Senate Community Affairs Legislation Committee: Vaporised Nicotine Products Bill 2017 – submission by Fact Asia Consultants Ltd ("factasia.org")

As an independent regional consumer advocacy with considerable experience of the important issue of tobacco harm reduction and in particular the often contentious debate over 'vaping', **factasia.org** welcomes the opportunity to submit comment on The Vaporised Nicotine Products Bill and background on the availability and regulatory treatment in Australia of alternative nicotine products.

factasia.org is an independent, not-for-profit, consumer-oriented advocate for rational debate about – and sensible regulation of – the rights of adult citizens throughout Asia to choose for themselves within sensibly defined guidelines.

factasia is currently concentrating on the issue of consumers' ability to choose tobacco harm reduction in numerous countries across Asia-Pacific including Hong Kong (with presentations to the Legislative Council), Malaysia (discussions with Minister of Health and officials at the Trade Ministry) and the Philippines, as well as Australia and New Zealand.

factasia does not support smoking or promote the use of nicotine, opposes all under-age use of personal vaporisers (with or without nicotine) or any other new nicotine product, and does not (and will not) engage in any manufacturing, distribution or retailing activities. factasia aims to act as a messenger, facilitating constructive dialogue between scientists and medical experts, legislators, regulators and the general public.

The last year has seen several in-depth analyses of the science and medicine involved in the arguments, not least with Australia's TGA and its consultation exercise. factasia submits that the body of scientific evidence is substantial and speaks for itself, and that the objections raised by the TGA in defending its maintenance of its position on Schedule 7 of the Poisons Act are at best emotional rather than rational.

factasia also accepts the evidence, and the independent and authoritative position, of august bodies such as the Royal College of Physicians and Public Health England (while wondering why their Australian counterparts have taken such a diametrically opposed position from the same evidence). Accordingly, this submission will concentrate on policy, regulatory and rights issues rather than the science.

factasia welcomes the opportunity to be involved in this inquiry in whatever capacity the Committee deems fit, and is more than willing to place this submission in public arena in its entirety. However, factasia prefers it not to be redacted as was the case with many submissions to the TGA exercise in 2016.

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Summary

Australian adults want, and should be allowed, to choose for themselves to switch from smoking to safer alternatives such as e-cigarettes or other alternative nicotine products. The Senate Community Affairs Legislation Committe is to be commended on addressing this important public-health opportunity.

- The fundamental distinction between smoking and nicotine – in usage as well as outcomes – must be recognised and accepted. **Vaping is not smoking**, and to continue to treat **not** smoking like smoking is perverse; likewise nicotine, which is what users enjoy, is no more dangerous than caffeine unless burned – people "smoke for the nicotine but die from the tar". Alternative, non-combustible delivery methods enable smokers to quit by switching, without the enormous difficulty of going 'cold turkey'.
- Such products should be widely available with appropriate regulation of quality and safety (to normal consumer product standards) and with age-of-sale restrictions (like other consumer products).
- Public health has a duty to accept that safer alternatives to smoking represent an opportunity (for improved public health) rather than a problem.
- In countries where the issue is regarded as an opportunity for improved public health rather than a problem, smoking rates are falling at record rates at the same time as vaping is increasing. There is a large body of evidence to show a link between the two. However, in these countries public health bodies report there is negligible take-up of new nicotine products (the so-called 'gateway effect') by non-smokers, and that youth usage is comparable to or even lower than that for smoking (but that young people experimenting with e-cigarettes do not endanger their lives as they do with smoking).
- In the absence of substantial long-term evidence of the 'non-danger' of the latest technology for alternative nicotine products, even short-to-medium term experience in Europe, the UK and other countries has shown massive benefits for smokers who have been able to switch away from smoking. "If we wait for long-term evidence, we will wait for ever – and people will die" - Public Health England.
- Australia is increasingly isolated on this important public-health issue as more progressive countries embrace the potential for public-health improvement afforded by switching from smoking to safer alternatives.
- Regulation for safer alternative nicotine products is in the public interest to ensure product quality and efficacy, but need not be complex and is largely covered by existing consumer-protection laws.

It is worth emphasising the cautionary words of the Royal College of Physicians of London in 2016 :

"A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks.

"However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking." (*Nicotine without smoke: Tobacco harm reduction*, Section 12.10 page 187)

Introduction

The Vaporised Nicotine Products Bill, and a current, separate but highly relevant, House of Representatives Committee enquiry into “The Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia”, represent an overdue reflection of the fact that a large number of Australia’s 2.6 million smokers want to be allowed to choose for themselves to use products that give them the nicotine experience they crave but without the dangers associated with smoking (which they overwhelmingly acknowledge to be real).

Such products are accepted in many developed countries as carrying a tiny fraction (if any) of the harm associated with smoking and are increasingly being shown to represent a genuine pathway away from the deadly habit. In the UK and EU, among other places, these new nicotine products have been removed from the realm of medicines (which by definition they are not, given they have no claimed or intended therapeutic effect) and enabled for sale to the general public with appropriate restriction – such as limiting their availability to adults. The results in the UK, where public-health authorities now actually *recommend* switching to new nicotine products as a way of getting off smoking, are particularly striking as e-cigarettes (personal vaporisers) have become the most popular method of attempting to quit smoking at the same time as the rate of quitting has hit an all-time high.

