



**Lung
Foundation
Australia**

celebrating
30
years

Submission to the Senate Inquiry on Tobacco Harm Reduction

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Lung Foundation Australia is Australia's only peak consumer-informed organisation focused on strengthening the lung health of all Australians and supporting Australians experiencing a lung disease.

Lung Foundation Australia has no direct or indirect links with, or receive funding from, the tobacco or e-cigarette industry.

In accordance with Australia's obligations under the Framework Convention on Tobacco Control¹, we request that the Select Committee removes from its consideration all submissions and representations from the tobacco industry and all submissions and representations from groups or individuals funded or supported in any way by the tobacco industry. We further request that participating Senators declare any links, engagement with or support with from the tobacco industry or groups or individuals funded or supported by the tobacco industry.

Lung Foundation Australia believes Australians want to, and will, achieve a tobacco-free and nicotine-free society. Our services and policy positions are consumer-informed and based on strong, well-established, credible and trusted evidence. We know that tobacco and nicotine addiction adversely impact individual health and well-being and ultimately undermines the overall health and economy of our nation.

In accordance with strong, well-established, credible evidence², we do not support the sale of combustible cigarettes, e-cigarettes (flavoured or nicotine), snuff, heat-no-burn or chewing tobacco for sale as consumer products in Australia.

There is an absence of strong evidence supporting the use of novel nicotine products as a smoking cessation method, and given their known risks, we do not support the use of e-cigarettes, heat-not-burn products, snuff or chewing tobacco as methods to assist smoking cessation.

Human lungs are designed to inhale clean air, not the by-products of burning tobacco or superfine particles and chemicals present in e-cigarette aerosol.

On behalf of our members and supporters we provide the following responses to the terms of reference established by the Select Committee on Tobacco Harm Reduction.

The treatment of nicotine vaping products (electronic cigarettes and smokeless tobacco) in developed countries similar to Australia (such as the United Kingdom, New Zealand, the European Union and the United States), including but not limited to legislative and regulatory frameworks.

We recommend the Committee seek assistance from the independent Parliamentary Library (Research Branch) to undertake and complete this assessment noting Committee timeframes and the breadth of this question. We recommend ongoing independent research and monitoring of these

¹ World Health Organization (WHO). Ratified by Australia on 27/10/04.

² McDonald, Christine F, et al. "Electronic Cigarettes: A Position Statement from the Thoracic Society of Australia and New Zealand." *Respirology (Carlton, Vic.)*, vol. 25, no. 10, 2020, pp. 1082–1089, National Academies of Sciences, Engineering, and Medicine. *Public Health Consequences of E-Cigarettes*. Washington, DC, The National Academies Press, 2018. Schraufnagel, Dean E, et al. "Electronic Cigarettes. A Position Statement of the Forum of International Respiratory Societies." *American Journal of Respiratory and Critical Care Medicine*, vol. 190, no. 6, 2014, pp. 611–618.

matters. We also caution, noting Australian sovereignty of law and uniqueness of character, that direct comparisons (or application) to the Australian situation and population may not be viable.

The impact nicotine vaping products have on smoking rates in these countries, and the aggregate population health impacts of these changes in nicotine consumption.

See answer to (a).

The established evidence on the effectiveness of e-cigarettes as a smoking cessation treatment.

E-cigarettes are not an approved smoking cessation aid anywhere in the world.

The Therapeutic Goods Administration has noted that “[the nicotine being used in e-cigarettes, e-juice, heat-not-burn tobacco products, chewing tobacco and snuff] ... **has not been approved by the Therapeutic Goods Association (TGA), nor by any equivalent foreign medicines regulator, as a smoking cessation aid.**”³

Consequently, until such approval occurs, these nicotine containing products must not be used as a smoking cessation aid. It is a fundamental tenet of the Australian health regulatory regime to protect the health of Australians from avoidable harm, including respiratory disease and addiction. Use of unapproved, addictive products undermines this fundamental premise.

Nicotine occurs naturally in the leaf of the tobacco plant, and in smaller concentrations in other plants. In the Australian legal system, nicotine is listed in the Commonwealth *Poisons Schedule* because it is well-established that nicotine is an addictive drug and harmful to human health. In Australia, nicotine is no longer used in veterinary or agricultural products because it has been superseded by safer and more effective products.

