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15 March 2016

Dear Minister,

**Slovenia’s proposed implementation of the Tobacco Products Directive threatens the public health potential of e-cigarettes and would protect the cigarette trade**

We are writing as British public health advocates to raise a significant public health concern regarding Slovenia’s implementation of the Tobacco Products Directive (TPD) as it applies to e-cigarettes. In our view, in regulating e-cigarettes the government should not go beyond the *absolute minimum* requirements of the TPD Article 20 – the approach now adopted in England. Almost every provision already included in the directive amounts to an expensive and unnecessary burden or restriction, which is more likely to cause unintended harms than to meet its stated objectives. Given that e-cigarettes are overwhelmingly used by smokers and ex-smokers as alternatives to smoking, every obstacle, unjustified cost or unnecessary restriction amounts to a *de facto* protection of the cigarette trade and serves to reinforce the high levels of smoking in Slovenia and around the EU. Article 20 of the directive is poorly crafted legislation<sup>1</sup> that was made in haste and in conflict with expert scientific advice<sup>2</sup>. It has a very weak health rationale, but strong and obvious potential for harmful unintended consequences<sup>3</sup>. To go beyond the minimum and mandatory requirements of the directive will simply compound the harms and further increase the protection of the cigarette trade – something that no government should wish for.

**In particular, we urge the government of Slovenia not to ban internet sales of e-cigarettes.** Such a ban is an obvious and harmful anti-competitive protection of the cigarette trade, and amounts to straightforward support to the tobacco industry. E-cigarettes are successful alternatives to smoking partly because of their diversity and the large range of options offered to smokers who can choose a product that suits them. Given the early stages of development of the e-cigarette market, it is commercially impractical to offer a wide range of products to smokers in ‘bricks and mortar’ stores across Slovenia. This because the sales volumes are too low, stocking a wide range of products would be prohibitively expensive, and the density of users is currently insufficient to make such operations profitable. In contrast, cigarettes are high volume products with relatively low diversity and have a market sufficiently large (30% of Slovenian adults smoke)<sup>4</sup> that allows them to be sold in shops across the country. The effect of the ban on internet sales will be three-fold.

1. Banning internet sales of e-cigarettes will amount to a protection of the cigarette trade by making e-cigarettes far harder for smokers to purchase and to choose effective products that work for them – in doing so it will inhibit smokers from switching, promote relapse among e-cigarette users, and, as a result, cause more smoking, disease and death;
2. Banning internet sales of e-cigarettes will unfairly favour the e-cigarette products of tobacco manufacturers who can use the same distribution channels for their e-cigarette products and they use for cigarettes. These products may be less effective as alternative to smoking;

3. Banning internet sales of e-cigarettes will sponsor informal markets and black-market activity – leading to users making their own products, trading in high strength liquids, and buying products from outside the EU.

**Evidence of safety and impact.** Major reviews of e-cigarette safety<sup>5 6 7</sup> give confidence that risks of e-cigarette use are likely to be *at least 95% lower than smoking cigarettes* – a view recently endorsed by the largest government public health agency in the UK, Public Health England<sup>8</sup>. At present, there is no evidence suggesting that e-cigarettes are a cause of any serious disease, so even the 5% residual risk estimate is an allowance for unknown future effects. In Britain, 850,000 ex-smokers are currently using e-cigs and a further 720,000 ex-smokers used e-cigs in the past but no longer – it has been a major public health success<sup>9</sup>.

According to the 2015 expert review for Public Health England, there is no evidence that e-cigarettes are causing gateway effects, renormalizing smoking or preventing smokers from quitting<sup>10</sup>.

*There is no evidence that EC [e-cigarettes] are undermining the long-term decline in cigarette smoking among adults and youth, and may in fact be contributing to it. Despite some experimentation with EC among never smokers, EC are attracting very few people who have never smoked into regular EC use. Recent studies support the Cochrane Review findings that EC can help people to quit smoking and reduce their cigarette consumption. There is also evidence that EC can encourage quitting or cigarette consumption reduction even among those not intending to quit or rejecting other support. More research is needed in this area.*

It follows that the case for imposing heavy restrictions on these products is simply not justified by any evidence of material risk. If the Slovenian government has an alternative analysis that justifies the proposed measures, we would welcome the opportunity to provide a critique.

