Implementing the Tobacco Products Directive in Latvia: e-cigarettes

Clive Bates
Counterfactual
London, United Kingdom
24th March 2015

I am writing to provide a brief contribution the Government of Latvia's consultation on Latvia's proposed implementation of the Tobacco Products Directive. I regret I am constrained to respond in English, but I hope the information and arguments presented are of value.

Summary: classifying e-cigarettes as medicines under a Latvian implementation of the EU Tobacco Products Directive will be: damaging to the health of Latvian citizens; protect the cigarette trade and increase smoking; create an unnecessary illegal market while damaging legitimate small businesses; and violate European Union law. There is no credible evidence to support the policy as proposed on either public health or legal grounds. There is however, a strong and growing evidence base to justify encouraging e-cigarette use among smokers as a 'harm reduction' strategy to reduce disease and premature death. The best approach is to adopt a 'light touch' regulatory regime for e-cigarettes using the flexibilities provided by the European Union Tobacco Products Directive.

1. The classification of e-cigarettes as medicines and so requiring manufacturers or importers to obtain a medicines marketing authorisation to place each e-cigarette or liquid variant on the market is extremely burdensome. It has repeatedly been found to be unlawful in the courts of European member states. This will continue for one obvious reason: e-cigarettes do not conform to the definition of a medicine either in law or in common sense. They are recreational nicotine products acting as rivals to cigarettes, and are not primarily for the "treatment or prevention of disease", even if that is the welcome effect. Please see the attached discussion of the legal status of e-cigarettes under the EU Medicines Directive [1].

2. Medicine regulation is disproportionately burdensome, restrictive and costly and will provide no net health benefits. It is an impediment to free movement of goods under the EU Treaties. It is not required by the Tobacco Products Directive and may not be permitted by it. To require highly burdensome regulation of e-cigarettes while allowing widespread availability of cigarettes with only the lightest regulation is discriminatory and counter to principles of the European Union treaties. I enclose a summary report on the impact of medicines regulation [2].

3. The practical effect of designating e-cigarettes as medicines will be to increase harm. The designation of e-cigarettes as medicines will create a *de facto* ban on almost all products and destroy almost all firms in the Latvian market. Its main effect will be fourfold:

    a) To protect the cigarette trade from competition and so increase smoking while sheltering the profitability of major tobacco companies;

    b) To shape the e-cigarette market to be a narrow niche that only large tobacco companies will have the financial resources to meet the high costs and cash flow strains of a lengthy and mostly pointless authorisation procedure;

c) To develop a black market in vapour products to meet the demand for such products in Latvia, which will not disappear simply because most products were removed from the legal supply chain;

d) To make a legal challenge more likely. Such a challenge would almost certainly succeed and lead to a costly defeat for Latvia's government.

4. The most damaging aspect of the proposal is the lost opportunity to reduce cancer, cardiovascular and respiratory disease by allowing and encouraging smokers to switch to much less risky products than cigarettes. I attach a briefing on the positive role that e-cigarettes and vapour products can play in public health. This document summarises the most important findings in the evidence base - and these should give the government some confidence that e-cigarettes will greatly benefit health in Latvia [3].

5. So far, neither the European Commission nor the Government of Latvia has provided any compelling evidence that regulating e-cigarettes as medicines is justified for public health reasons. So far, neither the European Commission nor Government of Latvia has shown that regulating e-cigarettes as medicines would not be disproportionate and discriminatory and therefore in violation of the European Union treaties. There is no credible impact assessment or evidence base to support the policy.

6. The Tobacco Products Directive has numerous flaws and is likely to be challenged successfully in the Court of Justice of the European Union [4]. However, it does provide a range of flexibilities and rules designed to implement the aim of developing the internal market. Latvia should adopt the rules and flexibilities of the Tobacco Products Directive. The Government should aim to establish a lawfully robust, light-touch regulatory regime for e-cigarettes with a view to maximising the public health benefit from smokers switching to e-cigarettes while mitigating any residual risks.

7. I have no competing interests. I was formerly head of the UK's main tobacco control organisation, Action on Smoking and Health (1997-2003), and a UK senior civil servant (2003-2012). I have been a long-standing advocate of harm reduction strategies in public health and tobacco control and believe these will ultimately bring an end to the epidemic of disease causes by smoking. These views do not necessarily reflect the positions of former employers.

[1] Bates C. Are e-cigarettes medicines? Counterfactual, March 2013

[2] Bates C. Stimson G. Costs and Burdens of Medicine Regulation for E-cigarettes, Nicotine Science and Policy, September 2013.

[3] Bates C. E-cigarettes, vaping and public health: a summary for policy makers. Counterfactual. February 2015. This contains links to many peer reviewed sources.

[4] Bates C. Totally Wicked legal challenge to the Tobacco Products Directive e-cigarette measures. Counterfactual, October 2014.