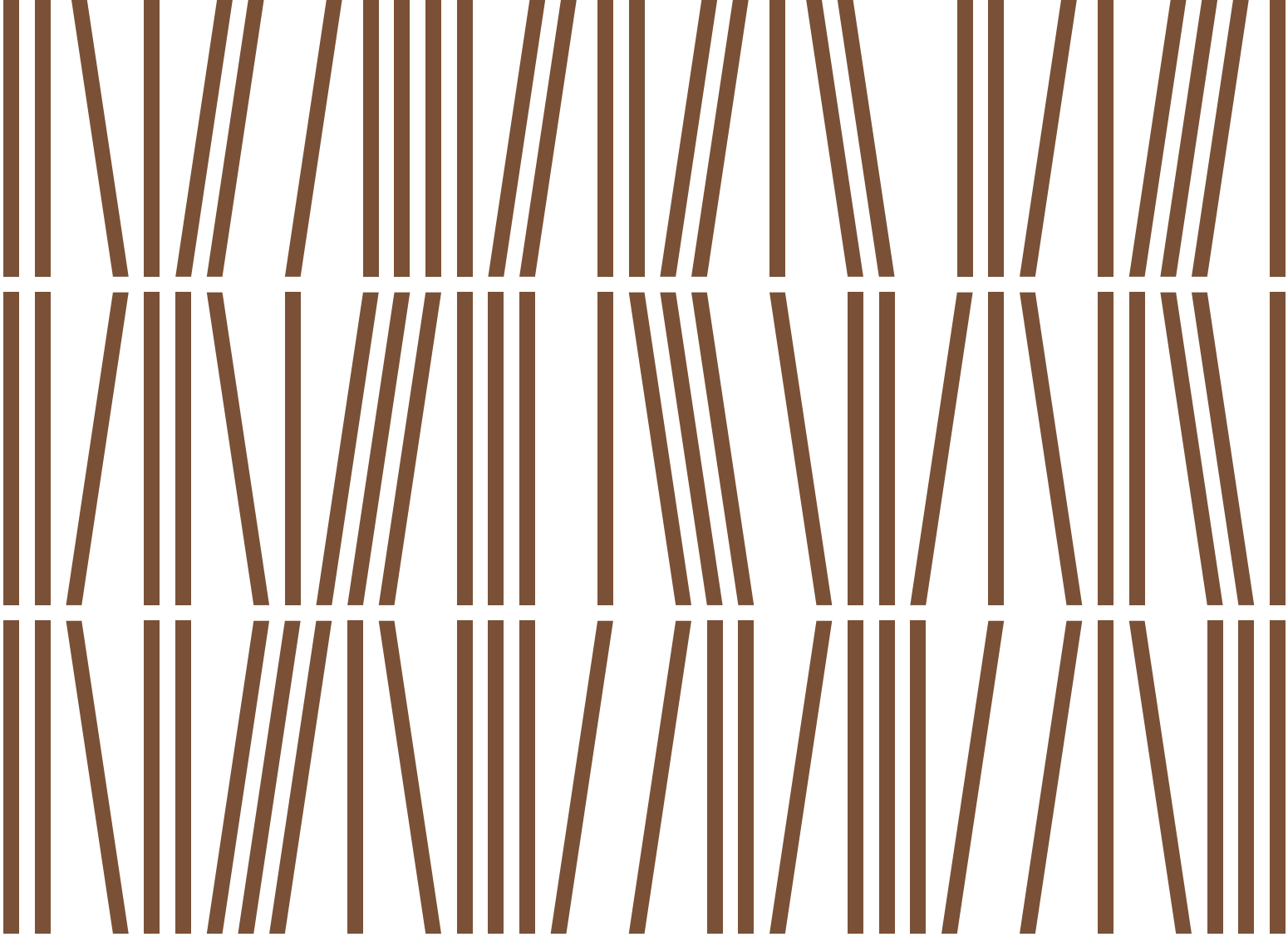

# Regulating Electronic Nicotine Delivery Systems and Heated Tobacco Products

A submission to the Philippines government

MAREWA GLOVER, PhD

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# Regulating Electronic Nicotine Delivery Systems and Heated Tobacco Products

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# Introduction

In December 2019, the Philippines House of Representives Committee of Trade and Industry and the Committee of Health jointly convened to hear submissions on a proposed Act to regulate the manufacture, distribution, sale, importation, use and advertisement of electronic nicotine delivery systems and heated tobacco products.

