacco control efforts.*

#### 1.4 Tobacco harm reduction and tobacco control are compatible (not alternatives)

There is a well-established package of tobacco control measures that aim to change the demand for tobacco products described by the acronym MPOWER<sup>11</sup>, and used by the World Health Organisation. We should stress that tobacco harm reduction is compatible with the established MPOWER policies that are adopted in the WHO FCTC.

The idea of tobacco control is to encourage changes in behaviour in response to tobacco control policies such as raising tobacco taxation, informing people about risks or banning advertising. The tobacco harm reduction options increase the range of beneficial options for responding while reducing the difficulty. Switching to a lower risk product is easier than complete cessation because smokers do not have to give up nicotine, flavour sensations or behavioural rituals. However, in following these easier-to-follow pathways, smokers can dramatically reduce risk. For example, an increase in taxes on cigarettes could prompt a range of behavioural response:

1. keep smoking but pay more, with a negative impact on household budget and welfare;
2. try to quit completely, but recognising that success rates are low;
3. switch to illicitly traded cigarette, creating a revenue loss but no health gain.

Switching to a vaping, smokeless or heated product adds a significant fourth option that should benefit tobacco control efforts by making established policies less painful and more effective.

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<sup>8</sup> Royal College of Physicians (London) *Nicotine without smoke: tobacco harm reduction* 28 April 2016 [\[link\]](#)[\[press\]](#)

<sup>9</sup> McNeill A, Brose LS, Calder R, Bauld L & Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England. 6 February 2018 [\[link\]](#) [\[Press release\]](#)

<sup>10</sup> Abrams DB, Glasser AM, Pearson JL, Villanti AC, Collins LK, Niaura RS. Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives. *Annu Rev Public Health*; 2018. [\[link\]](#)

<sup>11</sup> World Health Organisation, Tobacco Free Initiative: MPOWER. [\[Link\]](#)

## 1.5 The Final Impact Assessment

The Final Impact Assessment<sup>12</sup> for the Draft Bill synthesises a wide range of perspectives on the draft Bill and is based on the evaluation of three main options: (1) the status quo; (2) the proposed Bill; and (3) a more complete implementation of FCTC.

We would generally be inclined to support Option 3, but providing that the Bill embraced tobacco harm reduction and respected the definition of tobacco control used in the FCTC. We believe that this will deliver the best results for public health in South Africa. In our view, this option was not fully evaluated in the Final Impact Assessment – we would describe it as a fourth option: a “risk-proportionate implementation of the FCTC”. We believe that this would be a ground-breaking approach. Section 2 of this submissions sets out more detailed comments on the text of the draft Bill. However, we stress that we are calling for a different policy orientation, rather than just technical changes to the text of the Bill. With a different policy approach the Bill could be much stronger and reconcile the positions held by many more stakeholders.

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<sup>12</sup> Department of Planning, Monitoring and Evaluation. Socio-economic Impact Assessment System, Final Impact Assessment: *Proposed Control of Tobacco Products and Electronic Delivery Systems Bill*. March 2018 [[link](#)]

## 2 Advice regarding the draft Bill

### 2.1 Strategic approach

Our main advice is not about drafting or legalistic points, but that the government of South Africa should change the *policy intent* that provides the foundation for the draft Bill. This means three major adjustments:

1. Accept that reduced-risk products create a new front in the battle against smoking related-disease and adopt world-leading policies and legislation that exploit the opportunities, while addressing residual threats.
2. Make amendments to the draft Bill that make its provisions “risk-proportionate” – so that the most damaging products, cigarettes, experience the toughest regulation while switching to products that can save lives by replacing smoking is encouraged by lighter regulation.
3. Recognise the potential for serious harm caused by excessive regulation of lower risks resulting in unintended consequences. This can easily amount to regulatory protection of the cigarette trade and put obstructions in the way of people making decisions that will help their health.

In the remainder of this section we will look at specific changes that should be made to the draft legislation.

### 2.2 Preamble

The preamble uses ‘smoking’ and ‘tobacco use’ interchangeably. It should make clear that the primary problem is smoking. Almost all of the burden of disease is caused by toxic products of combustion in tobacco smoke.

*“RECOGNISING that there should be a precautionary approach to the regulation of electronic delivery systems”*. While this sounds responsible it can in fact be harmful, if it means that smokers are denied products that are much less risky than cigarettes. That is likely in this case. This is not a situation in which the precautionary principle can apply – that is because taking supposedly precautionary action that proves to be misplaced creates harm to health and unintended consequences.