Nicotine is a chemical substance that changes brain function, to create a physical dependence⁴. Nicotine is highly deceptive; it says one thing to the brain (reward for choice) and does another to the body (creates dependency on that same “choice”). When absorbed by the body, nicotine activates the mesolimbic system (the reward pathway in the brain) by increasing dopamine release in the central nervous system (this makes recipients ‘happy’); at the same time it enhances the activity of locomotor endurance that preserves appetite behaviours focused on seeking and self-administration of the substance⁵. In short nicotine tricks people into dependence through an apparent self-control/choice activity focussed on a vaping/smoking/chewing action. Nicotine can impact the development of the parts of the brain that control attention, learning, mood and impulse control. Young people are particularly susceptible to the effects of nicotine. The TGA note that there is evidence that nicotine use (from smoking or from use of e-cigarettes) can harm the human adolescent brain.

³ Interim decision on proposed amendments referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #25, June 2020), dated 23 September 2020.

⁴ Benowitz. “Nicotine addiction” (2010) 362 N Engl J Med 2295

⁵ Preedy. *Neuroscience of Nicotine : Mechanisms and Treatment*. Academic Press, 2019.

Tobacco – whether chewed, smoked or heated is a particularly efficient and effective vehicle for delivering nicotine⁶. In fact, published research has determined that tobacco delivered nicotine is not only *more toxic*, but more *addictive* than nicotine in a pure form (e.g. nicotine replacement therapy)⁷. The nicotine in e-cigarettes is equally efficient and addictive: the inhalation of aerosol from a nicotine-containing e-cigarette leads to peak serum nicotine concentration within 5 minutes. This rapidity of systemic delivery, combined with a method of use that is the same as that used for conventional cigarettes (i.e. oral inhalation) results in an experience for the user that is closer to cigarette smoking than the forms of nicotine replacement therapy (NRT) that have been approved by relevant authorities⁸.

It is widely acknowledged and documented that tobacco companies alter both the tobacco and nicotine used in their products to maximise the addictive properties of their products⁹.

Nicotine is not the only addictive substance used in e-cigarettes. Most nicotine e-cigarettes contain flavours, and emerging research suggests that the flavours (such as “green apple”) used in non-nicotine e-cigarettes, which are available in Australia as a consumer product, are as addictive as nicotine¹⁰. The National Health and Medical Research Council advises that flavoured e-cigarettes may expose users to chemicals and toxins such as formaldehyde, heavy metals, particulate matter and flavouring chemicals, at levels much higher than cigarettes, that have the potential to cause adverse health effects. Recent research, to be released in December 2020, commissioned by Lung Foundation Australia and Minderoo Foundation has identified a significant range of harmful chemicals in flavoured e-cigarettes sold in Australia. Many of these chemicals are known toxicants/poisons and cause adverse health impacts.

Approved smoking cessation methods – such as NRT are specially designed **not to be addictive**. The nicotine in NRT products reaches the brain slowly. People using approved NRT products are not trading one nicotine addiction for another because the likelihood of long-term dependence on NRT is low. These products have also been assessed as safe for humans to use as their side effects are minimal (e.g. headaches). The use of NRT (such as patches and gum) and oral medications (such as varenicline), promotes recovery from the deleterious effects of smoking on the lungs, hearts and other organs. Studies have consistently demonstrated that individuals quitting smoking via these methods can improve their respiratory function and avoid the excessive decline in their lung function that long-term smoking frequently causes¹¹. Smoking cessation, at any age, reduces the risk of cardiovascular diseases, Chronic Obstructive Pulmonary Disease (COPD), poor reproductive health and many types of cancer¹².

E-cigarettes cause known and unknown harms to human health.

As opposed to other approved smoking cessation medicines, the health impacts of e-cigarettes and smokeless tobacco products are **largely unknown**. However, all of these products have been

⁶ London, Edythe, et al. *Nicotine Psychopharmacology*. 1st ed. 2009. ed., Springer Berlin Heidelberg: Imprint: Springer, 2009, p. 462

⁷ *Ibid.*

⁸ Dinakar, Chitra, and O'Connor, George T. "The Health Effects of Electronic Cigarettes." *The New England Journal of Medicine*, vol. 375, no. 14, 2016, pp. 1372–1381.