One of the barriers to reducing smoking among indigenous peoples in New Zealand (NZ), Australia, the United States of America (USA), Canada and Greenland, has been the lack of recognition of socio-historical and cultural differences between indigenous peoples and the Euro-Western dominated tobacco control movement that thinks all peoples of the world are like them, or should live like them. The World Health Organisation's Framework Convention on Tobacco Control (FCTC)(1) is Eurocentric and this is one of the reasons why non-European non-Western sub-groups have not found the FCTC strategies as effective for them.

From a Euro-Western perspective, Asian countries are lumped together and seen as similar. It is thought that the FCTC strategies to reduce tobacco smoking should be able to be implemented across all countries as if every country is the same as Australia or New Zealand or Finland. In recognition of the sovereignty of the world's distinct nations, the FCTC is not a binding law. It is a set of guidelines. It is up to the Philippines to determine the most effective socio-economic and culturally appropriate tobacco control interventions to adopt.

In recognition of the unique political environment in the Philippines, the following insights and knowledge about the potential benefits of a tobacco harm reduction approach were submitted for the Committees to consider.

The Philippines Government is to be commended for progressing debate on the role of new risk-reduced alternatives to smoking tobacco and for inviting submissions from experts on the topic.

# Background

The Philippine Government ratified the World Health Organisation Framework Convention on Tobacco Control (FCTC) in 2005. Over the last 15 years the Government has implemented many FCTC strategies to reduce youth and adult smoking prevalence.

The goal is to reduce adult smoking prevalence to 15% by 2022. In 2018, about 24% of adult Filipinos smoked tobacco.

Other countries have experienced similarly desired rapid and large drops in smoking prevalence, for example: Iceland, Japan, Korea.

To reach the 2022 goal of 15% smoking, or below, by 2022, I strongly recommend that the Philippines Government adopt a harm reduction approach to tobacco smoking.

Relative risk regulation that encourages people who cannot quit smoking to switch to risk-reduced alternatives such as vaping or using tobacco heating devices or oral nicotine pouches could cause smoking rates to plummet.

# Smoking tobacco is a significant risk to health

It is well-established that long-term regular tobacco smoking causes many illnesses, and that half of people with smoking-related disease, on average, die several years earlier than their non, or ex-smoking country folk. Whilst, many of these deaths occur in old age, a quarter of regular long-term smokers die between the ages of 35 and 65.

The most common smoking-related diseases are cardiovascular disease (heart attacks and stroke), several cancers particularly lung cancer (see graph below); and, chronic obstructive pulmonary disease, which includes emphysema and chronic bronchitis. Smoking tobacco has been associated with a higher risk of many cancers. A recent analysis of the contribution of smoking to cancer incidence in USA adults aged 50 and over (shown in the following table) found that smoking contributed to a small fraction of even some cancers not previously thought to be affected by smoking (2).

Mean smoking-attributable fractions, U.S. adults ages 50+. Source: 1980–2004 U.S. vital statistics data.

| Causes of death | Female | Male |
|---|---|---|
| **Established and additional causes combined** | 15% | 22% |
| **Diseases established as caused by smoking** | | |
| Lip and oral cavity cancer | 14% | 35% |
| Esophageal cancer | 20% | 27% |
| Stomach cancer | 2% | 18% |
| Colorectal cancer | 14% | 32% |
| Liver cancer | 0% | 0% |
| Pancreatic cancer | 13% | 3% |
| Laryngeal cancer | 45% | 34% |
| Lung cancer | 83% | 87% |
| Cervical cancer | 0% | — |
| Urinary bladder cancer | 18% | 15% |
| Kidney and renal pelvis cancer | 10% | 18% |
| Acute myeloid leukemia | 11% | 16% |
| Diabetes | 0% | 28% |
| Ischemic heart disease | 25% | 20% |
| Other heart disease | 25% | 23% |
| Stroke | 8% | 7% |
| Atherosclerosis | 0% | 9% |
| Aortic aneurysm | 26% | 45% |
| Other arterial diseases | 22% | 38% |
| Pneumonia, influenza, and tuberculosis | 33% | 31% |
| Chronic obstructive pulmonary disease | 61% | 43% |
| **Additional diseases associated with smoking** | | |
| All other infections | 14% | 27% |
| Breast cancer | 12% | — |
| Prostate cancer | — | 17% |
| Rare cancers | 10% | 26% |
| Cancers of unknown site | 8% | 14% |
| Hypertensive heart disease | 0% | 9% |
| Essential hypertension/hypertensive renal disease | 29% | 14% |
| All other respiratory diseases | 24% | 32% |
| Intestinal ischemia | 44% | 21% |
| Liver cirrhosis | 0% | 47% |
| All other digestive diseases | 14% | 32% |
| Renal failure | 0% | 22% |
| Additional rare causes combined | 9% | 0% |
| Unknown causes | 0% | 0% |