An exercise in 2016 by the TGA to investigate the issue of tobacco harm reduction failed to sufficiently mark the distinction that needs to be drawn between smoking and *not* smoking: that vaping, even if it sometimes *looks like* smoking, and vapour, even if it sometimes *looks like* smoke, is neither smoking nor smoke; and that combustion – the action of burning the tobacco – is what produces the dangerous particulates and tars that characterise the dangers of tobacco “prepared and packed for smoking”, which remains openly on sale while at present the far safer alternative for a huge number of smokers remains illegal. It is this anomaly that the Bill under discussion seeks to rectify, together with addressing the very real public-health opportunity presented by allowing adults to switch to such non-combustible nicotine products – with appropriate, light regulation for public safety and curbs on the sale of such materials and products to youth.

Background

The 'inventor' of the e-cigarette was a Chinese doctor, Hon Lik, who developed a gadget in 2001 to help him quit smoking, motivated by his father’s death from lung cancer. In 2010, Hon Lik was nominated as a “hero” by the social network (of cancer victims) Kcancer in the US alongside Rudolph Giuliani, Lance Armstrong, and Steve Jobs.

Hon Lik has many times expressed his regret that he called the device an 'e-cigarette' because the term has since become conflated with 'smoking' and gave rise to the confusion that has been rife internationally.

The crucial difference between 'smoking' and 'vaping' is combustion.

Almost all the science examining the harm done by smoking has shown that the action of setting light to the tobacco and chemicals in a conventional cigarette is what causes the deadly cocktail of particles and tar which prompts disease – and kills two out of three smokers worldwide. 'Vaping' represents a **non-**combustible method of taking in nicotine.

Vaping is not smoking. Smoking kills – not nicotine.

Nicotine

According to Shirley Cramer CBE, Chief Executive of the UK's Royal Society for Public Health, nicotine is "a substance which in and of itself is not too dissimilar to caffeine addiction" and is "no more harmful to health than caffeine." [1]

Nicotine is not dangerous – in much the same way as caffeine is not dangerous. Nicotine is found in tobacco, of course, but also (in rather lower concentration) in many other plants including tomato, aubergine and broccoli.

- is not carcinogenic
- is a natural stimulant
- is not a medicinal product (per World Health Organization definitions) [2]
- can increase a person's heart rate and blood pressure
- does not cause, and is not a contributory factor in, smoking-related diseases.

Water vapour containing nicotine, as produced in many alternative nicotine products, is not toxic, nor dangerous when inhaled at intended levels.

It is possible to become addicted to caffeine or nicotine. However, the human body will regulate them and control the dosage. This threshold is different for each individual. Therefore, overdosing on nicotine or caffeine is highly unlikely (nb: the toxicity of a substance is determined by the dosage). There is no reason to assume that the likelihood of a vaper poisoning him/herself by 'overdosing' on nicotine-containing e-liquid is any greater than of chewing and perhaps swallowing excessive pieces of nicotine-containing chewing gum.

In any case, as science and medicine in many developed countries increasingly agree, nicotine is not the cause of the immense damage done to the human body by smoking. "People smoke for the nicotine but die from the tar" [3]. The damage is done by the action of burning a tobacco mixture.

Vaping, and similar technologies that produce (usually nicotine-containing) vapour without combustion, provide a highly efficient method of obtaining the nicotine effect that consumers enjoy, because they deliver the vapour direct to the lungs – the fastest method of obtaining the effect. Nicotine-containing chewing gums, or skin patches, by contrast, produce a far slower effect and are thus regarded as a relatively inefficient delivery method.

Vaping without nicotine may be compared to decaffeinated coffee in its effect – in every sense, it misses the point. In most countries where alternatives to smoking are legal, nicotine is allowed as an ingredient; banning it would mean the alternatives are ineffective.

Australia is an unusual case in (currently, in most states/territories) allowing vaping but not nicotine.

Problem or opportunity? Public health and regulatory background

Globally, there is division among the public health community; some experts argue vaping is essentially bad because it appears to replicate the act of 'smoking'; others see the evidence of actual smoking reduction and cessation (eg more than six million adults in the EU have been able to quit smoking with the aid of e-cigarettes) as more important. Experts have pointed to considerable and increasing misinformation in the public space over perceived 'dangers' of vaping.

Although e-cigarettes do not have to contain nicotine, e-cigarettes containing nicotine appear more effective as a smoking-cessation tool. E-cigarettes are not for use by youth (although consideration might be made for their

use as a smoking cessation tool for young people currently smoking) but on current evidence from countries where they are legally available (eg UK, EU) they are not being used by previous non-smokers (adult or youth) and represent a pathway away from smoking rather than towards it.

In the UK, where almost 3 million adults are now vaping, a coalition of 13 peak independent advisory bodies [Appendix 3, p 19] has recommended smokers to be "encouraged" to switch to vaping as the most popular means of quitting smoking. Australian peak bodies have hitherto taken a stance contrary to their UK counterparts despite evidence that Australian smokers want to be allowed to vape legally. Changes due in New Zealand after the impending general election, which will legalise availability of nicotine-containing eliquids, will likely exacerbate the problem with illicit product importation if Australia's regulations do not change.

