

**Submission
No 23**

E-CIGARETTE REGULATION AND COMPLIANCE IN NEW SOUTH WALES

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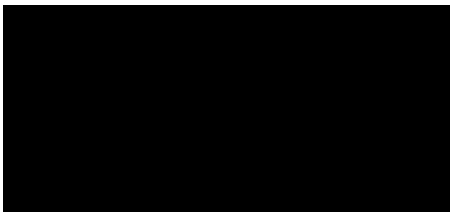


NSW Parliamentary Inquiry into E-cigarettes

E-cigarette regulation and compliance in New South Wales

Submission by Liam Croasdale on behalf of Oz-Eliquid Pty Ltd

- OZE are based in Smeaton Grange NSW are Australia's largest manufacturer and distributor of E-liquid and E-cigarette products.
- International and domestic distribution network
- ISO 9001 QMS certified business
- ISO 7 class clean room manufacture
- AICIS compliance
- In house Scientific Officer and compliance team
- Supply thousands of retail outlets across multiple channels from pharmacy, retail, specialist stores, Petrol & Convenience, and large distributors.



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The current situation in NSW

The prevalence of e-cigarette use among children and young people

When ascertaining the prevalence of vaping in any cohort it is of paramount importance that the frequency of vaping is captured in the data and reported correctly.

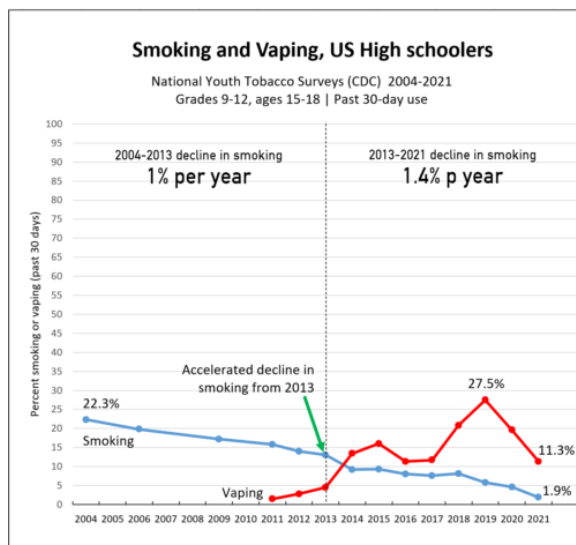
Young people often experiment with products that are restricted such as cigarettes, drugs and alcohol during adolescence. However, the experimentation period is often fleeting – therefore care must be taken when analysing data that crosses over multiple facets of frequency ie: daily, weekly, monthly or experimental. As per statistics in the Alcohol and Drug Foundation, the majority of young adults (74%) tried vaping because they were ‘curious’ which is in line with the experimental hypothesis.

<https://adf.org.au/talking-about-drugs/vaping/vaping-youth/vaping-australia/>

By using data that is deemed not ‘frequent’ or daily due to nicotine dependence we are skewing the data.

Youth vaping in NSW by teens that Vape frequently is ~5% which is defined as 6 or more times in the past 30 days as per the study by Watts et al. 2022 which surveyed 721 young people from 14-17 years old.

<https://pubmed.ncbi.nlm.nih.gov/36156328/>



It is also important to consider the affect that youth vaping is having on smoking rates.

As per the latest CDC Youth Tobacco Survey (Graph left) – smoking has almost been completely eradicated in young people in the U.S. The data shows a direct correlation between smoking rates reducing with the uptake of vaping.

The data also shows a sharp decline in vaping since 2019 – further establishing and confirming the hypothesis that most use is short and experimental.

It should therefore be celebrated that vaping



is driving smoking rates to non-existent levels in Western countries that adopt a strong, highly regulated consumer model.

The reason that there has been a sharp uptake in young person's using unregulated illicit E-cigarettes in NSW is completely attributed to the widespread ease of accessibility through convenience stores.

The introduction of single use disposables has also contributed to the uptake due to the ease of which they are used. They are easy to conceal, and the convenience of their purchase and the lack of required maintenance are undoubtedly the driving forces behind their huge popularity. However, it is important to note that disposables do have their place due to the ease of use with certain cohorts such as older people, people with disability or diseases such as arthritis whereby changing coils and device maintenance is more challenging.

The concern around youth vaping is not unfounded due to the recent reported uptake and anecdotal stories from educators and parents along with the sensationalised media coverage. However, it is important that we look at the data, not the headlines and take a pragmatic approach without irrational panic.