**Harm reduction and tobacco control.** Harm reduction is a pragmatic strategy to reduce disease, premature death and other harms caused by a widely practiced activity, in this case smoking, among people who are unwilling or unable to stop. E-cigarette are already fulfilling this function for nicotine users. The WHO Framework Convention on Tobacco Control (FCTC) explicitly endorses ‘harm reduction’ strategies as integral to tobacco control<sup>11</sup>:

*(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)*

As the Royal College of Physicians of London explained in its landmark report, *Harm reduction in nicotine addiction*<sup>12</sup>:

*This report makes the case for harm reduction strategies to protect smokers. It demonstrates that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved.*

It is very clear that e-cigarettes have considerable potential for advancing the harm reduction agenda and therefore to make a material contribution to improving health in Slovenia, the European Union and globally. But this requires regulators to adopt an enlightened approach and not to

introduce policies with perverse unintended consequences, such as those already included in the TPD and extensions and more restrictive options such as those proposed in Slovenia.

**The case for adopting the minimal approach.** The UK government, up to and including the Prime Minister, now recognises the value that e-cigarettes can play in reducing the health costs of smoking, and at no cost to the taxpayer and without burdens on the health care system. Prime Minister Cameron, said the following, on 16 December 2015<sup>13</sup>:

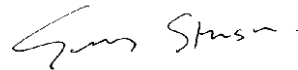
*...speaking as someone who has been through this battle a number of times, eventually relatively successfully, lots of people find different ways of doing it, and clearly for some people e-cigarettes are successful. We need to be guided by the experts, and we should look at the report from Public Health England, but it is promising that over 1 million people are estimated to have used e-cigarettes to help them quit or have replaced smoking with e-cigarettes completely. We should be making it clear that this a very legitimate path for many people to improve their health and therefore the health of the nation.*

We hope that the Slovenia government and other EU member states will reach similar conclusions and follow the UK in implementing only the minimum requirements of the Tobacco Products Directive as it applies to e-cigarettes, and no more. Given the directive is irreversible for the time being, member states should take steps to limit the damage it will cause to the minimum possible.

Yours sincerely



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Counterfactual  
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## Notes

- <sup>1</sup> Bates C. What's wrong with the EU Tobacco Products Directive for e-cigarettes? Counterfactual. 22 May 2015 [\[link\]](#)
- <sup>2</sup> Etter J-F, Farsalinos KE, Hajek P, *et al.* Scientific Errors in the Tobacco Products Directive: A letter sent by scientists to the European Union. 2014. [\[link\]](#)
- <sup>3</sup> Snowdon CJ. E-cigarettes and Article 20 of the Tobacco Products Directive. European Policy Information Center (EPICENTER), September 2015. [\[link\]](#)
- <sup>4</sup> European Commission, *Special Eurobarometer 429*, Attitudes of Europeans towards tobacco, May 2015 [\[link\]](#)
- <sup>5</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. doi:10.1186/1471-2458-14-18 [\[Link\]](#)
- <sup>6</sup> Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Ther Adv Drug Saf* 2014;**5**:67–86. [\[Link\]](#)
- <sup>7</sup> Hajek P, Etter J-F, Benowitz N, Eissenberg T, McRobbie H. Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction* [Internet]. 2014 Aug 31 [\[link\]](#)
- <sup>8</sup> Public Health England. E-cigarettes around 95% less harmful than tobacco estimates landmark review. [\[link\]](#) E-cigarettes: an evidence update [\[link\]](#) 19 August 2015.
- <sup>9</sup> Summary data and links to official sources: Smoking and vaping in Britain? Counterfactual, 18 February 2016 [\[link\]](#)
- <sup>10</sup> McNeill A, Brose LS, Calder R, *et al.* E-cigarettes: An Evidence Update. A Report Commissioned by Public Health England. London: 2015. [\[link\]](#)
- <sup>11</sup> WHO Framework Convention on Tobacco Control, Article 1(d), 2003 [\[link\]](#)
- <sup>12</sup> Royal College of Physicians Harm reduction in nicotine addiction: help people who cannot quit, London 2007 [\[link\]](#)
- <sup>13</sup> Cameron D. Prime Minister's Questions. Parliamentary Answer to Mark Pawsey MP, 16 December 2015, c1548 [\[link\]](#)