*Lariscy JT. Smoking-attributable mortality by cause of death in the United States: An indirect approach. SSM-Population Health 7, 2019. doi.org/10.1016/j.ssmph.2019.100349*

# Desire to quit

It is said that at any one time about 80% of smokers want to quit. Sustained quitting however has been difficult to achieve using World Health Organisation approved pharmaceutical products only, such as nicotine replacement products and medicines. Restrictive and punitive policies such as tax increases and fining smokers signals the Government's disapproval of smoking, but these approaches can also increase stress which is a trigger to smoke. People who are unable to quit smoking easily need empathic support, incentives to quit, and behavioural change interventions in conjunction with cessation aids. Governments also need to address the economic and social determinants of smoking to reduce smoking initiation and relapse.

Application of a comprehensive tobacco control programme based on the FCTC guidelines has assisted high income Eurocentric nations to slowly reduce their smoking prevalence rates over the last 40-50 years. For example, New Zealand which has been a world leader in tobacco control began its anti-smoking efforts after the USA Surgeon General's 1964 report that warned that smoking kills. On average smoking prevalence has been reduced at a glacially slow rate of only 0.5% per annum over the last 41 years:

| | 1976 | 2017/18 | Average drop over 41 yrs = |
|---|---|---|---|
| Total NZ | 36% | 15% | 0.5% per annum |

The world is currently experiencing a technological revolution that could almost eliminate, in a matter of decades, the practice of smoking tobacco. Innovative nicotine delivery products that do not deliver tar, carbon monoxide and carcinogenic toxins (that is, the constituents of smoke that cause disease) are proving to be acceptable to people who smoke.  As a result, we are seeing a global mass migration of tobacco smokers switching to greatly risk-reduced nicotine delivery products.

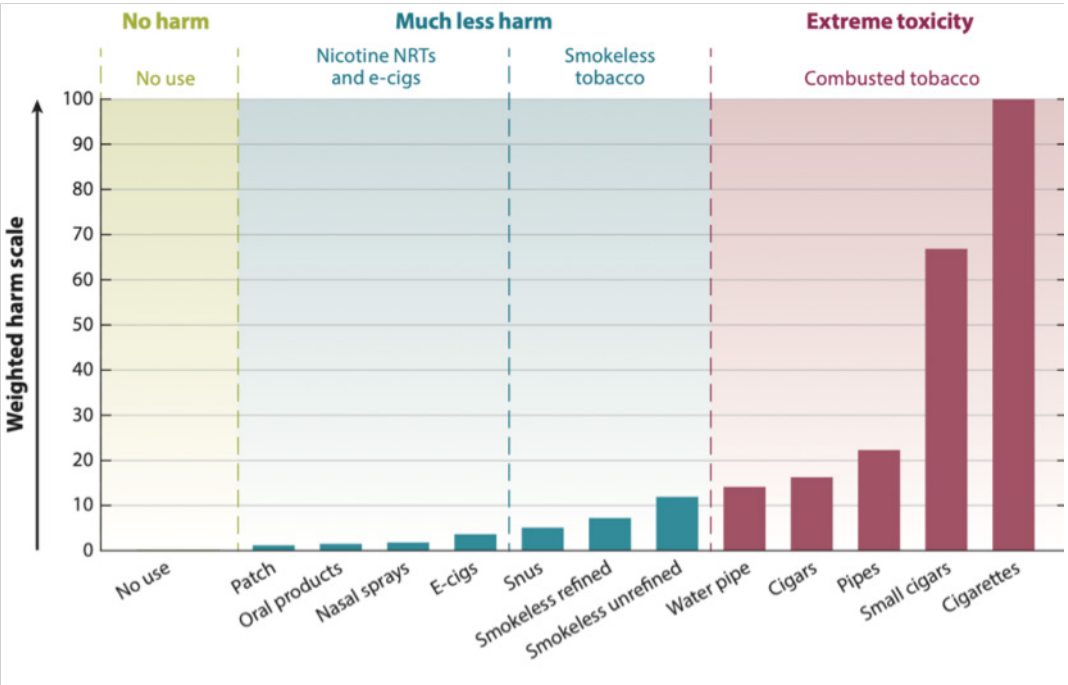
# Adopting a tobacco harm reduction approach