By definition there is as yet no long-term evidence available on vaping (with or without nicotine). Neither is there any report of harm caused by long-term exposure to nicotine through other cessation methods (eg patches or gums, the Scandinavian speciality 'snus', which has been in use for around a century and for which long-term harm reduction evidence is incontrovertible). In the absence of long-term evidence regarding vaping, it is recommended that there should be ongoing monitoring of concerns, especially

- potential youth usage: currently, in countries where e-cigarettes and other alternative nicotine products are in use, all evidence points to a near-total lack of youth 'take-up' except among young people who have already tried smoking (in which case the pro-vaping argument stands equal to that for adults). However, some US studies have promoted confusion in this area, misrepresenting survey data by labelling "ever trying an e-cigarette" as 'use', and "trying it in the past month" as 'current use'. Such massaging of the data naturally increase the apparent take-up (at least of those who have 'ever tried' vaping), but do not affect the underlying message: that young people who do not smoke are not turning to new nicotine products.

or

- use by non-smokers: the so-called 'gateway effect', where adults who have never succumbed to smoking suddenly take up vaping, is just not happening in any of the countries where new nicotine products are widely available. Typical is the EU survey [4] which found that just 0.09 percent – fewer than one in a thousand – of never-smokers use nicotine-containing electronic cigarettes on a daily basis.

Australia

Australia correctly classifies nicotine as a poison, which it is – in the sense of being dangerous if taken in excess. So is alcohol. However, there would be little point in listing the vast number of chemicals present in consumer products that are dangerous in excessive quantities. Instead, it is worth pointing out by way of example that nicotine is certainly no more dangerous than household (chlorine) bleach, which – with appropriate regulation on processing, handling and storage – is readily available in any supermarket.

[*There is one example of long-term evidence relating to the safety or otherwise of non-combusted nicotine: snus. This oral nicotine product has been a traditional favourite in Sweden, which currently has a special exemption granted by the EU to safeguard its continuing sale. In Sweden, current smoking prevalence is down to 7 percent - and 5 percent for daily smoking [5] – with a commensurate decrease in all the disease associated with smoking [6]. In January 2017, the UK High Court granted permission for a challenge in the EU Court in favour of overturning the ban on snus in other EU countries.*]

The key here is "appropriate regulation". factasia believes there has been a fundamental confusion – possibly fomented by vested interests opposed to progressive harm reduction – between the need for some sort of regulation, as with almost any other consumer good, and the Draconian approach of treating nicotine in the same manner as heroin or therapeutic goods. Nicotine is neither medicine (as already observed) nor therapeutic

in the sense that applies to the TGA; its handling and storage can easily be regulated by existing regulations such as apply to other substances which can be hazardous to health in quantity.

An adult determined to overdose on nicotine – and thus fall sick – must do so despite an array of overwhelming unpleasant sensations; otherwise he/she will 'self-regulate', stopping at a point well short of sickness.

If nicotine in forms for vaping is packed according to existing regulations for child-proof containers it will not be possible for children to obtain the substance.

Likewise, a plethora of existing regulations can take care of the need for regulation of electrical safety and manufacturing quality of 'hardware' involved in alternative nicotine products. A leading and strident local detractor of tobacco harm reduction, Prof Simon Chapman [7], recently claimed that "barely a day passes without a new reports [*sic*] of e-cigarette explosions causing serious burns", but this is simply not supported by any facts. Rather, it is of note that ten to 15 people die in Australia alone each year due to fires involving conventional smoking cigarettes [8] – considerably more than any global 'death toll' from alternative nicotine products. Chapman* goes on to claim that "nearly all airlines ban e-cigarettes because of the potential disaster that could follow an explosion and fire on board" an aircraft due to an e-cigarette. Again, this is contrary to the facts: they are not to be used on board, but nearly all airlines allow their carriage and many (including the likes of British Airways) actually sell them on board as duty-free items. Lithium-ion batteries for mobile phones too are subject to flight restrictions, but they are not banned on the streets.

In this instance, Chapman misses the self-evident but often overlooked point: it is not vaping, or 'use of e-cigarettes' that is banned in Australia: it is nicotine itself. And no airline delineates between nicotine and non-nicotine e-cigarettes.

Like its peers, Australia has federal standards of safety and quality in regard to consumer products in general that are entirely capable of effectively regulating all of the 'hardware' (electrical components, metal and plastic parts, et) and 'software' (liquids, ingredients and packaging) of alternative nicotine products.

The issue of 'regulation' has been a sticking point in numerous Asian countries, sometimes highlighting a local lack of effective existing consumer-protection legislation. However, Australia's regulatory framework is more than sufficient to regulate this new class of product. [*As an aside, the authorities in Singapore, not known for their liberal tendencies, went through the exercise of "regulating" vaping and e-cigarettes in 2015, but only to the extent that 'regulate' meant 'ban'. Such technology has now been banned there more or less in perpetuity, so regardless if someone invented a vape that brought people back from the dead, it would currently be illegal.*]

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** this is a man who – in the same diatribe – called the Royal College of Physicians "quacks". (A reminder: the RCP states: "E-cigarettes are marketed as consumer products and are proving much more popular than NRT as a substitute and competitor for tobacco cigarettes. E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking … the hazard to health arising from long-term vapour inhalation from the e-cigarettes available today is unlikely to exceed 5% of the harm from smoking tobacco … in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK."*
(Founded in 1518 by a Royal Charter from King Henry VIII, the Royal College of Physicians of London is the oldest medical college in England.)

Consumer-protection legislation extends in Australia to effective point-of-sale restrictions on products considered as 'adult' or lifestyle', including alcohol. In many Asian countries, either the legislation or its enforcement may be deficient, but in Australia both are considered adequate for other goods. There is no reason for concern that such regulation might be insufficient for keeping alternative nicotine products out of the hands of children – especially given they are deemed sufficient to deal with the proven danger of smoking materials.

Australia – political implications

In 2015, factasia commissioned its own independent research [9] among adult smokers aged 18+ in Australia.

The research found that adult smokers in Australia have strong opinions regarding the regulation of e-cigarettes.

