

Panel on Health Services hearing 6 July 2015 – written submission

From: Professor Gerry Stimson, Imperial College London
Clive Bates, Counterfactual

To: Clerk to Panel on Health Services
Legislative Council Secretariat
By email: panel_hs@legco.gov.hk

Date: 30th June 2015.

We write as advocates for best scientific and ethical practice in global tobacco control with a commitment to reducing the global burden of death and disease caused by smoking. We have no industry ties and our focus is on public health. We are writing to provide advice to the Panel on Health Services in advance of its 6th July 2015 special meeting on '*Legislative Proposals to strengthen tobacco control*'.

Future of tobacco control in Hong Kong

On 18th May, the Hong Legislative Council, Panel on Health Services considered proposals from the Department of Health on the future of tobacco control in Hong Kong¹. The paper considered three main areas for further development: (a) health warnings on tobacco products; (b) extension of smoke free areas in public transport infrastructure; (c) regulation of electronic cigarettes, amounting to a ban on all consumer varieties of these products [See Appendix: what are e-cigarettes?].

Major concern with proposed future direction for tobacco control

Tobacco control strategy should be focussed on reducing premature death and serious harms like cancer, cardiovascular and respiratory disease as rapidly as possible. To that end, the most effective tobacco control strategy has four main elements:

1. To provide strong incentives not to start smoking;
2. To motivate and help people to quit smoking tobacco;
3. To reduce harm to those who continue to use nicotine;
4. To reduce harm to non-smokers arising from exposure to toxins in second hand smoke

The proposed warnings and smoking restrictions are consistent with this strategy. However, the proposals for e-cigarette prohibition are counter to it. This is because they reduce the options to help people to stop smoking or to use nicotine in a way that is substantially less harmful. They make it more likely that people will continue to smoke tobacco, and that non-smokers will be exposed to tobacco smoke rather than relatively benign vapour.

A precautionary approach?

We start from an assessment based on what is known of the chemistry of e-cigarette vapour that e-cigarettes are likely to present *at least 95% lower risk* to health than cigarettes (see below). Our overall concern, therefore, is that the proposal to "*prohibit import, manufacture, sale, distribution, and advertising of e-cigarettes*" will prove harmful to health, unjustly protect the cigarette trade and deny many Hong Kong citizens options that could save their lives, presenting a significant ethical challenge to the legislative proposal. Although the proposal is framed as precautionary, given some remaining scientific uncertainties, this precaution is an illusion. We know *enough* to be confident

Panel on Health Services hearing 6 July 2015 – written submission

that vapour products present very much lower risks than smoking. The proposal is not precautionary because in practice the unintended consequences of a prohibition could be very harmful to health. It is *never* a responsible or cautious approach to ban new alternative products that are many times safer than the dominant market leader, cigarettes in this case – especially while cigarettes will continue to be freely available. We can think of no precedents for this kind of prohibition in any area outside tobacco control. In this market, banning low risk products is dangerous rather than precautionary. The papers presented to the Panel on Health Services so far have not explored the likely harmful unintended consequences of prohibiting alternative products that are at least 95% less risky than smoking.

Tobacco harm reduction is a critical strategy in tobacco control

At the heart of this strategy is the concept of 'tobacco harm reduction'. This concept recognises that smoking is primarily driven by seeking nicotine and that there are many people who cannot or will not stop using nicotine. It has been known for 40 years that people "*smoke for the nicotine and die from the tar*"². This creates the prospect that providing nicotine without the tar and toxic gases in tobacco smoke could have significantly positive health benefits. There is strong consensus among scientists that nicotine products that do not involve burning tobacco are far less risky than smoking. As the Royal College of Physicians of London explained in its landmark report, *Harm reduction in nicotine addiction*³:

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.