A harm reduction approach recognizes that total abstinence is not immediately achievable for everyone, or it may not be desired by everyone. We all engage in behaviours that put our health or our very life at risk every day when we drive, or when we go out fishing. To mitigate the risk, we wear lifejackets and seat belts. Workplaces sometimes require people to do dangerous tasks but they use rules and protective clothing to keep employees as safe as possible – this is harm reduction. The best way to reduce the risks associated with regular long-term tobacco smoking is to quit. Switching to a greatly risk-reduced alternative product is the next best option.

Millions of smokers across Europe, the United Kingdom and the USA, have completely switched from smoking cigarettes to vaping nicotine. In countries, like Japan, that had a pre-existing law banning nicotine (outside of tobacco) products, the heated tobacco products have provided millions of Japanese smokers with a risk-reduced alternative.

There are now a wide range of greatly risk-reduced alternatives to smoking tobacco and some of them are proven (for example, Swedish snus – a small pouch of tobacco used orally), or have been recently proven (vaping nicotine) as effective ways to stop smoking (3,4). The innovations in the new technologies hasn't stopped so we can expect to see more improved products and systems that will more quickly move people away from smoking. Continued innovation in the risk-reduced alternatives to tobacco smoking will also improve the speed of transition from smoking, and the permanence of the change.

A basic tobacco harm reduction concept to understand is that the alternative products exist on a continuum of risk to health compared to continued smoking (as illustrated in the following graph).




*Source: Nutt, et al. (2014) Estimating the harms of nicotine-containing products using the MCDA approach. Eur Addict Res, 2014;20:218-225.*

Most of the carcinogenic effects are delivered by the combustible products, that is – it's the smoke that kills. Vaping nicotine has been estimated to be at least 95% safer than smoking. Swedish snus has been estimated to be at least 95-98% safer than smoking and the more recent tobacco heating devices are estimated to be about 85% safer than smoking (5).

Very few Filipinos have tried e-cigarettes as an alternative. Only 31.7% have heard of e-cigarettes and 2.8% have tried while less than 1% are current users as of 2015.

Many highly esteemed public health scientists support the use of e-cigarettes as a less harmful alternative for smokers who have difficulty in quitting smoking. Public Health England supports UK smokers to switch to risk-reduced nicotine vaping products and tobacco heating devices. Electronic cigarettes are now the most popular aid to quit smoking (6).

In June 2019, the New Zealand Government launched a Vaping Facts website designed to combat misinformation about vaping (7). It is an important initiative because the lies are intended to put people off vaping and drum up support for bans or regulations that will heavily restrict access to vaping products. New Zealand's campaign is world-leading, second only to the campaigns run by Public Health England that encourage people who smoke to switch to vaping (7).

Enabling tobacco smokers to switch to vaping nicotine, or heated tobacco products, or oral nicotine pouches, and for some smokers a combination of products, will deliver significant public health benefits and reduced healthcare costs. The decision to do this has become a lot more difficult for Governments that are going through a concurrent cultural shift from prohibiting cannabis to permitting widespread recreational cannabis use – as is happening in the USA.

# The collision of two innovative technologies

The development of technologies that allow people to use nicotine without the disease-causing constituents contained in smoke is nothing short of revolutionary. These risk-reduced alternatives to smoking, as I've already said, could bring about the end of cigarette smoking. Within just a few decades, we will begin to see global deaths from smoking tobacco (estimated at over 7 million people a year now) reduce.

Technology that enabled the cannabidiol (CBD) and tetrahydrocannabinol (THC), to be extracted and separated has triggered a different but concurrent revolution in the attitudes towards cannabis, how it is used and the range of products that are now being produced and sold in countries where cannabis use was already legal, and in jurisdictions that are decriminalising cannabis use.

These are two different technological innovations that are now colliding and causing new dilemmas and concerns, especially for jurisdictions that prohibit cannabis.