Specifically of note:

- More than eight out of ten adult smokers (84%) agree that "through tax and regulatory policies, the [federal] Government should encourage adult smokers to switch to less harmful alternatives to cigarettes and ensure they are not used by youth."
- 82% agree with the statement "It would be wrong for the government to prevent or delay the introduction of less harmful alternatives to regular cigarettes for adult smokers."
- Nine out of ten (93%) agree that "if a new product is scientifically proven to have the potential to reduce the risk of smoking as compared to conventional cigarettes, adult smokers should have the right to access this information."

Additionally, support for these measures cut across the political spectrum, with wide-ranging agreement spread equally among both Liberal and Labor supporters.

The research also found that

- three-quarters of adult smokers (75%) agree that "e-cigarettes represent a positive alternative to today's cigarettes"
- two-thirds (65%) would "consider switching to e-cigarettes if they were legal, met quality and safety standards, and were conveniently available like regular tobacco products."

Current practice

Non-smokers may not fully appreciate the absolutist strategy of many public-health figures in Australia who apparently fail to accept that the so-called 'quit-or-die' approach ignores

- the difficulty smokers face of quitting ('going cold turkey', as often referred to) without help
- the fact that most smokers do actually enjoy their nicotine intake
- a very large number of smokers only want to stop smoking because of the known danger of combustible cigarettes, or – knowing of the danger – still do not want to give up their nicotine
- nicotine is 'innocent' – it is not the perpetrator of the death and disease associated with smoking
- nicotine is readily available on the supermarket shelf in the form of chewing gum*
- “nicotine packed for smoking” in the form of the known deadly traditional delivery method remains readily available and protected by current laws

'Quit-or-die' is contrary to the principle of adults' right to choose for themselves (within reason) and, to an increasing extent, denies the visible public-health opportunity to eradicate smoking. To suggest (as many within the TGA have done) that **not** smoking (vaping) somehow “renormalises” smoking is a paradox, while to ignore that unpalatable fact that Australia's smoking rates have remained stubbornly stable (while those of the UK and other countries are falling faster than ever before) is to refuse to face facts.

Illicit trade

Indeed actual smoking prevalence may be creeping up rather than down if the burgeoning illicit tobacco trade (ie smuggled or counterfeit) is factored in. Both ABF and AFP, while obviously unable to comment officially, express concern at this growing menace, which is partly a result of the punitive rates of excise levied on smoking materials that are proving ineffective in their *raison d'etre*: to reduce consumption. The most recent measure shows illicit consumption of tobacco in Australia at 14.0% of total consumption in the twelve months to December 2015 [10]. Many countries have experienced a sharp rise in this illicit trade as the cost of smoking rises beyond 'acceptable' levels compared to overall disposable incomes; Malaysia, for example, now reports that more than 60 percent of total consumption is illicit.

Illicit trade fuels illegal operations – including funding of terrorist groups [11].

Online availability of nicotine (notably from China where it is currently unregulated and therefore of potential danger to consumers) and other components of vaping or other such alternative nicotine products only serves to emphasise the futility of maintaining the current unilateral ban, especially given the likelihood of post-election regulation of these items in New Zealand and the near-inevitability of a dramatic increase in trans-Tasman illicit trade, with its consequent extra burden on hard-pressed law enforcement bodies.

** and no-one is suggesting any change here – advocates of vaping see no need to deny consumers the choice of NRT. Scientific evidence in many countries shows NRT to be less effective in aiding smoking cessation than vaping, but there is no logic or reason to restrict consumer choice in this area. Vaping is not for everyone; neither is NRT; and there are consumers who are entirely satisfied with non-nicotine vaping. The emphasis should be on the availability of alternatives that do not involve combustion, and consumers' right to choose them.*

Disinformation

Increasingly, there is a suspicion within the international tobacco harm reduction and tobacco-control sector, populated by impartial experts in medicine, science and policy, that the Australian stance is less about an opportunity to save lives and more about punishing smokers (for their habit), while ostensibly 'protecting' them (from a disruptive new technology that has only limited long-term known safety).

The ironic and absurd outcome is that the known and virulently dangerous 'old technology' – smoking – remains under protection from the law, fully available, while the safer, disruptive 'new technology' remains out of legal reach to ordinary Australians, many of whom are known anyway to be violating a series of laws they regard as little more than a death sentence for those who cannot or do not wish to stop taking what is for all practical purposes a harmless stimulant – nicotine.

Detractors and vested interests of the status quo (most notably 'Big Pharma': the major multinational pharmaceutical companies which enjoy the “$150 billion global cancer industry” and its appetite for expensive and lengthy courses of their products paid for by public health) continue to try to conflate 'smoking' and 'nicotine', and experts advocating harm reduction have recently noted the increase in misinformation that has reduced public confidence in safer alternative products. Self-evidently, public health's gain would be Big Pharma's loss.

In particular, Dr Derek Yach, former cabinet director at the World Health Organization and the man largely responsible for drafting the Framework Convention on Tobacco Control, called in September 2015 for governments to “end the war on e-cigarettes and view them as the smoking cessation aid that they are.” [12]

He called for e-cigarettes to be brought “into the mainstream” and for a “cultural change” that would end the “scary stories” that regularly distort the public's view of less harmful products such as e-cigarettes. “The impact of these distorted media stories has led many smokers who had moved to e-cigarettes to move back to regular cigarettes.”

Policy makers should “adopt regulations that encourage smokers to shift to reduced-harm products such as e-cigarettes and tighten up on regulatory actions aimed at regular cigarettes.” Physicians need to be made aware about “the difference between the health effects of nicotine and tar,” said Dr Yach. “Physicians dominate the policy space and their support will be needed to bring e-cigarettes into the mainstream.”