Current text	Suggested text
RECOGNISING that there should be a precautionary approach to the regulation of electronic delivery systems	RECOGNISING that regulation of electronic delivery systems should strike a balance between controlling risks and exploiting opportunities for health

### 2.3 Section 1: Definitions

Much of the problem with the draft Bill arises from definitions that conflate very different products and behaviours that have very different risks (i.e. combustible and non-combustible products, nicotine products and products containing tobacco, smoking and vaping). This has the effect of

building in, by default, undifferentiated approaches to regulation and does not provide flexibility to do this in future without changes to primary legislation. We strongly advise using different definitions for products or behaviours that are very different, and then building regulation on these more precise definitions.

The definitions suggested below would allow South Africa to define more nuanced policies that would exploit the benefits of tobacco harm reduction and encourage smokers who cannot or choose not to stop using nicotine to switch from high-risk to low-risk products.

Current text	Suggested text
<p>"tobacco product" means a product containing tobacco or an extract of tobacco leaves that is intended for human consumption. but does not include any food, drug or device that contains nicotine to which the Medicines and Related Substances Act. 1965 (Act No. 101 of 1965). applies.</p>	<p>"tobacco product" means a product containing tobacco <del>or an extract of tobacco leaves</del> that is intended for human consumption, but does not include any food, drug or device that contains nicotine to which the Medicines and Related Substances Act. 1965 (Act No. 101 of 1965). applies.</p>
	<p>[New] "ignited tobacco product" means tobacco products in which there is combustion of tobacco ;</p>
	<p>[New] "smokeless tobacco product" means a tobacco product not involving a combustion or heating process, including chewing tobacco, nasal tobacco and tobacco for oral use.</p>
	<p>[New] "heated tobacco product" a tobacco product in which tobacco is heated but not ignited.</p>
	<p>[New] "nicotine product" means a product containing nicotine but not tobacco that is intended for human consumption but does not include any food, drug or device that contains nicotine to which the Medicines and Related Substances Act 1965 (Act No. 101 of 1965) applies.</p>
<p>"electronic nicotine delivery system" means an electronically operated product designed to deliver an aerosol to users by heating a solution comprised of nicotine and typically, but not necessarily, propylene glycol, glycerol or both, and often flavouring and any other solution intended for use with or in the product:</p>	<p>[Retain]</p>

Current text	Suggested text
<p>“smoke” means inhale, exhale, hold or-</p> <p>(a) otherwise have control over an ignited tobacco product or a heated, but not ignited, tobacco product that produces an emission of any sort.</p> <p>(b) operate or otherwise have control over an electronic delivery system that produces an emission of any sort:</p>	<p>“smoke” means inhale, exhale, hold or otherwise have control over an ignited tobacco product;</p>

## 2.4 Section 2: Control over smoking

The appropriate policy aim should be to legislate a ban on “smoking” only where there is a material risk to bystanders and workers in the premises. Without such risks, the normal principles of property rights should mean that the decision about what happens in a given place is a matter for the owner or operator, and they should be able to allow or prohibit the use of these products to suit their own needs and clientele. That, of course, does not mean vaping would be allowed everywhere, it just changes who makes the decision – from the government to the owner or manager of the premises.

By defining “smoking” to cover vaping and use of heated tobacco products, the draft Bill goes far beyond any science that would suggest a risk to bystanders or workers – this can only be justified for ignited tobacco products. The science suggests much lower exposures to bystanders and negligible risk. For example, Burstyn says<sup>13</sup>:

*Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern.*

Avino et al suggest cancer risk for passive smoking is “five orders of magnitude larger” (approx. 100,000 times) than for vaping<sup>14</sup>

*The [estimated lifetime cancer risk] for second-hand smokers was five orders of magnitude larger than for second-hand vapers.*

At the same time there is emerging evidence that excluding vapers in the same way as smokers can have the unintended effect of increasing smoking<sup>15</sup> by making switch relatively less attractive.

<sup>13</sup> Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks, *BMC Public Health* 2014;**14**:18. [\[Link\]](#)

<sup>14</sup> Avino P, Scungio M, Stabile L, Cortellessa G, Buonanno G, Manigrasso M. Second-hand aerosol from tobacco and electronic cigarettes: Evaluation of the smoker emission rates and doses and lung cancer risk of passive smokers and vapers. *Sci Total Environ.* 2018 Nov **15**;642:137–47. [\[link\]](#)

<sup>15</sup> Cooper MT, Pesko MF. "The effect of e-cigarette indoor vaping restrictions on adult prenatal smoking and birth outcomes." *Journal of Health Economics*, Volume 56, 2017, Pages 178-190. [\[link\]](#)

The danger is that the Bill will lock in policies that are prone to harmful unintended consequences and so cause more harm. We therefore recommend apply legal bans only to smoking ignited tobacco products