Implementing the correct regulation with strong product safety standards in a consumer model that regulates E-cigarettes in the same way as tobacco and alcohol will result in an elimination of access through the black market – the driving force behind the sharp youth uptake.

Health risks associated with E-cigarette products.

It is important to highlight that inhaling anything other than fresh air into the lungs will carry potential health risks. However, we must maintain that E-cigarettes are a Tobacco Harm Reduction product first and foremost. Therefore, the health risks of vaping should only be compared to smoking combustible tobacco – not whether they are completely risk free.

There are around 7,000 toxic chemicals released when smoking a combustible cigarette along with tar and carbon monoxide. These are cancer causing toxins and smoking kills ~22,000 Australians every single year as a result of using these deadly products.

By contrast, vaping is the method of heating an aerosol which comprises of Food Grade flavourings, Propylene Glycol, Vegetable Glycerin and Nicotine. The E-liquid can contain between 100-200 chemicals – therefore presenting a significant reduction in terms of risk to health.

A recent study in the Internal and Emergency Medicine journal highlighted the biomarkers of potential harm in E-cigarette users vs Smokers. They showed statistically significant results in the reduction of potentially harmful biomarkers that contribute to diseases such as lung cancer.



Haswell, L.E., Gale, N., Brown, E. *et al.* Biomarkers of exposure and potential harm in exclusive users of electronic cigarettes and current, former, and never smokers. *Intern Emerg Med* **18**, 1359–1371 (2023). <https://doi.org/10.1007/s11739-023-03294-9>

Due to a number of studies that have been conducted in the past decade such as the above – the risk comparison between using vaping products vs smoking is consistently cited between 67-97%.

Public Health England state that in best estimates, vaping is conservatively 95% less harmful to your health than smoking based on the evidence.

https://assets.publishing.service.gov.uk/media/5b6c3f57ed915d30f140f822/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf

It is also worth noting that regulated E-liquids with strong product standards do not have prohibited ingredients which further protects Australian consumers. Currently, unregulated, high strength nicotine products with no product safety standards around batteries have flooded the Australian convenience sector. Therefore, the lack of regulation is extremely dangerous and presents health & safety concerns for consumers.

A regulated consumer model with a strong product standard eradicates these concerns. Chemicals in regulated products are also reported to AICIS on an annual basis by importers and manufacturers in Australia so the government, industry and consumers know exactly what is in the E-liquids in terms of chemicals and can rest assured that there are no prohibited ingredients.

It is also important that we address the health concerns around the EVALI outbreak in the US - there is absolutely no link to the use of Nicotine Vaping Products and the CDC / FDA both state on their websites that these deaths and lung injuries were caused by people vaping illicit cannabis THC products which were manufactured with Vitamin E Acetate. However, the media and certain health bodies in Australia along with companies such as the Cancer Council continue to use this misinformation to scare the public and drive fear mongering click bait which is catastrophic for public health as people will refrain from moving to vaping from smoking cigarettes.

There is also concern around the ‘gateway theory’ which implies that people who vape are more likely to go on to smoke cigarettes has recently been debunked by the most comprehensive investigation to date by Queen Mary University, London.

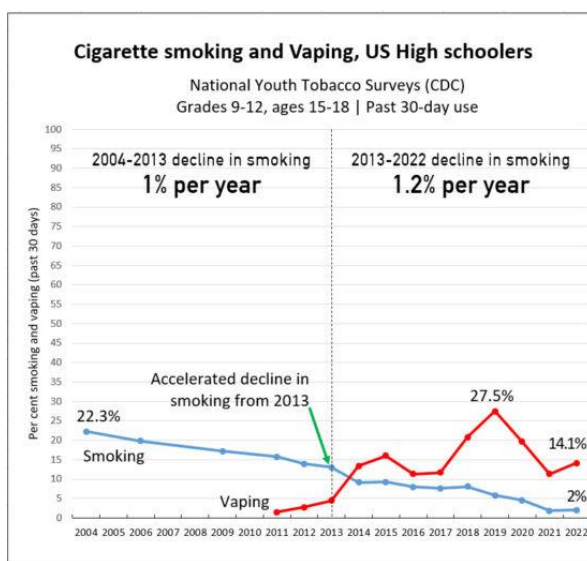
At the population level, the study reveals no evidence to support the idea that e-cigarettes or other alternative nicotine delivery products promote smoking initiation among youth.