Thanks to rapid technological innovation, there is now a growing range of products that can meet this need: e-cigarettes and other electronic nicotine delivery systems (ENDS); nicotine inhalers; purified smokeless tobacco like snus; heated tobacco vaporisers; and an increasingly wide range of novel nicotine products such as strips, gums and lozenges. These products eliminate the tar because there is no smoke involved. It is this basic fact of physics and chemistry that provides the opportunity to reduce smoking-related disease. The harm reduction strategy works because it does not require a smoker to give up both smoking *and nicotine*, or the behavioural or social rituals that go with it - only the harmful smoke itself. Because it is easier for many smokers to switch to a low risk nicotine product than to quit smoking and nicotine completely, switching therefore increases that likelihood of success in reducing disease. Unfortunately, it is the most promising of these products that would be banned in Hong Kong and this harm reduction strategy is being closed down unnecessarily. The alternative is not that more smokers will quit, but that more smokers will continue to smoke.

Ethics of denying smokers access to e-cigarettes

The prevalence of daily smoking among men is still around one in five (19.1% in 2012) and there are approximately 645,000 smokers in Hong Kong⁴. The impact of the proposed ban on e-cigarettes is to force those nicotine users who cannot stop using nicotine to use only the most dangerous form of nicotine delivery, namely smoking. The most paradoxical aspect of these bans is the protection they give to the cigarette trade. A ban on e-cigarettes protects the most harmful products from competition from low-risk alternatives. It denies smokers these better options, forcing them to use

the most harmful. To us this seems both unscientific and unethical - a "quit or die" ultimatum in which many will die unnecessarily.

Arguments against prohibition of e-cigarettes

For this reason the World Health Organisation was careful in its 2014 briefing to avoid proposing prohibitions on ENDS, instead stressing regulation rather than prohibition, and judging that⁵:

ENDS, therefore, represent an evolving frontier, filled with promise and threat for tobacco control. Whether ENDS fulfil the promise or the threat depends on a complex and dynamic interplay among the industries marketing ENDS (independent makers and tobacco companies), consumers, regulators, policy-makers, practitioners, scientists, and advocates (1)

The citation (1) at the end of this specific statement by WHO refers to a commentary by Dr David Abrams, Executive Director of the Schroeder Institute for Tobacco Research and Policy Studies and Professor in the Department of Health, Behavior and Society at the Johns Hopkins Bloomberg School of Public Health writing in JAMA⁶. Abrams concludes:

The more appealing e-cigarette innovations become, the more likely they will be a disruptive technology. Although the science is insufficient to reach firm conclusions on some issues, e-cigarettes, with prudent tobacco control regulations, do have the potential to make the combusting of tobacco obsolete. Strong regulatory science research is needed to inform policy. If e-cigarettes represent the new frontier, tobacco control experts must be open to new strategies. Statements based on ideology and insufficient evidence could prevent the use of this opportunity before it becomes established as part of harm reduction strategy.

It is clear that the leading edge in tobacco control is not in prohibition of these products, but in working out how best to exploit the huge opportunities while minimising any residual threats. In other words, tobacco control leadership means skilful design of regulation based on sound science, not ideology. Fifty-three experts in nicotine and tobacco science and policy wrote to Dr Margaret Chan, Director General of the WHO, to reinforce these points. They urged her organisation and the world community to take a positive approach to 'tobacco harm reduction' and to work towards exploiting the opportunities and to take a sceptical view of misleading scientific analysis^{7 8}.

The potential for tobacco harm reduction products to reduce the burden of smoking related disease is very large, and these products could be among the most significant health innovations of the 21st Century – perhaps saving hundreds of millions of lives. The urge to control and suppress them as tobacco products should be resisted and instead regulation that is fit for purpose and designed to realise the potential should be championed by WHO.

More detailed comments on scientific controversies

While we present the big picture above, there are many details to address that go beyond the scope of this submission. However, we believe it would be helpful to signal some of the available literature that may inform an evidence assessment. We provide a guide to some of the evidence on key points below:

1. **Toxicity.** The concentrations of toxins or carcinogens in e-cigarette vapour are generally tens to thousands of times lower than in cigarette smoke. Many toxins are simply not present at

Panel on Health Services hearing 6 July 2015 – written submission

detectable levels or equivalent to the tolerances allowed in medical products⁹. This is the reason why experts believe e-cigarettes to be at least 95% lower risk than smoking^{10 11} "

From analysis of the constituents of e-cigarette vapour, e-cigarette use from popular brands can be expected to be at least 20 times safer (and probably considerably more so) than smoking tobacco cigarettes in terms of long-term health risk".