Current text	Suggested text
(1) No person may smoke in -	(1) No person may <u>use ignited tobacco products</u> in – [(a)-(g)]
	[New] The owner of or person in control of a public place, public conveyance or workplace may designate the whole or part of any indoor space as an area where use of electronic delivery systems or heated tobacco products is either prohibited or permitted.
(2) The Minister may prohibit smoking in any prescribed outdoor public place or workplace, or such portion of an outdoor public place or workplace as may be prescribed, where smoking may pose a health, fire or other hazard. or such other place where the Minister considers it appropriate to prohibit smoking in order reduce or prevent the public's exposure to smoking.	(2) The Minister may prohibit <u>use of ignited tobacco products</u> in any prescribed outdoor public place or workplace, or such portion of an outdoor public place or workplace as may be prescribed, where smoking such products may pose a health, fire or other hazard. or such other place where the Minister considers it appropriate to prohibit smoking in order reduce or prevent the public's exposure to <u>tobacco smoke</u> .
(4) The person in control of a place or an area contemplated in subsection (1). (2) or (3) or an employer in respect of a work place must ensure that no person smokes in that place or area.	(4) The person in control of a place or an area contemplated in subsection (1). (2) or (3) or an employer in respect of a work place must ensure that no person <u>contravenes the policy on use of tobacco or nicotine in that area</u> .
(5) The owner or person in control of a place or an area contemplated in subsections (1). (2) or (3) must display the prescribed sign and must make the prescribed public announcements in order to inform any person who enters or who is on the premises of the prohibition on smoking.	(5) The owner or person in control of a place or an area contemplated in subsections (1). (2) or (3) must display the prescribed sign and must make the prescribed public announcements in order to inform any person who enters or who is on the premises of the <u>policy on use of tobacco or nicotine products</u> .

## 2.5 Section 3: Advertising, promotion, sponsorship, distribution and display of tobacco products and electronic delivery systems

The draft Bill takes an undifferentiated approach to advertising, promotion and sponsorship, banning most forms of marketing for all products. While this can be justified for the most harmful products, extending such a prohibition to new low-risk alternatives could have the effect of protecting the incumbent cigarette trade from alternatives that would displace smoking by

encouraging smokers to quit. One study assessed the impact of e-cigarette advertising bans on smoking cessation in the United States and concluded<sup>16</sup>

*Our results indicate that a policy to ban TV advertising of e-cigarettes would have reduced the number of smokers who quit in the recent past by approximately 3%, resulting in roughly 105,000 fewer quitters in that period.*

An earlier assessment<sup>17</sup> raised the prospect of bans on e-cigarettes *increasing cigarette smoking.*

*Analyzing household purchase data, I find that individuals reduce their consumption of traditional cigarettes after buying e-cigarettes, further suggesting that the products are substitutes. [...] I find that in the absence of e-cigarette advertising, demand for traditional cigarettes would increase, suggesting that a ban on e-cigarette advertising may have unintended consequences.*

Banning advertising of low-risk alternatives is like banning advertisements for smoking cessation – counterproductive for health and economically wasteful, given that such advertising paid for by the private sector. The case for banning advertising of a tobacco product is that it causes significant harm and may be addictive. However, the case does not work for low-risk alternatives because they can substitute for smoking and cause a significant reduction in harm and therefore a health benefit.

We therefore recommend confining outright prohibition of advertising (etc) only to ignited tobacco products. For low-risk alternatives, we recommend using controls over content and placement of advertising. This is the approach taken to alcohol advertising and sponsorship in many countries, including South Africa<sup>18</sup>, and this is the approach taken to domestic e-cigarette advertising in the United Kingdom<sup>19</sup>. Control over the advertising of low-risk alternatives should be covered by a new appendix to the Advertising Code of Practice and the Sponsorship Code.

Current text	Suggested text
3. (1) In this section. "relevant product" includes devices used in connection with tobacco products and electronic delivery systems such as pipes, water pipes and electronic devices, and components of those products or systems.	3. (1) In this section. "relevant product" means ignited tobacco products, devices used in connection with ignited tobacco products and components of those products or systems.
	[New] Marketing of tobacco or nicotine products that are not ignited tobacco products shall be

<sup>16</sup> Dhaval M. Dave & Daniel Dench & Michael Grossman & Donald S. Kenkel & Henry Saffer, 2018. "Does E-Cigarette Advertising Encourage Adult Smokers to Quit?," NBER Working Papers 24277, National Bureau of Economic Research, Inc. [\[link\]](#)