They conclude that “The results of this study alleviate the concern that access to e-cigarettes and other low-risk nicotine products promote smoking.”



Pesola F, Phillips-Waller A, Beard E, Shahab L, Sweanor D, Jarvis M & Hajek P. Effects of reduced-risk nicotine-delivery products on smoking prevalence and cigarette sales: an observational study. *Public Health Res* 2023;11(7)
<https://pubmed.ncbi.nlm.nih.gov/37795840/>

Furthermore, if vaping was a gateway to smoking, we would be witnessing drastic increases in smoking rates along with increases in vaping prevalence which isn't happening in western countries with a regulated E-cigarette consumer model (Refer CDC graph below).



The impact of programs and services aimed at preventing uptake or continuing use of E-cigarettes

The recent increased uptake in youth and young persons using E-cigarettes would suggest that the programs and campaigns such as the “Do you know what you’re vaping?” whilst extremely expensive have missed the mark completely and have been disastrous. With the greatest intentions whilst rolling out education programs, we will not prevent youth uptake of E-cigarettes if accessing these products is so easy through the black market in every street corner convenience store Australia wide.

Introducing an RSA style certification requirement for staff members in retail stores, licences for retailers, huge fines for retailers selling to minors are amongst the most important steps to initiate the prevention of uptake.

Furthermore, I would like to question why the state parliament would suggest that they would want to prevent the uptake of E-cigarettes within the adult population? Preventing widespread access to a safer alternative to cigarettes seems counterproductive to the mission of reducing smoking rates.



Considering E-cigarettes are proven to be less harmful than smoking combustible cigarettes which kills ~22,000 Australians every year and have proven to be the most successful and widely used NRT used globally as per the latest Cochrane review – the government’s reluctance adopt E-cigarette use to drive the Smoke free 2030 ambitions must be questioned.

Hartmann-Boyce J, Lindson N, Butler AR, McRobbie H, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2022, Issue 11. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub7

<https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub6/full>

Whilst education programs and services are important to protect public health, it must not be considered the silver bullet. It must be utilised as part of a multi-faceted policy approach that includes enforcement measures, updating licencing & legislation to address the failed regulatory framework and policy at state and federal level. Therefore, allocating an obscene amount of money in the budgets on education programs and instead of further funding the ABF or tobacco enforcement agencies with boots on the ground through adequate resource is a complete waste of taxpayers’ money and will do absolutely nothing to curb the black market and illicit trade in NSW.

NSW's current regulatory framework

Its effectiveness in reducing harm from e-cigarette use.

A huge, resounding public health failure.

It has contributed to a huge black market. Exposing consumers to unregulated, high strength nicotine, illicit products with unknown chemicals and toxins.

The prescription pathway is onerous, expensive, flawed and doesn’t work on several levels. It has been disastrous.

There are not enough G.Ps that are educated enough on vaping for use as a smoking cessation method, willing to prescribe or Authorised Prescribers in Australia – as of Jan 2023, there was only around 1900 applications to prescribe unapproved Nicotine vaping products.

<https://www.tga.gov.au/resources/resource/guidance/authorised-prescribers-unapproved-nicotine-vaping-products>

Considering that there are 1.4 million vapers conservatively we cannot accurately determine the size of the black market. The pressure and burden on the G.P network that we will witness from trying to force this number of prescriptions through an already stretched



healthcare system is not feasible and will push it to breaking point. It is also worth noting that prescriptions need to have a follow up in order to process repeats and show that the person is adhering to the nicotine levels or needs an increase or decrease through a weaning schedule. Do the maths on the numbers. . .

We must be realistic in our approach to policy making. Why would an E-cigarette user who can buy an unregulated vape device from any convenience store in Australia, make a booking to see their G.P, take time off work or from their busy social lives, pay for a prescription during a cost-of-living crisis and then be prescribed something that is subpar in terms of user experience and nicotine delivery with restricted flavours. They will simply not follow the process as humans follow the path of least resistance. The prescription model is idealistic, ideological and is not workable in the real world when Australia has a monstrous and widespread illicit market.

We believe that NSW Parliament should consider the failings of the prescription model and introduce real-world policy with common sense at the forefront of the reform and have the E-cigarette user in mind with the aim of protecting the consumer, stopping youth access and eliminating the black market in the process.

Furthermore, to confirm the optics around the undoubted failing of the prescription model, the latest Redbridge research found that only 2% of Australians are very confident that the current prescription pathway to access vaping products through a G.P is working.