⁹ Wayne and Carpenter, "Tobacco Industry Manipulation of Nicotine Dosing", in London, Edythe, et al. *Nicotine Psychopharmacology*. 1st ed. 2009.ed., Springer Berlin Heidelberg : Imprint: Springer, 2009.

¹⁰ Cooper, Skylar Y, Akers, Austin T, & Henderson, Brandon J. (2020). Green Apple e-Cigarette Flavorant Farnesene Triggers Reward-Related Behavior by Promoting High-Sensitivity nAChRs in the Ventral Tegmental Area. *eNeuro*, 7(4), ENEURO.0172–20.2020. <https://doi.org/10.1523/ENEURO.0172-20.2020>

¹¹ See: US Department of Health and Human Services. *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2014. Willemsse, B.W.M, et al. "The Impact of Smoking Cessation on Respiratory Symptoms, Lung Function, Airway Hyperresponsiveness and Inflammation." *European Respiratory Journal*, vol. 23, no. 3, 2004, pp. 464–476.

¹² *Ibid.*

demonstrated to cause short-term adverse health effects including nausea, vomiting, mouth and airway irritation, chest pain and palpitations.

Strong, credible evidence has found that e-cigarettes and heat-not-burn devices change lung cells and functioning, increase the risk of respiratory diseases, cardiovascular diseases, and cancer; cause slower wound healing, gum diseases, and eye irritation; and adversely impact the central nervous system. E-cigarettes have caused poisonings and deaths. As of January 7, 2020, a total of 2558 hospitalized patients with nonfatal cases and 60 patients with fatal cases of e-cigarette, or vaping, product use–associated lung injury (EVALI) had been reported to the Centers for Disease Control and Prevention (CDC) in the United States¹³. E-cigarette related deaths are not restricted to the United States. In the UK, respiratory failure caused by lipoid pneumoniae was reported in 2018 and the death of a 57-year-old male, back in 2010, was found to be directly linked to e-cigarette use after he suffered lipoid pneumonia ¹⁴. Similarly, in Belgium, the death of an 18-year-old male was recently reported as directly attributable to EVALI¹⁵.

In May 2018, an Australian toddler died following the ingestion of liquid nicotine prepared for use in e-cigarettes¹⁶.

E-cigarette liquids are chemically unstable, creating compounds that have toxicological properties that differ from the original chemicals¹⁷. The extent and type of health impacts of these toxic chemicals is not yet fully known.

These products are not safe to human health.

Furthermore, there are no standard or chemically consistent e-cigarettes, and devices have modifiable heat settings; in other words, every use will deliver a different set of chemicals, reactions and harms. The Thoracic Society of Australia and New Zealand (TSANZ) and others including the US Surgeon General, have noted that “drawing conclusions about absolute exposure levels and associated risk based on comparisons between e-cigarettes and combustible tobacco use is not possible. There are thousands of e-liquid solution variants and a range of devices with different settings¹⁸.”

E-cigarettes and other novel nicotine products may cause infinitely, varied degrees and types of harms over short and long periods.

The EVALI outbreak in the US, at the very least, demonstrates that the variable and changeable nature of these products can cause significant damage to individuals. However, we also note that the full causes of the EVALI outbreak remain undetermined: “One of the main causes of the EVALI outbreak is thought to be vitamin E acetate, which has been added to vaping products as a diluent; [however] the exact causes of the outbreak, which are probably multifactorial, are likely to remain uncertain, although research is ongoing¹⁹.”

¹³ Werner, Angela K, et al. “Hospitalizations and Deaths Associated with EVALI.” *The New England Journal of Medicine*, vol. 382, no. 17, 2020, pp. 1589–1598.

¹⁴ Miyashita, Lisa, and Foley, Gary. “E-Cigarettes and Respiratory Health: the Latest Evidence.” *The Journal of Physiology*, 2020, pp. The Journal of physiology, 2020–06-18.

¹⁵ *Ibid.*

¹⁶ <https://www.coronerscourt.vic.gov.au/liquid-nicotine-awareness-needed>

¹⁷ Erythropel, Hanno C, et al. “Flavorant–Solvent Reaction Products and Menthol in JUUL E-Cigarettes and Aerosol.” *American Journal of Preventive Medicine*, vol. 57, no. 3, 2019, pp. 425–427.