International context

Access to new nicotine products is growing in EU, Canada and US, but throughout Asia-Pacific governments have generally so far failed to come to terms with either consumer demand or public health imperatives, mostly arguing unconvincingly that they want to wait for “long-term evidence” of the harm-reduction effectiveness before making them available. However,

- most Asian administrations have made little or no effort to investigate or understand the fundamental distinctions between vaping and smoking
- several Asian administrations have vested interests in the form of national tobacco monopolies which they wish to protect (eg India, Thailand), or a government desire not to upset the domestic tobacco industry (eg Indonesia, where as many as half a million jobs depend on it)
- globally, public health experts say the opportunity to save lives and reduce disease associated with smoking will be missed if governments wait for decades for 'long term evidence'
- regionally and globally, media coverage has often been distorted. Numerous leading figures in the scientific and regulatory community have condemned what they call “disinformation”.

The WHO is renowned – or reviled – in Australia for its stance that 'snags on the barbie may be carcinogenic', as well as its open hostility to anything short of quit-or-die. However, even WHO, in its document [13] presented at

the FCTC/COP7 Convention in November 2016, admitted: "If the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, and eventually stop using it, this would represent a significant contemporary public health achievement."

European Union

Evidence from the Eurobarometer survey of nearly 28,000 European Union consumers shows that more than six million smokers have been able to quit smoking with the aid of e-cigarettes, while the number of people taking up either vaping or smoking from a position of being a non-smoker (the much-talked-about "gateway effect") is negligible.

Using data from the Eurobarometer survey [4], scientists from the University of Patras-Greece, Onassis Cardiac Surgery Centre-Greece and the French National Research Institute for Health and Medical Research found that in the EU:

- 48.5 million adults have tried electronic cigarettes
- 7.5 million are current users.
- among current users, 35.1 percent have quit smoking altogether while an additional 32.2 percent are smoking less.

The principal investigator of the study, Dr. Konstantinos Farsalinos, commented: "These are probably the highest rates of smoking cessation and reduction ever observed in such a large population study. The European Union data show that the use of electronic cigarettes seems to have a positive impact on public health for two main reasons: 1. High smoking cessation and reduction rates are observed, and 2. Electronic cigarette use is largely confined to smokers (current and former), with minimal use by non-smokers."

UK

The experience and policies of the UK provide a contrast to the treatment of new nicotine products in Australia. The most recent evidence [14] from the Office of National Statistics shows some 2.9 million adults in the UK are using e-cigarettes:

In 2016, of all adult survey respondents in the UK, 15.8% smoked which equates to around 7.6 million in the population.
In Great Britain, 5.6% of respondents in 2016 stated they "currently" used an e-cigarette in 2016, which equates to approximately 2.9 million people in the population and represents a growth of almost 25 percent year-on-year.
Within that group, more men than women (6.3 to 4.9 percent) are users, while the age group using them most is the 35-49 group (7.5 percent).

By contrast the AIHW's latest bulletin [15] states: "Most e-cigarette users only try them and no longer use them. Nearly one third of smokers (31%) had tried e-cigarettes in their lifetime, but the majority had only tried them once or twice (20%) and only 4.4% currently use them (the remaining 6.8% no longer use them)." The definition used is "devices for creating aerosols, which contain nicotine and/or flavouring agents", meaning the AIHW was asking many respondents to admit they were using something illegal, which in turn may have influenced the responses.

AIHW continues to conflate the issues, stating "Tobacco contributes to more drug-related hospitalisations and deaths than alcohol and illicit drug use combined." In fact it is **smoking** that is the contributor, not **tobacco**. This is a crucial distinction that has been recognised and embraced by authorities in the UK, where the most consistently anti-smoking group ASH recently praised the change made by so many smokers.

ASH UK's latest survey [16] (May 2017) "finds more ex-smokers (1.5 million) who use e-cigarettes than current smokers and the main reason people offered for their use of e-cigarettes was to stop smoking." Commenting, Professor Ann McNeill, Professor of Tobacco Addiction at King's College London, said: "This year's ASH survey finds that around 1.5 million vapers are ex-smokers, for the first time a larger number than those who continue to smoke. This is encouraging news as we know that vapers who continue to smoke continue to be exposed to cancer-causing substances. The message for the 1.3 million vapers who still smoke is that they need to go further and switch completely."

Canada

Canada has recently introduced regulations regarding new nicotine products that allow for availability and acknowledge the harm-reduction potential of such alternatives to smoking. David Sweanor (adjunct professor of law at the University of Ottawa), who helped develop his country's less authoritarian position on safer alternatives to smoking, recently issued a powerful plea for a more enlightened approach elsewhere in a commentary for the *Financial Times**.

New Zealand

In New Zealand, the government is going ahead with legalising vaping despite the proximity of a general election. In a statement in March 2017, Associate Health Minister Nicky Wagner announced the sale of nicotine e-cigarettes and e-liquid will be made legal with appropriate controls. "This is an opportunity to see if restricted access to e-cigarettes and e-liquid can help lower our smoking rates, reduce harm and save lives," she commented. "Scientific evidence on the safety of e-cigarettes is still developing but there's a general consensus that vaping is much less harmful than smoking," Ms Wagner said. "The Government is taking a cautious approach by aligning the regulations around vaping with those for cigarettes. This ensures cigarette smokers have access to a lower-risk alternative while we continue to discourage people from smoking or vaping in the first place."