<https://aacs.org.au/wp-content/uploads/2023/10/Research-into-attitudes-towards-nicotine-vapes-2023-09-27.pdf>

The alternative of course, is blind continuation of the prescription model and NSW Parliament essentially being a facilitator in the further explosion of the black-market putting consumers and young people at risk.

“Insanity is doing the same thing over and over and expecting different results.” – Albert Einstein.



Its effectiveness in preventing illegal supply.

A huge, resounding failure.

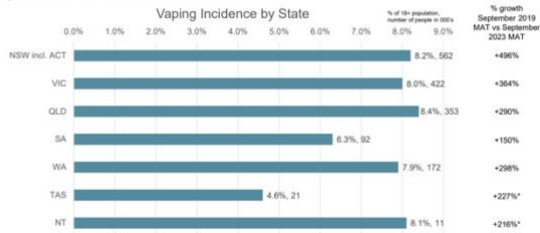
Australia has the largest illicit black market for E-cigarettes in the world per capita. As per 2022 Roy Morgan data there are around 1.3 million vapers – of which ~92% use the black market.

<https://aacs.org.au/new-data-exposes-australias-rampant-vape-black-market/#:~:text=%E2%80%9CAccording%20to%20Roy%20Morgan%2C%2092,last%20year%2C%E2%80%9D%20he%20said.>

(Roy Morgan 2022 data graphs below)

Vaping in Australia by state – among total 18+ population

- NSW has led the growth of vaping in Australia +496% - with over half a million 18+ Vapers, representing about 34% of all Vapers in Australia

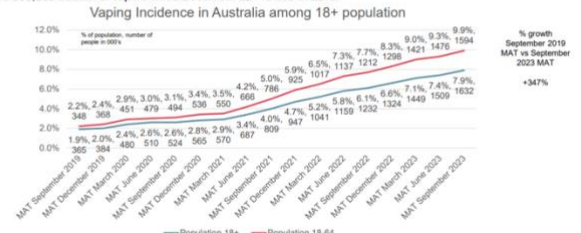


Source: Roy Morgan Single Source, September 2022 – September 2023
 2 Base: Australians 18+
 * Omits low historic sample size – interpret % growth figures with caution



Vaping in Australia

- Vaping has grown by 347% in the last 5 years
- Now 7.9% of the adult 18+ population vapes = 1,632,000 people
- 9.9% of people in the 18-64 population vapes – making up 97.7% of the total market.
- There are 308,000 additional vapers since December 22 – a rise of 23%.



Source: Roy Morgan Single Source.
 1 People that have vaped at least once in the last month. Base: Australians 18+, Australians 18-64



The problem is no longer individual persons importing through the Personal Import Scheme and on selling to friends and family. This is organised criminal activity.

There have been around 30 firebombings of retailers in Victoria and QLD, intimidation of store owners, to name a couple of recent media reports. The scale of the operation and problem is significant.

<https://www.theage.com.au/national/victoria/another-tobacco-shop-torched-as-police-probe-link-between-turf-war-and-fatal-shooting-20231009-p5eaom.html>

The ABF Chief Michael Outram recently said in Senate estimates that they cannot stop the Tsunami of millions of E-cigarettes flooding into Australia as they simply do not have the resource and currently stop ~25% of illicit products from entering the country – therefore they will be unable to prevent the black market to continue to explode.

<https://www.abf.gov.au/newsroom-subsite/Pages/ABF-Commissioner-Budget-Estimates-Opening-Statement.aspx>

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It was also recently reported NSW Health Minister Ryan Park on 2GB that NSW Health employs just SEVEN people to enforce the crack down on illicit vapes. Considering there are thousands of outlets in NSW, it begs the question of how on earth the NSW State Gov expects these seven enforcement officers will ever be able to ensure compliance across an entire state?

In the UK, they had a similar problem with illicit vaping products entering the market and immediately allocated \$6m to a Vaping Task force to work with trading standards to tackle illicit vapes and nefarious retailers. This was actioned imminently, and the task force works commenced, whereas in NSW the speed to action a similar department to initiate retail busts has been sluggish at best. The inaction makes NSW Health complicit in the problem.

The UK taskforce undertakes specific projects such as test purchasing in convenience stores and vape shops. It will also produce guidance to help build regulatory compliance and will have the power to remove illegal products from shops and at the borders.

<https://www.gov.uk/government/news/crackdown-on-illegal-sale-of-vapes>

Huge investment is required into personnel and resource within the state of NSW to begin to tackle a black market the size of which we have in NSW, the required funding is likely significantly more than the allocated \$6.8m announced in September. The speed at which it needs to be implemented is yesterday.