Though the electronic cigarette was invented for vaporising nicotine-containing liquid, the technology was quickly adopted and exploited by people outside of the stop smoking and tobacco product market. Over 5 years ago I found (online) a number of vaping devices being marketed as weight loss devices. Instead of nicotine, they claimed to contain flavours and sometimes guarana. Another website corruptly claimed that their vaping devices and liquids enabled people to vape vitamins. Other early retailers sold vaping e-liquids along with wild health claims, such as that vaping a particular liquid could cure baldness. Regulation and research have helped to curb some of this 'snake oil salesmen' behaviour.

One of the concerns raised in the Philippines is that nicotine vaping devices could be used as delivery devices for illicit drugs.

As early as 2015, I heard that cannabis users (in Euro-Western nations including NZ) were trying to adapt vaping technology to vape cannabis. I am not talking about dry-herb "vaporisers" – devices that heat dry leaf material. The "vapor" from a dry-herb heating device refers to the natural liquids in the leaf that are released

during the heating process. The early nicotine-containing liquid vaporisers reportedly could not cope with the more viscous solutions cannabis users were experimenting with. That is, the devices broke. The technology has since advanced and CBD-containing and THC-containing liquids for vaporising now exist and specific devices for vaporising these liquids also exist. They are usually different from the nicotine vaporising devices.

The legal status of cannabis, its derivatives and products and devices designed specifically for 'delivering' CBD or THC varies by country, and within the USA, by state.

In countries, where nicotine vaping was established such as the USA, which then state-by-state overturns cannabis prohibition, vaping CBD and or THC becomes an established and accepted practice among adults who are legally permitted to purchase cannabis products. In the USA this is usually at 21 years of age. An illicit market still exists to supply to people aged 20 years and under, and for people who cannot afford the permitted, but often high priced, cannabis products.

In countries where cannabis use remains illegal, such as in New Zealand, a black market in cannabis products exists. Dry-herb vaporisers are openly sold throughout NZ (the devices are not illegal). Based on anecdotal reports, I believe some people in NZ are vaping CBD and THC-containing liquids.

# Understanding the anti-vaping hysteria

At the time of writing this submission an anti-vaping hysteria was sweeping through the USA and beyond causing confusion and alarm in less developed countries.

There was already alarm among some parents of teenagers about an uptick in youth experimentation with nicotine vaping. Anti-vaping lobbyists deliberately exaggerated the prevalence of this teen experimentation with vaping to manipulate politicians to adopt their prohibitionist ideology. They obfuscated facts, for example, implying that the use rates represented regular ongoing vaping by teens, when in fact most had only tried vaping once or were infrequent experimenters. Many unsubstantiated claims of harm were made to scare parents and teachers into a frenzy of concern.

Then in August, some primarily middle-upper class young people developed an inflammatory lung illness, and some of them died. Despite some medical professionals knowing from the outset that the victims had been vaping cannabis-containing liquids, the outbreak was blamed on "vaping" generally. Anti-vaping health professionals seized upon the truly tragic outbreak of hospitalisations and deaths to convince the American public that nicotine-vaping was the culprit. This was a deliberate lie.

It was two months before the USA Centre for Disease Control (CDC) finally announced that vitamin E acetate (an oil) found in vaping cartridges was the "strong culprit" likely to be causing the lung injuries and associated deaths. By then over a thousand people had been affected and almost 40 people had died. But still the CDC did not clearly and strongly state that it was contaminated cannabis vaping cartridges mostly purchased on the blackmarket, NOT nicotine vaping, that were to be avoided.

More lung injury and deaths due to vaping contaminated cannabis-containing cartridges have occurred than should have because the anti-nicotine lobby in the USA deliberately exploited the tragedy to incorrectly implicate nicotine vaping. The death toll is continuing to rise because the people interested in vaping cannabis

are not being told to avoid illicit cannabis-containing liquids for vaping and they are not being told not to vape oil. To deliver this truthful advice, would reveal that nicotine vaping is not to blame - nicotine e-liquids do not contain oil.

As at the 5th of December, 48 people had died and 2,291 cases of lung injury had been noted.

Nicotine vaping will save many Filipino people from living many years disabled by disease, and nicotine vaping will reduce the number of years some smokers will lose due to smoking.

Quite apart from the debate on legalising cannabis, at the moment cannabis use is illegal in the Philippines and enforcement is aggressive. Just like in the UK and NZ, where nicotine vaping is established and supported as a legitimate and highly effective stop smoking aid, the vaping of cannabis-containing liquids is likely to remain contained to a minority of people willing to break the law and risk the punishments. No deaths from vaping oil have occurred in the UK or NZ.