<sup>17</sup> Tuchman AE. Advertising and Demand for Addictive Goods: The Effects of E-Cigarette Advertising, Stanford University, (working paper), Semantic Scholar, 1 April 2016 [\[link\]](#)[\[PDF\]](#)

<sup>18</sup> The Advertising Standards Authority of South Africa, Advertising Code of Practice, Appendix A: Alcohol Advertising. [\[link\]](#) Sponsorship Code [\[link\]](#)

<sup>19</sup> Committee on Advertising Practice (UK), UK Code of Broadcast Advertising: 33. E-cigarettes Broadcast [\[link\]](#); UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code): 22. E-cigarettes [\[link\]](#)

Current text	Suggested text
	controlled by Advertising Standards Authority of South Africa and relevant codes.

## 2.6 Section 4: Standardised packaging and labeling of tobacco products

The aim of policy on standardised packaging should be to degrade the appeal of combustible tobacco products with a view to reducing use (though reducing price is a likely response). Evidence of any beneficial public health effect from this measure remains elusive<sup>20</sup>. However, such measures if they are to be implemented at all should be strictly limited to the most harmful products, cigarettes. For similar reasons to advertising and promotion, it is likely to be counterproductive to introduce excessively stringent regulation of products that function as alternative to cigarettes, including vaping products, smokeless tobacco and heated tobacco products.

Current text	Suggested text
4. (1) The Minister must prescribe standardised packaging and labeling of tobacco products	4. (1) The Minister must prescribe standardised packaging and labeling of <u>cigarettes</u>
4.(3) No person shall manufacture for sale import or sell a tobacco product unless...	(3) No person shall manufacture for sale import or sell <u>cigarettes</u> unless...

Section 4(4) of the draft Bill control claims and marketing messages transmitted through the packaging. The objective should be to ensure that all communications via packaging are truthful and, even if strictly correct, that they are non-misleading. However, the legislation should not prevent communications that are truthful and not misleading – information which could mean life or death if the consumer acts on it.

On this basis, we believe that it is wrong and harmful to the consumer to place a legal *barrier* communication of relative risk through 4(4)(a) – a communication creates the impression “a tobacco product is less harmful than another tobacco product”. It is beyond any reasonable dispute that some tobacco products are *much safer* than others<sup>21</sup>, and this is important information for consumers to have access to. To deny them access to that information is an abuse that puts them at risk. For example, the US National Academies<sup>22</sup> found that:

<sup>20</sup> World Trade Organisation, Dispute Settlement Panel. DS467: Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, Panel Report, 18 June 2018. [\[link\]](#)[\[article\]](#)

<sup>21</sup> It is inconceivable that products that do not involve combustion could even come close in risk to products that create smoke. The toxic products or combustion dominate the harms caused by tobacco use and there are few other sources of risk in non-combustible products.

<sup>22</sup> National Academies of Science, Engineering and Medicine (US). The Public Health Consequences of E-cigarettes. Washington DC. January 2018. [\[link\]](#) Launch presentation summary (slide 44) [\[link\]](#)[\[link\]](#)

*While e-cigarettes are not without health risks, they are likely to be far less harmful than combustible tobacco cigarettes.*

The Royal College of Physicians<sup>23</sup> and Public Health England<sup>24</sup> came to similar conclusions about e-cigarettes and it is clear that use of conventional smokeless tobacco or snus is much safer than cigarettes<sup>25</sup> and there is a compelling case that heated tobacco products are also much less harmful than cigarettes<sup>26</sup>. So we do not believe it can be ethical<sup>27</sup> to actively prevent consumers having access to information about relative risk, or that the authorities should imply that the products are indistinguishable in terms of risk – as this law implies.

We believe it is important that potentially life-saving relative risk information is available to consumers, and should be ruled out by law. The

Current text	Suggested text
No person shall manufacture for sale in the Republic, import or sell a tobacco product that has packaging or labeling that is false, misleading, deceptive or likely to create any erroneous, deceptive or misleading impression about its characteristics, properties, health effects, toxicity, composition, merit, safety, hazards or emissions...	[Retain... this text already covers misleading claims, but allows truthful no-misleading claims]
... including any term, descriptor, trade mark, figurative, colour, number or other sign that directly or indirectly creates the impression that a particular tobacco product-	... including any term, descriptor, trade mark, figurative, colour, number or other sign that directly or indirectly creates the impression that a particular tobacco product-
(a) is less harmful than another tobacco product:	<del>(a) is less harmful than another tobacco product:</del>
(b) aims to reduce the effect of any harmful content of the product or its smoke:	<del>(b) aims to reduce the effect of any harmful content of the product or its smoke:</del>
(c)-(e)	(c)-(e) [retain]