In particular, NZ is also concerned about high smoking rates and low incomes of Maori, and is instigating policies to try to switch Maori smokers (including a large proportion of women) away from combustible consumption.

"Public consultation showed a strong appetite for change so the Government is looking to introduce an amendment to the Smoke-free Environments Act this year. The changes will likely come into force later in 2018," Ms Wagner said.

Japan

Japan has high and culturally-ingrained smoking rates (more than 20 million smokers) but no marketing of e-cigarettes (in the sense of using e-liquids) and looser restrictions on tobacco than other rich countries. But it is now pushing harder to develop a tobacco-control infrastructure ahead of the 2020 Tokyo Olympics. As the government clamps down on smoking, consumers appear to be waking to the health risks associated with tobacco and a heat-not-burn tobacco product has enjoyed initial success in the marketplace. Essentially this is a less messy (no liquids) and slightly 'higher-tech' means of obtaining a dose of nicotine similar to vaping without burning, so producing the same less-harmful result for a smoker wanting to switch. Such products are legal to use in Japan.

* *because the FT has a paywall, and also because the piece is of extraordinary interest to legislators, the article is repeated in full on page 17 (Appendix 1)*

Sweden

Sweden likewise has little or no vaping, in this case because of a product almost unknown outside Europe: snus (moistened tobacco placed in a sachet under the lip) which has been delivering a nicotine experience satisfactory to Swedes for more than a century. Snus is pasteurised, making it much safer than other "chewing tobacco" such as that popular in India. Snus is one of the best-proven non-combustible methods of getting nicotine, in that lung cancer and heart disease rates in Scandinavian countries where it remains legal (due to an exemption granted by the EU in its 2016 TPD) are the lowest in Europe, as is the incidence of smoking (percentage of population):

UK: 25-34 years 26%; 35-49 years 22%
Sweden: 16-29 years 8%, 30-44 years 5% and 45-64 9%

In the UK, the Royal College of Physicians' view is that snus "demonstrates proof of the concept" for tobacco harm reduction, while even WHO admits snus is "considerably less hazardous than cigarettes."

China

China is known to be near the end of a two-year investigation by its state tobacco corporation into the effects on public health (and finance) of its high smoking prevalence and ways to reduce them while taking account of its income from tobacco and the considerable number of jobs in the sector. In short, Beijing knows there is a problem and is interested in solving it. The results, when published, will be of global interest, not least because most of the 'hardware' associated with vaping worldwide is made in China – notably Shenzhen.

Indonesia

Despite its desire not to upset the domestic tobacco industry (as many as half a million jobs depend on it), Indonesia is investigating the potential for harm reduction afforded by vaping. The country's beloved 'kretek' (clove) cigarettes are cheap and popular, but a similar-flavoured e-cigarette liquid is already available and being tested.

Some other Asian administrations, notably the military junta in **Thailand** and the government of **India**, have vested interests in the form of national tobacco monopolies which they wish to protect at all costs, including the cost of death and disease. Both countries have strict bans on alternative nicotine products.

Finance implications

Smoking has long been used as a revenue tool, the credibility of assertions that excise or tax increases are justified as disincentives being variable at best given the stall in reduction of smoking prevalence. Australia's pack prices are believed to be the world's highest, yet consumption remains stubbornly high. The burden thus falls disproportionally on lower-income adults and those with other problems, such as mental health issues (smokers inhabit all socio-economic groups but the preponderance of heavy smoking is seen in lower demographics, as well as regional and rural populations. 56 percent of Australian adult smokers have TAFE or lower education level, 55 percent earn less than AUD1400/week, and, according to data from South Australia, "some populations still have dramatically higher smoking rates than the population average. People with mental illness, indigenous people, country residents and people living in the two most disadvantaged quintiles of our society are still much more likely to smoke" [17]).

Many current vapers report massive savings from switching to safer alternatives to smoking, adding personal financial benefits to personal health improvement. (This point, together with the high smoking rates among indigenous people, has prompted New Zealand's Maori Party to prioritise the legalisation of vaping in that country.)

The question of how to replace tobacco revenue is beyond the scope of the inquiry (or at least this submission). However, the Department of Health uses a figure above AUD30 billion as the cost of smoking, a figure quite similar to the income received nationally (of which some 14 percent is missing due to the above-mentioned, growing, illicit trade).

If the Australian authorities in general are indeed committed to zero smoking, they must also be prepared to forgo the revenue from the habit. To do otherwise would demonstrate that, as in some other Asian nations, tobacco control is subservient to the generation of income and that public health is merely a secondary concern.

Latest global thinking

factasia attended (and presented to) the 2017 edition of the annual Global Forum on Nicotine in Warsaw in June. We asked a number of leading international figures in medicine, science and law to comment on the situation in Australia and the results are available in a series of short video clips:

Terry Barnes - AU health policy expert
https://vimeo.com/223930066

Clive Bates – ex-director, ASH UK – AU
https://vimeo.com/223929600

David Sweanor - Adjunct Professor, Faculty of Law, University of Ottawa - short
https://vimeo.com/223929768

David Sweanor - Adjunct Professor, Faculty of Law, University of Ottawa – long
https://vimeo.com/223929688

Deborah Arnott – CEO, ASH UK -short
https://vimeo.com/223929790

Deborah Arnott - ASH UK- long
https://vimeo.com/223930014

Prof Gerry Stimson, Emeritus Professor, Imperial College London
https://vimeo.com/223929840

Prof Linda Bauld Professor of Health Policy, University of Stirling
https://vimeo.com/223929862

Prof Riccardo Polosa, Institute for Internal and Emergency Medicine, University of Catania
https://vimeo.com/223929964

The comments include unusually forthright terms from such eminent experts, such as “insane” and “daft”. The main sentiment expressed was that Australia is out of step in its repressive policies and increasingly isolated in the war to reduce the death and disease associated with smoking, because of its steadfast refusal to acknowledge the public-health benefit of alternative nicotine products and delivery systems, and its legislators' failure thus far to uphold the right of Australian adult citizens to choose for themselves to switch to them.