2. **Second hand vapour exposure.** Exposure to second hand cigarette smoke is thought to create risks of disease in bystanders and is a legitimate cause for restrictions on use in the workplace. E-cigarettes do not emit smoke because there is no combustion. Any toxins and nicotine in exhaled vapour are at extremely low levels compared to the sidestream and mainstream emissions from cigarettes. In his detailed review of the toxicity evidence, Igor Burstyn concluded that risks to active users were well below thresholds used to set workplace exposure standards and concluded that¹²:

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

3. **Particulates.** Though particulates from diesel engines, power stations and cigarette smoke are harmful, it cannot be assumed that particles from ENDS vapour are harmful simply because they are the same size. The aerosol particles in e-cigarette vapour do not have the same aggressive surface chemistry and physics as smoke particles, which contains thousands of products of combustion. The size of the particles is of little importance if they are not actually toxic¹³.
4. **Nicotine related risks.** For *any* nicotine user an e-cigarette product will be much less risky than continuing to smoke – that applies to pregnant smokers and adolescents. The safety profile of nicotine has been well established through years of trials of nicotine replacement therapy, and more recently through the assessment of health risks from Swedish snus, which provides nicotine but without smoke. Nicotine is not a carcinogen or a cause of cardiovascular disease. Though it is the addictive agent in cigarettes, there is no evidence of significant harm from nicotine use, *per se*¹⁴.
5. **Smoking cessation.** There are now millions of ex-smokers who use e-cigarettes or smokeless tobacco. For example in Britain, there are 2.6 million e-cigarette users of which 1 million are ex-smokers¹⁵. They are not using e-cigarettes as a smoking cessation treatment, but as a relatively low risk alternative to harmful smoking as way of consuming nicotine. A Cochrane Review of e-cigarette *trials* suggests that, on the limited data available, vapour products are likely to be effective for smoking cessation¹⁶. Most studies have been observational, rather than trials and have generally shown success with e-cigarettes. For example, one of the best designed observational studies found¹⁷:

People attempting to quit smoking without professional help are approximately 60% more likely to report succeeding if they use e-cigarettes than if they use willpower alone or over-the-counter nicotine replacement therapies.

6. **Gateway effect and renormalisation: unfounded.** There is no evidence anywhere in the world supporting a 'gateway effect' in which low risk products such as e-cigarettes cause people who would not have smoked to become cigarette smokers. Generally we have seen declines in teenage smoking accompany any rise in e-cigarette use and e-cigarette use highly concentrated among smokers. It is likely that e-cigarette use is an *alternative* to smoking in young people who

Panel on Health Services hearing 6 July 2015 – written submission

would otherwise have started to smoke - and thus have a protective effect. Longer term data are needed but there is no basis to draw any conclusion that use of e-cigarettes leads to an increase in smoking.¹⁸

7. **Proof of concept: the Swedish experience.** We have a strong proof of concept that alternative sources of nicotine can radically reduce smoking and related disease - and this is an opportunity that should not be wasted with badly designed legislation. In Europe, Sweden stands out as having by far the lowest smoking rate, 11% in Sweden compared to the EU average of 26%.¹⁹ The reason for this is the high use of smokeless tobacco instead of smoking. This has led to very substantial reductions in disease in Sweden²⁰ that cannot be even partly replicated in the rest of the EU because snus has been banned in the EU other than Sweden.
8. **Professional practice.** There is now recognition among professional tobacco control and public practitioners that e-cigarettes (ENDS) can be used constructively to reduce harm. For example in Britain, cautious evidence-based guidance for professionals has been developed by the National Centre for Smoking Cessation and Training and Public Health England, the government's public health agency. It provides a clear and measured assessment of science and best practice that could be valuable to any country wishing to exploit the opportunities and minimise the risks²¹.