<sup>23</sup> Tobacco Advisory Group of the Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016 [\[link\]](#)

<sup>24</sup> McNeill A, Brose LS, Calder R, Bauld L & Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England. 6 February 2018 [\[link\]](#) [\[Press release\]](#)

<sup>25</sup> Lee PN, Hamling J. Systematic review of the relation between smokeless tobacco and cancer in Europe and North America. *BMC Med. BioMed Central*; 2009 Jul 29;7(1):36. [\[link\]](#)

<sup>26</sup> Smith MR, Clark B, Lüdicke F, Schaller J-P, Vanscheeuwijck P, Hoeng J, et al. Evaluation of the Tobacco Heating System 2.2. Part 1: Description of the system and the scientific assessment program. *Regul Toxicol Pharmacol*. 2016 Nov 30;81 Suppl 2:S17–26. [\[link\]](#)

<sup>27</sup> Kozlowski LT, Abrams DB. Obsolete tobacco control themes can be hazardous to public health: the need for updating views on absolute product risks and harm reduction. *BMC Public Health*. England: BioMed Central; 2016 May 24;16(1):432. [\[link\]](#)

## 2.7 Section 5: Packaging and labeling of electronic delivery systems

The aim of this section should be to allow the government apply section 4(4) to electronic delivery systems. However a ban on non-tobacco flavours would amount to a near-prohibition. The government should reserve more flexibility to address flavours – not just the all-or-nothing language about flavours in 4(4)d. The aim should be to give the Minister the power, but not the obligation, to place controls on flavours or flavour descriptors and other ingredients – thereby creating a more flexible power. The use of such powers should be justified as necessary for public health, thereby ensuring that policy is evidence-based and providing a defence against claims use of ingredient regulation as a discriminatory barrier to trade<sup>28</sup>.

Current text	Suggested text
5. (1) No person shall manufacture for sale, import or sell an electronic delivery system unless it is packaged and labeled in the prescribed manner.	[ <i>Retain</i> ]
(2) Section 4(4) applies with the changes required by the context to electronic delivery systems: Provided that section 4(4)(d) does not apply unless prescribed.	(2) No person shall manufacture for sale in the Republic, import or sell an electronic delivery system product that has packaging or labeling that is false, misleading, deceptive or likely to create any erroneous, deceptive or misleading impression about its characteristics, properties, health effects, toxicity, composition, merit, safety, hazards or emissions.
	[ <i>new</i> ] (3) Where appropriate for the protection of public health, the Minister may prescribe standards and restrictions to control ingredients, including, flavourings and description of ingredients used in conjunction with electronic delivery systems.

## 2.8 Section 6: Health warning messages and required information

The purpose of warnings should be to inform consumers and help them to make better, more informed, choices including the choice to stop using tobacco or nicotine product and the choice to switch from a high-risk to low-risk product. The communication of risk is greatly complicated by the availability of new tobacco and nicotine products for which there is no established disease burden and that may substitute for high risk combustible products.

We advise therefore that the warnings as specified in 6(1) are applied to combustion products only, and the Minister uses regulations to prescribe risk communications for smokeless and heated tobacco products and electronic delivery systems.

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<sup>28</sup> Foltea M. International Trade Rules for Banning E-vapor Products, R Street Institute Policy Paper 104, August 2017 [[link](#)]

Current text	Suggested text
6. (1) The packaging for a tobacco product must display the following information:	6. (1) The packaging for <u>an ignited tobacco product</u> must display the following information:
(2) The packaging for an electronic delivery system must contain such health warnings as may be prescribed.	(2) The packaging for <u>a nicotine product that is not an ignited tobacco product</u> must contain such health warnings as may be prescribed.
(3) The packaging of a relevant product must contain a leaflet, which must be in the prescribed form, of the prescribed size and have the prescribed appearance and which must contain nothing else except of the following information  (a)-(g).	(3) The packaging of <u>an ignited tobacco product</u> must contain a leaflet, which must be in the prescribed form, of the prescribed size and have the prescribed appearance and which must contain nothing else except of the following information
	[New] (4) The packaging <u>a nicotine product that is not an ignited tobacco product</u> may contain such information as prescribed.

## 2.9 Section 7: Standards for manufacturing and importing of tobacco products and electronic delivery systems

No comments.

## 2.10 Section 8: Prohibitions in respect of tobacco products and electronic delivery systems

This section addresses access to tobacco and nicotine products. The most problematic part relates to the prohibition on selling electronic delivery systems online. There are several reasons for caution about such a measure:

1. It favours products that are most readily sold in shops – that means cigarettes and the entry level ENDS products (most usually sold by tobacco companies).
2. The appeal of vaping products as an alternative to smoking relies in part on the diversity of the product and personal experience. Specialised vaping shops can meet this need in urban areas where there is adequate density of users, but in other areas users will rely on the internet.
3. It is better to have well-regulated local internet-based suppliers than users buying products across borders via the internet, which is already easy to do.

