Open Letter to the Government of Singapore: banning novel tobacco or nicotine products

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To:  Mr. Gan Kim Yong, Minister for Health, Singapore
      Mrs. Tan Ching Yee, Permanent Secretary (Health)

Date:  18th June 2015.

Dear Mr Gan and Mrs Tan

We write as advocates for best scientific and ethical practice in global tobacco control with a passionate 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 comment on the government's announcement of bans on a range of tobacco and nicotine products, and to urge caution and a reconsideration of this policy. It is a good time for Singapore to lead in tobacco control, but not through prohibition, but world-class regulation.

Prohibition or tobacco harm reduction

On 15th June, the Singapore Ministry of Health announced a significant extension to its tobacco control programme banning a range of tobacco and nicotine products from December this year [1]. Although Singapore has been a long-standing leader in tobacco control, it cannot be assumed that these new bans, and the existing ban on e-cigarettes, are in fact an enhancement. We suggest that it is much more likely that these measures will reverse progress in Singapore, protect the cigarette trade and lead to more disease and premature death in Singapore. We write to set out some of the arguments and to suggest that the government pauses to reassesses the evidence base and reconsider the likely harmful unintended consequences of such bans.

We refer to the concept of 'tobacco harm reduction'. This concept recognises that smoking is primarily driven by seeking the legal mildly psychoactive drug 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 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 vapourisers; 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
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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 than to quit completely, it therefore increases that likelihood of success in reducing disease. Unfortunately, it is these products that are the focus of bans in Singapore 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.

The number of nicotine users, primarily smokers, is not falling in Singapore - and may be rising [4]. The impact of these bans is to force those nicotine users to use only the most dangerous form of nicotine delivery, namely smoking. The most troubling aspect of these bans is the protection they give to the cigarette trade. Why protect the most harmful products from competition from low-risk alternatives? Why deny 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. Also, for a nation that is built on innovation, it is surprising that Singapore should use the law to protect a harmful 19th century product from innovative 21st century alternatives that might one day make the cigarette obsolete.

For this reason the World Health Organisation was careful in its 2014 briefing to avoid proposing bans on ENDS, instead stressing regulation rather than prohibition [5], and judging that:

*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 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 JAMA [6]. 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 banning 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
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community to take a positive approach to 'tobacco harm reduction' and to work towards exploiting the opportunities [7] and to take a sceptical view of misleading scientific analysis [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 – scientific controversies

While this is the big picture, there are many details to address that go beyond the scope of this letter. However, we thought it would be helpful to signal some of the available literature that may inform an evidence assessment. We have drawn on a letter to the Straits Times (Adverse health effects of e-cigarettes June 16th) from Singapore Ministry of Health, which sets out some arguments about e-cigarettes. 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 detectable levels or equivalent to the tolerances allowed in medical products [9]. 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 exposure.** Exposure to second hand cigarette smoke is thought to create risks of disease in bystanders. However, the toxins and nicotine in exhaled vapour are at very much lower levels than 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 that: _Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern_ [12].

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 toxic [13].

4. **Vulnerable users.** Any pregnant woman would be well advised to avoid using alcohol or nicotine, but for those who cannot or will not quit using nicotine, then an e-cigarette or smokeless tobacco product will be much less risky than continuing to smoke. Risk to the foetus is not an argument to ban low-risk products for all adults, while leaving the high risk product widely available. The safety profile of nicotine has been well established through years of trials of nicotine replacement therapy, and there is no proposal to ban these products on account of nicotine-related risks [9].

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-smokers [14]. They are not using e-cigarettes to as a smoking cessation treatment, but as a relatively low risk alternative to harmful smoking as way of consuming nicotine. A Cochrane
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Review of e-cigarette trials [15] suggests that, on the limited data available, vapour products are likely to be effective for smoking cessation. Most studies have been observational, rather than trials and have generally shown success with e-cigarettes. For example, one of the best designed [16] found: 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 & 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 smokers. In 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 would otherwise have started to smoke - and thus have a protective effect. Longer term data is needed but there is no basis to draw any conclusion that e-cigarettes increase smoking [17].

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% [18]. The reason for this is the high use of smokeless tobacco instead of smoking. This has led to very substantial reductions in disease in Sweden [19] 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 risks [20].

**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 maintain and extend bans on products that 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? There is nothing ‘precautionary’ about banning safer products - being cautious about safety is no different to being complacent about harm. 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 being [21]:

> 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.
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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 Government of Singapore should insist on a more complete assessment of evidence, pause the introduction of any bans and move to reassess its policy approach.

We urge the Government of Singapore to heed this message and to adopt a world-leading progressive policy in this area - based on proportionate risk-based product regulation, protective marketing restrictions, a fair excise risk-based regime, accurate information and advice to consumers and a recognition that excessive regulation has harmful unintended consequences through the protection of the cigarette trade.

We hope that Singapore will become a world leader in the regulation of these innovative and disruptive products, improving on the emerging regulatory regimes of the European Union and US Food and Drug Administration. If that happens, by 2040 we are confident that Singapore will have played a significant leadership role in rendering cigarettes obsolete and bring forward the 'endgame' for tobacco related disease.

We would be pleased to assist in any further assessment, and we would welcome a response to the points made in this letter.

Yours faithfully,

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

Sources
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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.