Conclusion – towards a credible endgame for tobacco related disease

The only thing really threatened by ENDS is the manufacture, import, sale and consumption of *cigarettes*. To prohibit ENDS when they compete with cigarettes but have far lower risk to the user would be an unscientific, unethical and a lethal error based on current evidence: on what ethical basis should a government prevent a smoker substantially reducing their risk by switching to these products? We would like to finish with the words of Derek Yach, the former WHO Director for tobacco policy who led the effort to bring the global Framework Convention on Tobacco Control into being²²:

At the moment, it's estimated that there will be a billion tobacco-related deaths before 2100. That is a dreadful prospect. E-cigs and other nicotine-delivery devices such as vaping pipes offer us the chance to reduce that total. All of us involved in tobacco control need to keep that prize in mind as we redouble efforts to make up for 50 years of ignoring the simple reality that smoking kills and nicotine does not.

We hope we have provided enough information and analysis to show that there is at least a deeper debate about the role of these products. We believe the Legislative Council should insist on a more complete assessment of evidence and not agree to proceed with the proposed prohibition. We do not think the mandatory classification of these products as medicines is a good policy: this applies large costs, burdens and restrictions that only major tobacco companies can meet and amounts to a regulatory protection of the cigarette trade, barrier to innovation and denying smokers the wide variety of products and forms that are making this disruptive technology so successful²³.

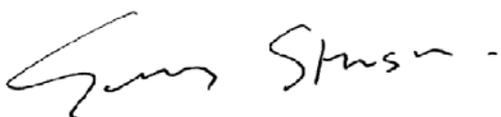
Technological innovation provides a 21st century alternative that might one day make the cigarette obsolete. The challenge for Hong Kong is therefore to shape this technological innovation through appropriate regulation. We believe that the legislature has an opportunity to develop world-class regulation for ENDS, with a view to exploiting their potential for bringing public health benefit while minimising any residual risks.

Panel on Health Services hearing 6 July 2015 – written submission

We have included a more detailed briefing for further information - *E-cigarettes, vaping and public health: a summary for policy-makers*²⁴

We would be pleased to assist in any way.

Yours faithfully,



Professor Gerry Stimson

Emeritus Professor, Imperial College London;
Visiting Professor, London School of Hygiene and
Tropical Medicine



Clive Bates

Director Counterfactual Consulting and Advocacy
Former Director Action on Smoking and Health
UK (1997-2003). Founding member, Framework
Convention Alliance for the FCTC

Note: Both writers speak in a personal capacity and do not necessarily represent the views of previous employers.

Appendix: What are e-cigarettes?

E-cigarettes generally consist of a battery, a heating coil and a liquid containing nicotine. Drawing on the e-cigarette or pressing a switch activates the battery to heat the coil, which heats and vaporises the liquid without burning it. This is then inhaled and the nicotine absorbed into the blood via mouth, throat and lungs. The liquids contain nicotine, water, a 'diluent' such as propylene glycol or glycerol, and a flavouring, such as tobacco, mint, vanilla or fruit.

There are now hundreds of flavours and these are an intrinsic part of the appeal to smokers and help to break the link to tobacco. The devices and the liquids can be sold as integrated units or with liquids sold separately. Some look like cigarettes (1st generation 'cig-a-likes'), some look like pens (2nd generation 'Ego' type), and the larger ones with tanks can look very different (3rd generation 'tanks' or 'mods').



Types of e-cigarette or vaping equipment

It is possible to create e-cigarettes without nicotine, but this overlooks their main public health value – as a substitute for smoking. Non-nicotine e-cigarettes typically account for less than 5% of sales.