Current text	Suggested text
8.(5) No person shall sell, offer for sale, supply, distribute or buy a relevant product through the postal service the Internet or any other electronic medium. or by any other remote means.	8.(5) No person shall sell, offer for sale, supply, distribute or buy <u>an ignited tobacco product</u> through the postal service the Internet or any other electronic medium. or by any other remote means.

Alternatively, the text could be drafted with an exclusion;

Current text	Suggested text
8.(5) No person shall sell, offer for sale, supply, distribute or buy a relevant product through the postal service the Internet or any other electronic medium, or by any other remote means.	8.(5) [Retain]
	[New] Section 8(5) shall not apply to electronic delivery systems.

## 2.11 Section 9: Regulations

This section sets out discretion provided to ministers to make regulations. The main weakness is that it does not place objective control of the purpose for which these powers are to be used. We recommend specifying a public health or welfare duty in exercising these powers.

Current text	Suggested text
9. (1) The Minister may make regulations regarding-	9.(1) <u>Where appropriate for the protection of public health or the enhancement of the welfare of the public,</u> the Minister may make regulations regarding-

## 2.12 Sections 10 to 15 – final sections

No comments.

### 3 Five insights inspired by the Royal College of Physicians

To provide background on tobacco harm reduction, we draw on five key findings of the April 2016 Royal College of Physicians (London) report<sup>29</sup>: *Nicotine without smoke: tobacco harm reduction*. The Royal College first put the dangers of smoking on the public agenda with its ground-breaking 1962 report, *Smoking and Health*<sup>30</sup>.

#### 3.1 On the relative risks of vaping and smoking

*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. (RCP Section 5.5 page 87)*

People who smoke need to know that they have the option to switch to vaping and that doing this will radically reduce their incremental risks. Likewise, professionals involved in health care and policy need a good feel for the relative risks. The RCP aimed provide some clarity and has provided its own best estimate of relative risk based on what is known about these products – and this estimate is independent of other studies. Vaping involves completely different chemical and physical processes, and the main harmful or potentially harmful agents in cigarette smoke are either not present or present at levels well below 5% of those found in cigarettes. Even if new harmful agents are discovered, it is much easier to remove them from e-liquids than it is to remove target chemicals from cigarette smoke. Note how carefully worded this statement is – it is steering the reader to the right ball-park, acknowledging uncertainty, and pointing out it is a cautious estimate.

#### 3.2 On the idea that allowing e-cigarettes will somehow cause people to smoke

*There are concerns that e-cigarettes will increase tobacco smoking by renormalising the act of smoking, acting as a gateway to smoking in young people, and being used for temporary, not permanent, abstinence from smoking. To date, there is no evidence that any of these processes is occurring to any significant degree in the UK. Rather, the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely. (RCP Key recommendations)*

The finding is what a rational observer would expect – that people will use much safer products to reduce the risks to their health and as a way of quitting smoking, rather than to smoke more. The rise of vaping in the UK and US has been accompanied by rapid falls in adult smoking. There are strong *associations* between smoking and vaping because the same personal characteristics or circumstances that cause people to smoke also cause them to use ENDS, there is no compelling evidence that vaping causes smoking<sup>31</sup>.

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<sup>29</sup> Royal College of Physicians (London) *Nicotine without smoke: tobacco harm reduction*, 28 April 2016 [[report](#)] and [[press release](#)]

<sup>30</sup> Royal College of Physicians (London) *Smoking and Health*, 1962 [[link](#)]

<sup>31</sup> Kozlowski LT, Warner KE. Adolescents and e-cigarettes: Objects of concern may appear larger than they are. *Drug Alcohol Depend.* 2017 May;174(1 May 2017):209–14. [[link](#)][[PDF](#)]

The American experience is of *rapidly declining teenage smoking* coinciding with the rise in vaping, much of which is occasional and without nicotine. The National Academies of Science, Engineering and Medicine states “*for youth and young adults, there is substantial evidence that e-cigarette use increases the risk of ever using combustible tobacco cigarettes*”. However this has not translated to increases in smoking. In fact, the opposite effect, an anomalously rapid *decline* in adolescent smoking, has occurred, as the National Academies point out:<sup>32</sup>

*Overall, the population-based data broadly show opposing trends in e-cigarette and cigarette use prevalence across time among U.S. youth in recent years and thus do not provide confirmatory evidence of the epidemiologic person-level positive associations of vaping and smoking.*

