**"Regulation of innovative smoke-free products"**

**State Duma of the Russian Federation**

# ENDS: the five most important findings from the UK Royal College of Physicians report

**Memo to accompany verbal testimony**

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## Introduction

The World Health Organisation estimates that smoking prevalence in the Russian Federation in 2015 was 37 percent (59 percent among men and 19 percent among women)[1]. For men, this is the second highest in the world after Indonesia (excluding small island states). Under agreements made to reduce non-communicable diseases, Russia has joined other nations in committing to reduce smoking prevalence by 30 percent by 2025[2] [3], compared to 2010. However, WHO modelling suggests only a 9 percent reduction Russian smoking prevalence is likely by 2025, less than one third of the target[1]. This means a smoking prevalence of 35 percent instead of the target of 27 percent in 2025.

It follows that new approach is needed if these targets are to be met. The use of non-combustible products – Electronic Nicotine Delivery Systems (ENDS) or heated tobacco products provides an opportunity to accelerate the decline in smoking in Russia, with benefits for health, life-expectancy and the economy.

## Five talking points inspired by the Royal College of Physicians

To frame a discussion we draw on five key findings of the April 2016 Royal College of Physicians (London) report[4]: *Nicotine without smoke: tobacco harm reduction*. It was the RCP that first put the dangers of smoking on the public agenda with its ground breaking 1962 report, *Smoking and Health*[5].

## 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

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1 World Health Organisation, WHO global report on trends in prevalence of tobacco smoking 2015. [link]

2 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]

3 World Health Assembly Resolution 66/9 Draft action plan for the prevention and control of non-communicable diseases 2013–2020 [link]

4 Royal College of Physicians (London) *Nicotine without smoke: tobacco harm reduction*, 28 April 2016 [report] and [press release]

5 Royal College of Physicians (London) *Smoking and Health*, 1962 [link]

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.

## 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[6].

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:[7]

> *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[8]:

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6 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]

7 National Academies of Science, Engineering and Medicine (US). The Public Health Consequences of E-cigarettes. Washington DC. January 2018. [link]

8 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]

*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.*

## 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.

The list of potential mechanisms for harmful unintended consequences arising from poorly designed regulation is long[9]. There is already evidence that superficially attractive regulation of ENDS can have the effect of perpetuating smoking[10] [11] [12], 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[13].
- Arbitrary standards, for example for maximum nicotine concentration for e-liquids or maximum size of containers or tanks[14], serve no purpose and may inhibit uptake or promote relapse to smoking.

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9 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.

10 Friedman AS. How does Electronic Cigarette Access affect Adolescent Smoking? *J Health Econ* Published Online First: October 2015. [link]

11 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]

12 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]

13 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]

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

- 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[15].
- 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[16]. In most cases, the cost of tax administration would outweigh the value of the appropriate tax, so ENDS should generally have no additional tax applies, 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[17] – but not to impose them.

## 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[18], including this substantial 2017 study from the United States[19]:

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15 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]

16 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]

17 Public Health England, Use of e-cigarettes in public places and workplaces, 6 July 2016 [link]

18 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]

19 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]

*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.*

## 5 On the public health interest in supporting 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[20]:

*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.

## About the author

**Clive Bates** is director of Counterfactual, a consulting and advocacy practice focused on a pragmatic approach to sustainable development, energy policy and public health that he founded in 2013. From 1997 to 2003, he was the United Kingdom's director of Action on Smoking and Health, campaigning to reduce the harms caused by tobacco. From 2003 to 2013 he was a senior civil servant in the UK and for the UN in Sudan on unrelated business. Clive Bates and Counterfactual have no competing interests with respect to e-cigarette, tobacco or pharmaceutical industries.

[20] Royal College of Physicians (London) Nicotine without smoke: tobacco harm reduction. 26 April 2016 (Press release)