Conclusion

A **rational** analysis of the cases for and against alternative nicotine products – alternatives to smoking, the known danger – shows that the only 'downside' is the lack of hard long-term evidence of safety. Clearly the consumption of any substance – including alcohol or caffeine – is unlikely to, of itself, improve health, but virtually nothing in life is completely risk-free (indeed in many of the jurisdictions in which factasia is active, merely breathing the air is more dangerous than even the most dire predictions for the health impact of vaping).

Otherwise, all evidence available to date shows that thousands of lives are being saved in countries where such products are available (with appropriate, proportionate and readily-available regulation). The public health opportunity is being recognised and grasped by authorities in UK, Canada, New Zealand and other developed countries; not to do so in Australia would be a derogation of duty on the part of legislators, and failing to heed this opportunity will lead to more unnecessary suffering and cost to the state.

Careless talk costs lives [18], and will continue to do so until adult Australians are allowed to choose for themselves to switch from smoking to safer alternatives.

Recommendations

Clearly, if non-combustible means of obtaining nicotine can help achieve the spectacular smoking-cessation figures seen in the EU and UK, they should be taken seriously in Australia too, so **recommendation 1** is

*the fundamental distinction between smoking and nicotine – in usage as well as outcomes – needs to be recognised and understood. A precise definition of vaping is that it is **not smoking**, and to continue to treat **not smoking** like **smoking** is perverse.*

2. Regulation should be sufficiently "future-proofed" to take account of current and future emerging nicotine delivery technologies that may differ in detail from today's e-cigarettes but which still represent the principle of safer alternatives to smoking. Of course they should be subject to quality and safety standards, and availability restrictions as appropriate, but as with other consumer goods and disruptive technologies, it is possible to draft regulations in such a way as to avoid the need for controversy and re-drafting every time a development comes into the public domain.

3. However, it is not always necessary to start with a blank sheet of paper; as discussed above, existing consumer regulations relevant to product design, quality standards and materials/ingredients are usually capable of being applied to new items and technologies. The Senate Community Affairs Legislation Committee has a duty, as well as an opportunity, in recommending in its report that the law be changed along the lines of this Bill, which elegantly switches the roles, to deter "nicotine packed for smoking" at the expense of "nicotine packed for heating" or "nicotine for producing nicotine-containing vapour".

NOTES

1. https://www.rsph.org.uk/about-us/news/nicotine--no-more-harmful-to-health-than-caffeine-.html

2. The WHO definition of a drug or medicine, consistent with medicine regulations applied globally, is that it should stop, cure or mitigate the course of a disease. The drug or medicine has to have the ability to alter the function of mind or body to obtain its claimed result. Nicotine, like caffeine, is a natural occurring alkaloid that does not have the ability to alter the function of mind or body. Also, it lacks the ability to provide any pharmacological effect like a medicine.

3. Prof. Michael Russell, British Medical Journal, 1976

4. *Addiction*. 2016 Jun 24. doi: 10.1111/add.13506. "Electronic cigarette use in the European Union: analysis of a representative sample of 27 460 Europeans from 28 countries." Farsalinos KE1,2, Poulas K2, Voudris V1, Le Houezec J3,4. http://www.ncbi.nlm.nih.gov/pubmed/27338716

5. *Eurobarometer 458*

6. click to open links: link link link link link link link link link

7. http://www.smh.com.au/comment/keep-tga-control-of-ecigarettes-or-risk-repeating-the-smoking-health-disaster-20170619-gwtyux.html

8. http://www.mja.com.au/public/issues/181_06_200904/cha10373_fm.html

9. Ipsos-factasia Asia Pacific survey 2015

10. KPMG report: https://home.kpmg.com/uk/en/home/insights/2016/04/illicit-tobacco-in-australia.html#01

11. http://www.abc.net.au/news/2016-12-05/illegal-tobacco-trade-fuelling-drug-trafficking-and-terrorism/8075174

12. Johns Hopkins Bloomberg School of Public Health's Global Health Now. http://www.globalhealthnow.org/news/why-an-anti-smoking-crusader-would-embrace-e-cigarettes

13. http://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf?ua=1

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15. http://www.aihw.gov.au/alcohol-and-other-drugs/data-sources/ndshs-2016/tobacco/

16. http://ash.org.uk/media-and-news/press-releases-media-and-news/large-national-survey-finds-2-9-million-people-now-vape-in-britain-for-the-first-time-over-half-no-longer-smoke/

17. Final Report of the Select Committee on e-cigarettes, Tabled in the House of Assembly and published pursuant to Standing Order 346 - 24 February 2016

18. A popular "anti-gossip" campaign from Britain during the World War 2.

APPENDIX 1

Financial Times, Feb 22, 2017: [**Copyright The Financial Times Limited 2017. All rights reserved.**]

