

Mr Trent Zimmerman MP
Chairman
Standing Committee on Health, Aged Care and Sport
Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia
Parliament House
Canberra

25 October 2017

Dear Mr Zimmerman

It was a privilege to appear before the House Health, Aged Care and Sport Committee on 19th October. Thank you for inviting us and for making us feel welcome. I said I would follow up a couple of the points raised in discussion:

- the smoking status of British vapers and possible gateway effects
- vaping, smoking and inequalities
- the reasons not to regulate vaping products only as medicines.

1. Vaping population in Britain

There was some committee interest in the smoking status of UK vapers. There are various sources, but the Office of National Statistics gives the official data¹. Table 2b provides the 2016 vaping prevalence and allows for calculation of numbers of vapers in each smoking status sub-group..

Table 2b. Self-reported e-cigarette use, by cigarette smoking status, Great Britain, 2016^{1,2,3}

All persons aged 16 and over Self-reported e-cigarette use	Percentages		
	Cigarette smoker	Ex-smoker ¹	Never smoked ²
No, I have never used one and I will not use one in the future	28.5	75.9	93.7
No, I have never used one but I might use one in the future	6.6	0.7	0.6
Yes, I have used one in the past but no longer use one	34.2	6.1	1.4
Yes, I currently use one	13.7	12.1	0.6
I tried one, but did not go on to use it	16.8	4.2	2.6
I don't know what an e-cigarette is (spontaneous only)	0.2	1.0	1.1
Weighted base 2016 (000s) ³	8,198	12,594	30,190
Unweighted sample 2016	1,313	2,129	4,271

Source: Opinions and Lifestyle Survey
Office for National Statistics

Notes

1. This group covers those who said that they do not smoke cigarettes at all nowadays, but used to smoke cigarettes regularly.

2. This group covers those who said they have never smoked a cigarette, and those who said they have never smoked cigarettes regularly.

3. Weighted bases are given to the nearest thousand.

Smoking status of British vapers 2016. From this we may calculate the following using the prevalence figures and weighted base populations in each sub-group set out in the table below.

¹ Office for National Statistics (UK) *E-cigarette use in Great Britain. 2016*, 15 June 2017 [\[link\]](#).

Smoking status sub-group	Number of vapers (thousands)	Share of vapers	Share of sub-group
Smoker	1,123	40%	14%
Ex-smoker	1,524	54%	12%
Never-smoker	181	6%	0.6%
All adults	2,828	100%	5.5%

Ex-smoker, ex vapers. In addition to the data presented in the table above, it may be calculated from table 2b that there were 768,000 ex-smoker ex-vapers in 2016 - that is people who have given up both smoking and vaping. It is possible that vaping was a 'staging post' to quitting completely for these smokers in which e-cigarettes have functioned as an aid. Equally, it is possible these smokers may have quit anyway without vaping. Some mixture of the two is likely.

Never-smoker vapers – is this a gateway effect? There was some interest among the committee in the 181,000 never-smokers who have become vapers and whether this constitutes a gateway effect. This requires careful interpretation – there are four points to consider.

1. It should not be assumed that never-smoker vapers represent a net health detriment. It is quite possible that these are younger people who would have otherwise smoked in the absence of vaping products. It would not be a surprise if this category grows, and it would not be a problem if it is primarily a result of diversion from smoking initiation. In Sweden, we see snus initiation without prior smoking concentrated in those who would otherwise have a propensity to smoke.
2. Even if these are completely new users attracted to vaping and would never have otherwise smoked, the risk to them is likely to be very low. There is no evidence that they would go on to smoke via this route of initiation, though we do not have data that would capture this. We would normally consider a gateway effect to be a transition to smoking that occurred only because of the availability of vaping products. That is not the case with these 181,000.
3. There is likely to be some misreporting: for example, Table 3b in the survey shows 12.8% of vaping 'never-smokers' cite 'aid to stop smoking' as a reason for using e-cigarettes, which is clearly a reporting inconsistency.
4. Current use can mean once monthly, weekly or daily. Many use only infrequently and not all use nicotine. Some use will be experimental and short-term only, but captured in this statistics.

Causality. We should stress that no causality can be inferred from these numbers – we cannot say the ex-smokers have become ex-smokers *because* of vaping – this is an inherently difficult assessment to make. But these numbers illustrate the scale of the phenomenon in Britain as a comparison with the 8.2 million base of smokers and 51.0 million adult population in 2016.

The fall in smoker numbers has been rapid and unprecedented. Between 2014 and 2016, the period corresponding with the rise of vaping, the number of smokers in Britain fell from 9.7 million to 8.2 million². It is hard to identify anything else that would have caused such a large and rapid effect.

² To maintain compatibility with e-cigarette use figures, I have used the weighted base of smokers in the e-cigarette use surveys from 2014 to 2016: Office for National Statistics (UK) *E-cigarette use in Great Britain. 2016*, 15 June 2017 [[link](#)].

2. Vaping and smoking/health inequalities

English data. There is, as I reported to the Committee, a bias towards e-cigarette use by higher social grade smokers³. The table below provides a more complete picture for England.