Likewise, a 2017 analysis of UK survey data concluded<sup>33</sup>:

*In summary, surveys across the UK show a consistent pattern: most e-cigarette experimentation does not turn into regular use, and levels of regular use in young people who have never smoked remain very low.*

A comprehensive American independent review of the studies and methodologies purporting to reveal ‘gateway effects’ found multiple flaws in methodology and interpretation, concluding<sup>34</sup>:

*Only a small proportion of studies seeking to address the effect of e-cigarettes on smoking cessation or reduction meet a set of proposed quality standards. Those that do are consistent with randomized controlled trial evidence in suggesting that e-cigarettes can help with smoking cessation or reduction.*

### 3.3 On the potential for bad policies to cause additional harm

*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. (RCP Section 12.10 page 187)*

The Royal College draws our attention to the challenge of unintended consequences and the idea that supposedly cautious policies are not necessarily cost-free if the risk “*perpetuating smoking*”. Policy-makers can believe they are being ‘precautionary’ and risk-averse, while actually being ‘reckless’ by protecting the cigarette trade and discouraging smokers from quitting.

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<sup>32</sup> National Academies of Science, Engineering and Medicine (US). The Public Health Consequences of E-cigarettes. Washington DC. January 2018. [\[link\]](#)

<sup>33</sup> Bauld L, MacKintosh A, Eastwood B, Ford A, Moore G, Dockrell M, et al. Young People’s Use of E-Cigarettes across the United Kingdom: Findings from Five Surveys 2015–2017. Int J Environ Res Public Health. Multidisciplinary Digital Publishing Institute; 2017 Aug 29;14(9):973. [\[link\]](#)

<sup>34</sup> Villanti AC, Feirman SP, Niaura RS, Pearson JL, Glasser AM, Collins LK, et al. How do we determine the impact of e-cigarettes on cigarette smoking cessation or reduction? Review and recommendations for answering the research question with scientific rigor. *Addiction*. 2017 Oct 3; [\[link\]](#)

The list of potential mechanisms for harmful unintended consequences arising from poorly designed regulation is long<sup>35</sup>. There is already evidence that superficially attractive regulation of ENDS can have the effect of perpetuating smoking<sup>36 37 38</sup>, and therefore doing more harm than good.

Recommendations for regulatory policy:

- The application of standard consumer protection legislation should be the starting point. Further regulation, should be carefully justified and assessed for unintended consequences.
- The optimum regulatory regime would set transparent standards for chemical, electrical, thermal and mechanical safety when these are of material benefit to consumers, together with standard testing procedures. The French AFNOR standards are good model<sup>39</sup>. Arbitrary standards, for example for maximum nicotine strength for e-liquids or maximum size of containers or tanks<sup>40</sup>, serve no purpose and may inhibit uptake or promote smoking relapse.
- Warnings and labelling should inform consumers rather than scare them and not convey the impression that vaping is especially harmful. The most important information would convey relative risk: that ENDS are much less harmful than cigarettes.
- There is no case to ban ENDS advertising and promotion. Firstly, because advertising for ENDS is effectively privately funded anti-smoking campaign spending. Secondly, because the justification for banning tobacco advertising is because of the great risk to health that it causes. Some safeguards to prevent targeting of youth may be justified: the UK Codes of Advertising Practice provide a reasonable model<sup>41</sup>.
- Any taxation on ENDS should create a price incentive to switch from the high risk cigarette to the low risk ENDS and as far as possible reflect relative risk<sup>42</sup>. In most cases, the cost of tax administration would outweigh the value of the appropriate tax, so ENDS should generally have no additional tax applied, other than standard sales taxes.
- Policy on indoor use of ENDS should be a matter for owners and managers of building. The application of law can be justified where there is evidence that exposure to emissions creates material harm to bystanders, but no such evidence exists for ENDS. The role of the state is to provide guidance on making these decisions<sup>43</sup> – but not to impose them.

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<sup>35</sup> New Nicotine Alliance (UK consumer organization) Assessing and mitigating unintended consequences of policies for vapour technologies and other low risk alternatives to smoking, 29 April 2016 [\[link\]](#) See especially Appendix 1.