## Regulation, rather than a ban, is needed

Regulation of risk-reduced alternatives to tobacco smoking can ensure that only quality nicotine vaping, or heated tobacco products, are able to be sold. Given the relative novelty of vaping in the Philippines, vaping and heated tobacco product use could be similarly confined to areas where smoking is permitted. Advertising could be restricted so it is only seen by adults aged 18 and over and sales could be restricted to adults. If health warnings are to be required on packaging, they should be truthful and specific to scientifically established risks of the product. In order to encourage current smokers to switch to the risk-reduced alternatives, tax should be scaled relative to risk.

## Encouraging faster cessation of smoking

In addition to regulating to support adoption of a tobacco harm reduction approach, other effective solutions for assisting smoking cessation exist that could be used in conjunction with switching or as a standalone cessation option. For example, financial incentives appear to be effective (8). Quit competitions, retail vouchers, prize draws and gift packs could all be used to incentivise quitting or switching, and appointment attendance and treatment adherence (9). Many mobile health apps exist internationally. Philippine specific research should be encouraged to identify locally effective approaches.

# Recommendations

I strongly recommend that the Philippines Government adopt a harm reduction approach to reduce smoking. All people who smoke should be encouraged to quit or switch to any, or a combination of, the greatly risk-reduced nicotine and tobacco products that exist.

Access to risk-reduced alternatives to smoking needs to be cheaper than tobacco for smoking, and as convenient as buying a pack of cigarettes is now. Thus, the new risk-reduced alternatives should not be taxed initially, or a tax relative to risk could be considered.

It is important that the acceptability of the products is not undermined by unnecessary restrictions on the nicotine levels or the flavours. If the nicotine level is set too low, the products will become useless for people with high need for nicotine, such as is the case for many people with mental health disorders. With regards to nicotine vaping liquids, if the flavours are banned, one of the key ingredients that helps people transition away from smoking will be gone.

# Disclosures

This submission was prepared by Marewa Glover, as Director of the Centre of Research Excellence: Indigenous Sovereignty & Smoking in New Zealand. Dr Glover is a New Zealand Professor of Public Health with 30 years experience in smoking cessation and tobacco control. She has worked in community health centres, at a Government policy level, in health promotion and as a trainer of stop smoking counsellors. Dr Glover was one of the first people in New Zealand to do a PhD on smoking cessation. Since then, she has been involved in, and or led, the conduct of many studies and intervention trials to reduce tobacco smoking. She is a lead author or co-author on over 100 scientific journal articles and is an internationally recognised expert on smoking cessation and tobacco harm reduction. Dr Glover  was a speaker at the 2nd Asia Harm Reduction Forum in Manila last year and spoke again at the 3rd Asia Harm Reduction Forum in Seoul this August. Last month, she was a keynote speaker at an Asia Harm Reduction Dialogue in London at Asia House.

After 17 years in academia, with the help of a grant from the Foundation for a Smoke-Free World, Dr Glover established her own research centre focused on reducing the harms of tobacco use amongst indigenous peoples worldwide. Of special importance to her is the reduction of smoking harm among women, especially during pregnancy.

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# References


1. World Health Organisation. *WHO Framework Convention on Tobacco Control.* Geneva: WHO; 2005. 42 https://www.who.int/tobacco/framework/WHO_FCTC_english.pdf

2. Lariscy JT. Smoking-attributable mortality by cause of death in the United States: An indirect approach. SSM-population health, 2019 Apr 1;7:100349.

3. Walker N, Parag V, Verbiest M, Laking G, Laugesen M, Bullen C. Nicotine patches used in combination with e-cigarettes (with and without nicotine) for smoking cessation: a pragmatic, randomised trial. The Lancet, 2019; published online first.

4. Hajek P, Phillips-Waller A, Przulj D et al. A randomized trial of e-cigarettes versus nicotine-replacement therapy. NEngl J Med, 2019;380:629-637.