	Social grade ⁴	Proportion of smokers or recent ex-smokers using e-cigarettes	Smoking prevalence	Vaping prevalence
Higher	AB	24.8%	8.5%	4.0%
	C1	22.6%	15.2%	5.3%
	C2	20.5%	20.2%	6.5%
	D	19.3%	24.2%	6.0%
Lower	E	17.7%	30.4%	8.8%

We would expect uptake of new technology to be led by those with higher social grade (column 2, in the table above). However, smoking itself is concentrated in poorer socio-economic status groups (column 3). Because vaping is an alternative to smoking more of the vapers are concentrated in the more disadvantaged groups (column 4), suggesting a likely beneficial impact on health inequalities.

There is suggestive evidence for this: a recent analysis of smoking cessation trends in England concluded⁵:

Quit smoking success rates in England in the first six months of 2017 were higher than the average rate during the preceding decade. This improvement was exclusively in those with lower socioeconomic status.

The current study indicates an important improvement in this regard. The improvement has resulted in parity between the groups in quit success rates for the first time in over 10 years and possibly ever.

Australia and smoking/health inequalities. In Australia, as in the UK, smoking is concentrated in the most disadvantaged groups⁶, with 20.0% smoking prevalence in the most disadvantage fifth of the Australian population and 9.3% in the most advantaged fifth, and with higher rates in particular sub-groups among the most disadvantaged fifth (poorer sub-groups, persons with mental health conditions, other substance users, Indigenous groups). The same survey shows that more disadvantaged smokers also smoke more heavily, with average consumption of 113 cigarettes per week in the most disadvantaged fifth and 68 in the most advantaged fifth of the population in 2016.

³ Smoking in England, Smoking Toolkit Survey, Trends in smoking and e-cig use, STS20721, 30 September 2017 [\[link\]](#) with additional data provided from the survey by Dr Jamie Brown as a personal communication 24 October 2017.

⁴ This system of social grading is based on occupation [\[link\]](#)

⁵ Brown J, West R (2017) Quit success rates in England 2007-2017, Smoking in Britain, Vol 5, 1-8 19 September 2017 [\[link\]](#)

⁶ National Drug Strategy Household Survey, 2016. Table 3.44: Tobacco smoking status by social characteristics; Table 3.45: Mean number of cigarettes smoked per week by social characteristics 27 September 2017 [\[link\]](#)

Pricing, tax and cost to smokers. Australia has a strategic policy of raising cigarette prices through taxation justified on health grounds – with 12.5% annual excise rises from 2013 to 2017, and a further three rises planned for 2018-20⁷. Observations made at a Woolworths store show current prices for 20 Marlboro at A\$26.9 and the budget brand Horizon at \$19.95 for 20. The *average* smoker in the most disadvantaged fifth of the population would spend A\$5,900 per year on smoking 113 budget cigarettes per week. For some, it would cost far more than that.

Options available to Australian smokers. Smokers currently have options to respond to rising prices driven by tax policy:

1. to quit smoking, but many find that hard and cessation rates are low, especially for smokers in disadvantaged groups;
2. to try to cut down, but that usually means smoking more intensively with no health benefit;
3. to pay the full cost, but that places a great burden on the household budget;
4. to access the black market, but that nurtures criminal networks with other societal harms.

Vaping and tax policy. We argue that making vaping a legally accessible option for Australians should be a fifth option. This would offer multiple benefits to health, welfare and family finances and be fair and compassionate. We also argue that it is *an ethically essential* companion measure for an aggressive cigarette tax policy and will improve smoking cessation responsiveness to the tax-induced price signal. There are deliberate policy actions that could be taken to address health inequalities through tobacco harm reduction⁸. Forcing smokers into illegal internet e-liquid or black market sourcing and risky home mixing, combined with enormous maximum fines for possession is a barrier to wider uptake and to realising health gains and easing of the financial pain. It would be far better to have a legal, proportionately-regulated, quality-controlled domestic industry. Australian firms already exist in this market, but produce for export only.

3. Should vaping technologies be regulated as medicines?

There was a significant discussion over this question in 2013 in the European Union. This was resolved in the European Parliament on 8 October 2013 in favour of *not* regulating these products as medicines. I would like to summarise the arguments against regulating vaping products exclusively as medicines..

- **TGA regulation functions as a *de facto* ban.** The pragmatic argument is that, in practice and whatever the theory or intent, this approach has led to no nicotine-based consumer products being available on the Australian market. Indeed, no vaping products have been approved by a medicines regulator and brought to market in any country. Smokers in Australia are denied alternatives that are much lower risk than smoking and widely adopted elsewhere. The requirement for TGA approval is, in practice, functioning as a prohibition.