Sources

- ¹ This response is based on two papers for the Hong Kong Legislative Council Panel on Health Services papers: LC Paper No. [CB\(2\)1456/14-15\(07\) *Progress of Tobacco Control Measures*](#) and LC Paper No. [CB\(2\)1456/14-15\(08\) *Updated background brief*](#), 18 May 2015.
- ² Russell MA. [Low-tar medium-nicotine cigarettes: a new approach to safer smoking](#). *BMJ*. 1976
- ³ Royal College of Physicians [Harm reduction in nicotine addiction: help people who cannot quit](#), London 2007
- ⁴ Government of Hong Kong Census and Statistics Department, Thematic Household Survey Report - Report No. 53 [[Reports](#)] [[PDF](#)] [COSH Press release] 8 Nov 2013
- ⁵ World Health Organisation. [Electronic Nicotine Delivery Systems: report by WHO](#). Report to the COP-6 of the FCTC. FCTC/COP/6/10 Rev.1 September 2014
- ⁶ Abrams DB. [Promise and peril of e-cigarettes: can disruptive technology make cigarettes obsolete?](#) *JAMA*. 2014
- ⁷ Statement from fifty three specialists in nicotine science and public health policy, [Reducing the toll of death and disease from tobacco – tobacco harm reduction and the Framework Convention on Tobacco Control \(FCTC\)](#). 26 May 2014 [[full context](#)]. A group of non-specialist activists and academics wrote a [response](#) - but this drew criticism from the original authors: [The importance of dispassionate presentation and interpretation of evidence](#) for its misleading analysis and false statements.
- ⁸ McNeill A. et al [A critique of a WHO-commissioned report and associated article on electronic cigarettes](#), *Addiction*, 2014. [Release: [WHO commissioned report on e-cigarettes misleading say experts](#)]
- ⁹ Farsalinos KE, Polosa R. [Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review](#) (Studies on the safety/risk profile of ECs) *Therapeutic Advances in Drug Safety*, 2014
- ¹⁰ Hajek P. et al. [Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit](#), *Addiction*, 2014
- ¹¹ West R. et al [E-cigarettes - what we know so far](#), Briefing to the All Party Parliamentary Group, June 2014.
- ¹² 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
- ¹³ Bates C. [Scientific sleight of hand: constructing concern about ‘particulates’ from e-cigarettes](#). *Counterfactual blog*. 2014
- ¹⁴ Farsalinos KE, Polosa R. [Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review](#) (Risk differences compared with conventional cigarettes and the issue of nicotine) *Therapeutic Advances in Drug Safety*, 2014
- ¹⁵ Action on Smoking and Health (ASH), [Use of electronic cigarettes \(vapourisers\) among adults in Great Britain](#), London, May 2015

- ¹⁶ McRobbie H. et al. [Electronic cigarettes for smoking cessation and reduction](#). *Cochrane Database of Systemic Reviews*, 2014
- ¹⁷ Brown J et al. [Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study](#), *Addiction*, May 2014 [Press Release: [E-cigarettes can help smokers quit, new research shows](#)]
- ¹⁸ Abrams DB, Niaura R. [The importance of science-informed policy and what the data really tell us about e-cigarettes](#). *Israel Journal of Health Policy Research*, 2015
- ¹⁹ European Commission; [Attitudes of Europeans Towards Tobacco](#), [field work November / December 2014] *EuroBarometer 429*, 2015.
- ²⁰ Ramström L, Wikmans T. [Mortality attributable to tobacco among men in Sweden and other European countries: an analysis of data in a WHO report](#). *Tobacco Induced Disease*, 2014
- ²¹ McRobbie H. McEwen A. (ed) [E-cigarette briefing](#). National Centre for Smoking Cessation and Training, Public Health England. London, 2014
- ²² Yach D. [E-cigarettes save lives](#). Commentary in *The Spectator*. February 2015
- ²³ Bates C, Stimson G. [Costs and burdens of medicines regulation for e-cigarettes](#). (Report PDF) *Nicotine Science and Policy*, September 2013.
- ²⁴ Bates C. [E-cigarettes, vaping and public health: summary for policy-makers](#), Counterfactual, February 2015