The overwhelming majority of convenience stores in NSW stock illicit vaping products. Many through necessity to stay in business against their moral compass, due to the huge reduction they have witnessed from tobacco sales due to the astronomic surge in the vaping black market and illicit tobacco. Furthermore, the fines for selling nicotine in NSW are negligible as many outlets make enough to cover the fine during a single lunch time trade and many retailers don't display vapes until after business hours when the enforcement officers do not inspect retail stores.

Challenges to enforcement and compliance and ways to overcome these.

As previously stated, the ABF, NSW Health Department and Tobacco Enforcement officers do not have anywhere near adequate resource in terms of personnel on the ground and administrative support. The way to overcome this is self-explanatory – investment. We can learn from established, mature, regulated markets like the UK by implementing similar departments and enforcement task forces with significant funding along with,



legislative change that includes the introduction of huge fines and removal of Tobacco Licences for offending businesses, retail compliance will be achieved.

The current penalties for selling illicit products are laughable and are not substantial enough to be considered a deterrent for offending retailers so this must be addressed as a priority in policy reform.

It is important to note there is now huge demand for E-cigarette products therefore if there is no reform to allow a free market to eliminate illicit trade - the black market will continue to explode as many people have quit smoking through using E-cigarettes and there are now ~1.4 million vapers in Australia who require access to these products - resultantly, retailers or illicit networks will continue to supply products and prohibition will not work.

The quickest way to eliminate illicit trade is to allow a regulated market with strong product safety standards to displace the black market as has recently been proven in Finland.

Finland have had great success through regulatory reform in the tobacco harm reduction space by rescheduling Snus from a medicine to a consumer product which effectively allowed a consumer model to displace a huge black market to the tune of 80% in the space of 12 months.

It is worth noting that Finland have one of the most stringent tobacco harm reduction stances, but this strategy worked quickly and effectively. We can learn much from their experience and from other historical prohibition strategy failings.

[Snus smuggling plummets after nicotine pouch law reform](https://yle.fi/a/74-20053109)

Link: <https://yle.fi/a/74-20053109>

How NSW can work with the Federal Government to implement reforms on e-cigarette products

- Scrap the failed prescription model.
- The implementation of a consumer model framework with stringent product safety standards like the EU TPD and a notification scheme for products like the MHRA in the UK and HARP in NZ is of paramount importance.
- No restrictions on flavours. Given they will be ranged in age restricted settings for adults only, there are no requirements for any flavour restrictions. Flavours play a huge role in assisting smokers in making the transition away from cigarettes.
- Licences for retailers and RSA equivalent certification for staff members along with strict age verification.



- Huge fines for offending retailers who sell to minors or illicit / non-compliant products.
- Significant investment and funding into the Tobacco / Vaping enforcement department to allow for adequate resource across all facets of the department to be able to effectively shut down offending retailers.
- Nicotine concentration also needs to be adequate for the current market of 1.4 million vapers. The black-market products sold in Australia are 5% (50mg). Therefore, the introduction of a model that applies a Nicotine concentration of less than 5% such as the proposed level of nicotine in the recent TGA Consultation paper of 2% (20mg) will not be high enough for existing vapers. Consequently, vapers will then return to smoking high strength cigarettes to achieve the adequate nicotine concentration.
- Implementation of packaging and labelling requirements in the product standard such as no allowances cartoons, restriction of certain flavour names and types of packaging that may appeal to young people.
- Taxation and advertising of E-cigarette products in line with the risk comparison to cigarettes. To tax the same as cigarettes and implement plain packaging implies that the risk to health is the same. When it is a significantly far less harmful product.
- Increased taxation on single use disposables to deter young people from being able to afford them would a more pragmatic approach than banning them as prohibition will drive the desire for the product in this cohort.

Our proposals are also echoed by the Australian Public who also support this approach and according to new Redbridge research, nearly 90% agree or strongly agree that Nicotine E-cigarette products should be available for sale to adults and be regulated in the same way as tobacco and alcohol.

<https://aacs.org.au/wp-content/uploads/2023/10/Research-into-attitudes-towards-nicotine-vapes-2023-09-27.pdf>

In summary, there is no need to reinvent the wheel when it comes to the E-cigarette regulatory reform. The EU Tobacco Products Directive (TPD), UK MHRA or the NZ Vaping HARP are examples of successful and established frameworks that Australia can replicate and implement in a streamlined and effective fashion.