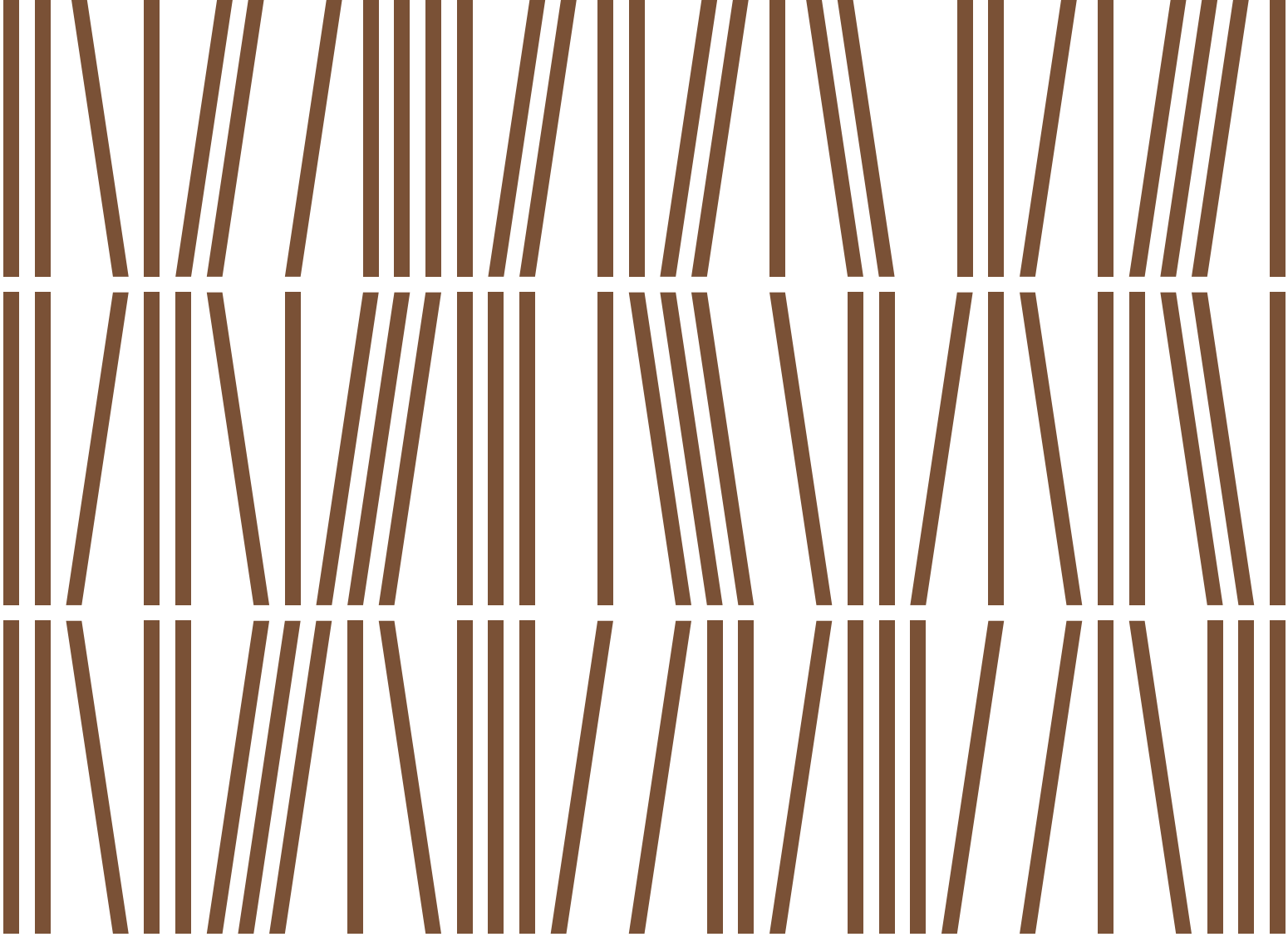
5. Shapiro H. *No Fire, No Smoke: The Global State of Tobacco Harm Reduction 2018.* London: Knowledge-Action-Change, 2018.

6. Bosley S. Public Health England maintains vaping is 95% less harmful than smoking. The Guardian. 28 Dec 2018. https://www.theguardian.com/society/2018/dec/28/vaping-is-95-safer-than-smoking-claims-public-health-england

7. Health Promotion Agency. Vaping Facts. https://vapingfacts.health.nz/

8. Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews, 2019;(7).

9. Glover M, Cowie N, Kira A, Gentles D, Paton C & Moetara W. The WERO group stop smoking competition: Main outcomes of a pre- and post- study. BMC Public Health, 2014; 14(599). doi: 10.1186/1471-2458-14-599



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