Comment: Pragmatism on nicotine could save lives
Encouraging safer alternatives to smoking can help end epidemic

by: **David Sweanor ***

The regulation of tobacco and nicotine products has become less straightforward. Historically, high taxation and restrictions were aimed at achieving total nicotine abstinence. But product innovation now means that there are increasing numbers of products that allow users to satisfy their need for nicotine at a fraction of the risk.
The stakes are extraordinarily high. There are well over a billion smokers globally, spending roughly $700bn a year on the cigarettes that are currently killing over 6m of them annually. This death toll and the associated economic costs are expected to continue to climb long into the future without a fundamental change in current trends in consumption.
From a pragmatic public health perspective, solving the problem should be easy. The deaths are almost entirely due to consumers getting nicotine from the deadly delivery system of inhaling smoke from burning tobacco. Yet nicotine at the dosage levels smokers seek is not particularly harmful on its own. Great numbers of smokers are already keen to reduce risks, and are ready to try the emerging alternatives such as vaping products, various forms of smokeless tobacco, medicinal nicotine and products that heat, rather than burn, tobacco. But regulation has failed to adapt to these new possibilities. A mix of marketing restrictions, smoking bans, health warnings and tax increases are aimed at stopping people from starting to smoke, getting them to quit and protecting others from second-hand smoke.
Reducing risks by helping smokers switch to less hazardous products has been opposed rather than endorsed, with regulation serving to restrict alternatives to cigarettes. The push to ban potentially less hazardous alternatives to cigarettes, or to put them at a marketplace disadvantage, has largely come from anti-tobacco organisations that fear such products might perpetuate nicotine use and further enrich tobacco companies.
The resulting scenario has thrown up modern-day alliances as odd as the coalition of “bootleggers and Baptists” that propped up the failed anti-alcohol policies of the US in the Prohibition era. For instance, anti-tobacco groups focused on nicotine abstinence co-operated with Altria, which sells over half the cigarettes in the US, to enact stringent controls on less hazardous alternatives to cigarettes by the US Food and Drug Administration.
In this area, the UK has been an outlier. Organisations including the Royal College of Physicians, a professional body, Public Health England, representing the UK government, and Action on Smoking and Health (ASH), an antismoking lobby group, have lined up to promote switching to vapour products, which they acknowledge to be far less hazardous than smoking.
In being open to the benefits rather than just the risks of vaping and other nicotine products, the UK is adhering much more closely to a rational template of health regulation by offering cigarette smokers a

viable alternative to total nicotine abstinence. By doing so, it might move more quickly towards ensuring cigarette smoking follows in the path of other unreasonably hazardous activities that now fill history books rather than hospital wards.

** adjunct professor of law at the University of Ottawa. He helped develop tobacco-control laws in Canada and other countries. Canada has introduced regulations regarding new nicotine products that allow for availability and acknowledge the harm-reduction potential of such alternatives to smoking.*

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Public Health
England

Protecting and improving the nation's health

July 2016

E-cigarettes: a developing public health consensus

Joint statement on e-cigarettes by Public Health England and other UK public health organisations

Since 2000, smoking among adults in England has fallen by one third and among children by two thirds. Yet almost one in five adults continue to smoke, with higher rates in the more deprived communities meaning that they bear the majority of the harm caused. There is a strong public health consensus on tobacco control, embodied in the landmark report Smoking Still Kills.

We all agree that e-cigarettes are significantly less harmful than smoking. One in two lifelong smokers dies from their addiction. All the evidence suggests that the health risks posed by e-cigarettes are relatively small by comparison but we must continue to study the long-term effects.

And yet, millions of smokers have the impression that e-cigarettes are at least as harmful as tobacco. Over 1.3 million UK e-cigarette users have completely stopped smoking and almost 1.4 million others continue to smoke. We have a responsibility to provide clear information on the evidence we have, to encourage complete smoking cessation and help prevent relapse to smoking.

The public health opportunity is in helping smokers to quit, so we may encourage smokers to try vaping but we certainly encourage vapers to stop smoking tobacco completely.

We know that e-cigarettes are the most popular quitting tool in the country with more than 10 times as many people using them than using local stop smoking services. However, we also know that using local stop smoking services is by far the most effective way to quit.

The current national evidence is that in the UK regular e-cigarette among youth use is almost exclusively confined to those young people who have already smoked, and youth smoking prevalence is continuing to fall. This is an area that we will continue to research and keep under closest surveillance. Since October 2015, regulations to

protect children make it an offence to sell e-cigarettes to anyone under 18 or to buy e-cigarettes for them and the Tobacco and Related Products Regulations 2016 ban print and broadcast advertising of e-cigarettes as part of an extensive range of regulations.

We should not forget what is important here. We know that smoking is the number one killer in England and we have a public health responsibility to provide smokers with the information and the tools to help them quit smoking completely and forever.

We share a commitment to provide up-to-date information on the emerging evidence on e-cigarettes, as shown in PHE's review, which is the third in this area. This commitment drove PHE and Cancer Research UK to set up the UK E-cigarette Research Forum and the Royal College of Physicians to publish Nicotine without smoke, honouring our longstanding promise to monitor and share the evidence, providing clear messages to the public.

There is no circumstance in which it is better for a smoker to continue smoking – a habit that kills one in every two and harms many others, costing the NHS and society billions every year. We will continue to share what we know and address what we don't yet know, to ensure clear, consistent messages for the public and health professionals.

Public Health England

Action on Smoking and Health

Association of Directors of Public Health

British Lung Foundation

Cancer Research UK

Faculty of Public Health

Fresh North East

Healthier Futures

Public Health Action

Royal College of Physicians

Royal Society for Public Health

UK Centre for Tobacco and Alcohol Studies

UK Health Forum

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