Any other related matter

The 2023 TGA Consultation paper and submission.

The TGA is proposing a ban on all vape products, whether they contain nicotine or not and Health Minister Mark Butler is proposing an import ban will be enforced by the end of December.

If the proposed bill passes in the Senate, this proposal will effectively put us out of business in 8 weeks time.

OZE is a local NSW business with an international footprint that has been built from the ground up over the past 6 years with blood sweat and tears - with the mission to get as many people as possible off deadly cigarettes and to switch to a far less harmful alternative. We have succeeded so far - despite many regulatory challenges and being hamstrung by overreaching policy we have meaningfully contributed to the decline in smoking rates in Australia. Now, the TGA is proposing to shut down our business and an entire industry without any desire to pay compensation.

We employ casual staff members, full time employees, sponsored staff from overseas, contractors all working full time hours.

The TGA are essentially making all 25 employees redundant - unable to pay rents and mortgages in extremely difficult times with cost of living increasing alongside unprecedented inflation. The lack of empathy or consideration by the TGA in a closed stakeholder webinar highlighting that there will be ZERO compensation at state or federal level for us to wind down our business and ensure our employees do not end up homeless is absolutely disgusting.

Please note - if no compensation is of consideration at a state or federal level, as a business and an industry we will be forced to commence legal proceedings as we cannot and will not make our employees redundant without adequate funds to navigate the transition into them finding a new job and support their families in the interim.



Morbidity and mortality caused by smoking among Aboriginal and Torres Strait Islander peoples

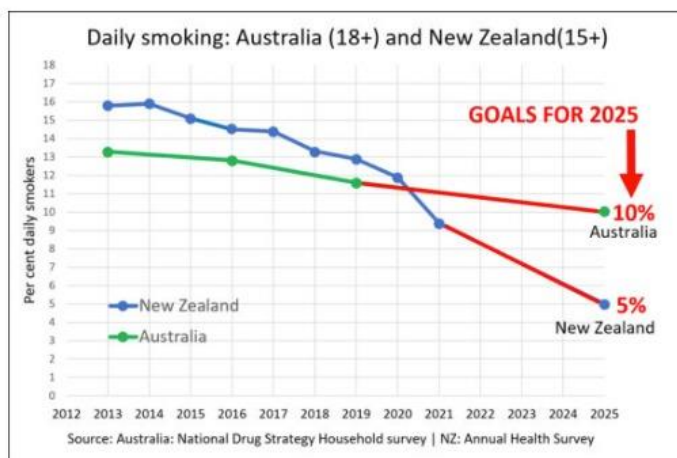
Research published in 2021 estimated that that smoking causes 37% of all deaths, and 50% of deaths at age 45 years and over, in Aboriginal and Torres Strait Islander peoples. This equates to more than 10,000 preventable premature deaths between 2009 and 2018. In 2018, tobacco use accounted for 11.9% of the burden of disease, more than any other risk factor.

<https://www.tobaccoaustralia.org.au/chapter-8-aptsi/8-3-prevalence-of-tobacco-use-among-aboriginal-peo>

As per the peer reviewed literature mentioned above in the Cochrane review showing the efficacy for utilisation of E-cigarettes as the most effective primary smoking cessation NRT modality, Vaping should be utilised to reduce smoking rates in Aboriginal and Torres Strait Islander peoples. However, Health Minister Butler announced in the May Federal budget that he is allocating \$141.2 million to implement a program that is designed to prevent the uptake and reduce the prevalence of vaping in Aboriginal and Torres Strait Islander peoples when vaping is potentially the best smoking cessation NRT that they could be using.

It would seem that Minister Butler has been misinformed by his peers, advisers and bought into the media propaganda around the concerns and limited evidence for the use of E-cigarettes as an effective quitting aid.

Minister Butler should be advocating and promoting the use of E-cigarettes to First Nations people to make the switch from deadly cigarettes to strengthen Australia's Smokefree by 2030 ambitions through taking an evidence-based approach to policy making as they are doing in the UK and New Zealand. See graph below that highlights goals and predicted trajectory for Australia and New Zealand smoking rates.



trajectory for Australia and New Zealand smoking rates. Utilising and adopting Vaping as an effective quitting aid with common sense regulatory reform whilst not demonising the product is at the forefront of New Zealand's strategy to achieve their Smokefree nation (<5%) target.

With this strategy, they will achieve their target considerably quicker than Australia.