⁷ Department of Health, Tobacco Taxation, we page accessed 24 October 2017 [\[link\]](#)

⁸ Bates CD. The real challenge is to make e-cigarettes accessible for poor smokers. *Lancet Respir Med*. Elsevier; 2015 Sep 1;3(9):e30. [\[link\]](#)

- **Vapour technologies are consumer products rather than medicines.** The key reason why these products are unsuited to a ‘therapeutic goods’ regulatory regime is that they are not bought or sold as therapeutic goods. A regulatory framework used to assess medicines or devices making therapeutic claims has been imposed although no therapeutic claims are made⁹. Vaping technologies are consumer products designed to replace an existing but much more harmful consumer nicotine product, combustible cigarettes, and fit in the same place in the market and consumer psychology. Two examples could illustrate this:
 1. if it was only possible to place diet cola on the market if it was approved as an anti-obesity drug, then there would be few if any diet cola options.
 2. the lowest rate of smoking in the world, in Sweden (7% prevalence), has been achieved mainly via an alternative nicotine product, ‘snus’. This is a low-risk smokeless tobacco product and widely used as an alternative to smoking. It would never be described as a medicine and could not be regulated as a therapeutic good, but it has a beneficial effect on smoking behaviour in the same way that e-cigarettes do.
- **Medicalisation.** Vaping has arisen as a grass-roots, consumer driven behaviour. Many smokers do not see themselves as sick and needing a medical intervention and will be unwilling and not attracted to use a medical pathway. TGA regulation will require visits to the doctor for a prescription and pharmacist with the associated inconvenience to the user and costs to the user and government. Cigarettes also deliver nicotine, but do not require TGA authorisation. This one-sided exemption creates a strong regulatory protection of the most harmful product.
- **The importance of consumer appeal and difficulty for a medicine regulator.** *Consumer appeal* is integral to the process of diverting smokers away from smoking through branding, flavours, pleasure, and an active consumer community. A hypothetical perfectly safe, officially-approved product that few smokers are willing to try is of little public health value. The medical regulation system tends to treat appeal as ‘abuse liability’ and it does not have good techniques for validation of the role that appeal plays in realising a public health, rather than medical, outcome.
- **The pace of innovation is inconsistent with the slow TGA approval process.** A further reason why companies may be unwilling to submit applications to the TGA is that the process of approval is slow and the pace of innovation in the industry is very rapid. The one application to the TGA that I am aware of was made by a tobacco company in 2015 and had already been approved as a therapeutic good by the UK regulator. It was initially rejected by TGA, and only after TGA’s decision was reversed in court, did the product enter the approval process. The product remains under evaluation but has now become obsolete.
- **Barriers to entry.** The costs per application are high – running from hundreds of thousands of dollars to substantially more depending on the demands of the regulator – and vendors typically have dozens of product variants. It is likely that only tobacco companies will have the resources to make applications. TGA regulation would lead to a greatly reduced range of products with reduced appeal to users. Most would continue to access preferred products illegally.

⁹ If therapeutic claims are made, then TGA approval is appropriate – and this option should always be available, but not the only option. The EU provides two pathways to market: as a therapeutic product and under specific regulations in the Tobacco Products Directive. Much of this regulation is poorly designed and could be done better in Australia.

4. Final observations

The issue before the Committee is whether to recommend a change in regulatory philosophy that will offer a new way for smokers to quit smoking that has now been embraced elsewhere. This includes England, where the government now funds TV ads to encourage smokers to switch to e-cigarettes, and New Zealand which announced on 11 October that it recognised e-cigarettes as a contributory strategy to meet its *Smokefree 2025* objective and to help address health inequalities¹⁰.

The historical decline in smoking in Australia has stalled, with the number of adult daily smokers actually increasing between 2013 and 2016¹¹. Australia's tobacco policy is focussed on raising taxes on products widely accepted to be addictive. However, smoking is disproportionately concentrated in the most disadvantaged groups where the regressive effects of such a tax are felt most painfully.

The option of regularising sale of nicotine vaping technologies in Australia could help to resume the downward trend in smoking by allowing smokers to take personal responsibility for their health by making use of emerging technology at their own expense, while helping to address some of the unwanted 'collateral damage' caused by an aggressive tobacco taxation policy. Against this, we acknowledge there is some residual uncertainty about the long term health consequences of vaping, but everything we do know (physics and chemistry, emission toxicology, biomarkers of exposure, medium term impact on smokers health) suggests risks will be very much lower than smoking.

In the face of uncertainty, policymakers can make two types of error. They can allow access and use by smokers, only to find that vaping technologies are much more harmful than anticipated. Alternatively, through excessive risk-aversion and concern to avoid the first type of error, they can deny smokers access, only to find that they have perpetuated smoking and blocked a valuable option that would reduce the burden of disease. We argue that the second type of error is far more likely in Australia and will have serious negative health consequences.

I hope the Committee can focus some attention on the likely harmful consequences of *not allowing* a legal, accessible market in vaping, while criminalising those Australians determined to quit smoking and to protect their health and welfare by using vapour technologies. Why prevent them?

I wish the committee well with its work and look forward to reading its findings. If I can assist further in any way, please do not hesitate to contact me.

Yours sincerely

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¹⁰ Ministry of Health, New Zealand. Ministry of Health position statement – E-cigarettes, 11 October 2017 [\[link\]](#)

¹¹ See analysis by Dr Colin Mendelsohn, *Why is the number of smokers in Australia increasing?* 18 August 2017 [\[link\]](#)