<sup>36</sup> Friedman AS. How does Electronic Cigarette Access affect Adolescent Smoking? *J Health Econ* Published Online First: October 2015. [\[link\]](#)

<sup>37</sup> Cooper MT, Pesko MF. "The effect of e-cigarette indoor vaping restrictions on adult prenatal smoking and birth outcomes." *Journal of Health Economics*, Volume 56, 2017, Pages 178-190. [\[link\]](#)

<sup>38</sup> 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 [\[link\]](#)

<sup>39</sup> AFNOR (France) Electronic cigarettes and e-liquids Part 1: Requirements and test methods for e-cigarettes XP D90-300-1 March 2015 [\[link\]](#) Part 2: Requirements and test methods for e-cigarette liquid XP D90-300-2 March 2015 [\[link\]](#) and Part 3: Requirements and emission-related test methods XP D90-300-3 July 2016 [\[link\]](#)

<sup>40</sup> Bates CD: What is wrong with the Tobacco Products Directive for vapour products? Counterfactual May 2015 [\[link\]](#)

<sup>41</sup> Committee on Advertising Practice (UK), UK Code of Broadcast Advertising: 33. E-cigarettes Broadcast [\[link\]](#); UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code): 22. E-cigarettes [\[link\]](#)

<sup>42</sup> Chaloupka FJ, Sweanor D, Warner KE. Differential Taxes for Differential Risks--Toward Reduced Harm from Nicotine-Yielding Products. *New England Journal of Medicine* 2015;373:594-7. [\[link\]](#)

<sup>43</sup> Public Health England, Use of e-cigarettes in public places and workplaces, 6 July 2016 [\[link\]](#)

### 3.4 On quitting smoking as a consumer behaviour

*E-cigarettes are marketed as consumer products and are proving much more popular than NRT as a substitute and competitor for tobacco cigarettes.*

*E-cigarettes appear to be effective when used by smokers as **an aid to quitting smoking**. (RCP Key recommendations, original emphasis)*

Vaping products are *consumer products* marketed as an alternative to smoking. They are not smoking cessation medications any more than diet soda is an anti-obesity drug. The overall public health impact of any given approach is a function of both uptake and impact on the person's health. Vaping works well on both of these – by being attractive as an alternative to smoking and by mirroring many of the things that people want from smoking it is an effective low-risk substitute. We now have 1.5 million ex-smoker vapers in the UK. The number of UK smokers fell by 1.5 million between 2014 and 2016 (from 9.7 to 8.2 million) – a dramatic decline. Another 1.1 million people both smoke and vape – and many may be on a journey to quitting or substantially cutting down. There is an abundance of evidence that ENDS are promoting reductions in smoking<sup>44</sup>, including this substantial 2017 study from the United States<sup>45</sup>:

*The substantial increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level. These findings need to be weighed carefully in regulatory policy making regarding e-cigarettes and in planning tobacco control interventions.*

### 3.5 On the public health interest in vaping as a harm reduction strategy

*However, in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK. (RCP Key recommendations, original emphasis).*

Professor John Britton, chair of the RCP's Tobacco Advisory Group, said<sup>46</sup>:

*The growing use of electronic cigarettes as a substitute for tobacco smoking has been a topic of great controversy, with much speculation over their potential risks and benefits. This report lays to rest almost all of the concerns over these products, and concludes that, with sensible regulation, electronic cigarettes have the potential to make a major contribution towards preventing the premature death, disease and social inequalities in health that smoking currently causes in the UK.*

This is a strong recommendation from the Royal College of Physicians to embrace the concept of tobacco harm reduction as a public health policy. *That is not an alternative to other tobacco policies* – in fact it makes the traditional tobacco control policies more effective and less ethically challenging by giving smokers a viable way to respond to incentives or pressures.

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<sup>44</sup> Bates CD, Mendelsohn C, Submission 336 - Evidence to Standing Committee on Health, Aged Care and Sport (Australia) Inquiry The Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia Do vapour products reduce or increase smoking? A summary of published studies. 19 October 2017 [\[link\]](#)

<sup>45</sup> Zhu S-H, Zhuang Y-L, Wong S, Cummins SE, Tedeschi GJ. E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. *Bmj*. 2017;358:j3262. [\[link\]](#)

<sup>46</sup> Royal College of Physicians (London) Nicotine without smoke: tobacco harm reduction. 26 April 2016 ([Press release](#))

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**Clive D. Bates** is Director of Counterfactual, a consulting and advocacy practice focussed on a pragmatic approach to sustainability and public health. He has had a diverse career in the public, private and not-for-profit sectors. He started out with the IT company, IBM, then switched career to work in the environment movement. From 1997-2003 he was Director of Action on Smoking and Health (UK), campaigning to reduce the harms caused by tobacco. In 2003 he joined Prime Minister Blair's Strategy Unit as a senior civil servant and worked in senior roles in government and regulators, and for the United Nations in Sudan.

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**The authors have no competing interests with respect to e-cigarette, tobacco or pharmaceutical industries.**