¹⁸ McDonald, Christine F, et al. “Electronic Cigarettes: A Position Statement from the Thoracic Society of Australia and New Zealand.” *Respirology (Carlton, Vic.)*, vol. 25, no. 10, 2020, pp. 1082–1089.

¹⁹ Medicine, The Lancet. “The EVALI Outbreak and Vaping in the COVID-19 Era.” *The Lancet Respiratory Medicine*, vol. 8, no. 9, 2020, p. 831.

There is no evidence that e-cigarettes provide a mechanism for ending nicotine addiction that is safer or more effective than the current medicines and services.

There is currently an absence of strong, population level evidence that e-cigarettes are a reliable, safe and effective method to end smoking and nicotine addiction.

The recently released Cochrane review²⁰, the foreshadowed Australian National University review of the evidence and efficacy of e-cigarette use for smoking and nicotine cessation²¹, and the US Surgeon General's 2020 report on Smoking Cessation²² conclude that more reliable, large-scale studies are needed to confirm whether e-cigarettes are more efficacious than existing smoking cessation methods to completely end nicotine addiction and at what cost. We note that a recent randomized trial investigated the efficacy of e-cigarettes compared with nicotine replacement therapy, in addition to face-to-face cessation counselling, in smokers attending a smoking cessation service. At 1 year, the rate of continuous abstinence from smoking traditional cigarettes among e-cigarette users was 18.0% compared to 9.9% in the nicotine replacement group (relative risk: 1.83; 95% CI: 1.30–2.58; $P < 0.001$). However, after 1 year, 80% of e-cigarette users continued to use e-cigarettes, whereas 9% of nicotine replacement therapy users were still using nicotine replacement²³.

Furthermore, there is emerging evidence that suggests e-cigarette use counteracts attempts at smoking cessation, by increasing a smokers' desire to use tobacco cigarettes, as opposed to approved NRT methods²⁴. A systematic literature review conducted by the ANU has found that former smokers who have used e-cigarettes are around twice as likely to relapse and resume current smoking than former smokers who have not used e-cigarettes²⁵.

Currently, there are existing quit options available which are proven to be both safe and more effective at ending nicotine addiction than novel nicotine products. These products also encourage restoration or improvement of the respiratory health of the smoker.

Harm reduction and the road to respiratory recovery occurs the moment a person starts NRT. We are mindful that the goal for quitting is ending nicotine addiction and restoring/repairing lung and other physical functions. Current approved NRT and quit medicines and methods meet this goal.

If a person uses e-cigarettes in an attempt to quit smoking, harm reduction **will not occur until they stop using** the e-cigarettes (and the tobacco cigarettes). By using e-cigarettes, individuals may, in fact, be causing new and unknown harm to their respiratory system and overall health. Research has found that around 80% of people who use e-cigarettes to quit smoking are still using the nicotine e-cigarettes 12 months later²⁶.

²⁰ Hartmann-Boyce J, McRobbie H, Lindson N, Bullen C, Begh R, Theodoulou A, Nottley C, Rigotti NA, Turner T, Butler AR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2020, Issue 10. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub4.

²¹ See Banks E, Beckwith K, Joshy G. Summary report on use of e-cigarettes and impact on tobacco smoking uptake and cessation, relevant to the Australian context. Commissioned Report for the Australian Government Department of Health, September 2020. Available at <http://hdl.handle.net/1885/211618>.

²² Adams, Jerome M. "Smoking Cessation—Progress, Barriers, and New Opportunities: The Surgeon General's Report on Smoking Cessation." *JAMA : the Journal of the American Medical Association*, vol. 323, no. 24, 2020, pp. 2470–2471.

²³ Hajek P, Phillips-Waller A, Przulj D, Pesola F, Myers Smith K, Bisal N, Li J, Parrott S, Sasieni P, Dawkins L *et al*. A randomized trial of E-cigarettes versus nicotine-replacement therapy. *N. Engl. J. Med.* 2019; **380**: 629–37.

²⁴ King, Andrea C, *et al*. "Passive Exposure to Electronic Cigarette (e-Cigarette) Use Increases Desire for Combustible and e-Cigarettes in Young Adult Smokers." *Tobacco Control*, vol. 24, no. 5, 2015, pp. 501–504.

²⁵ "E-Cigarette Use and Combustible Tobacco Cigarette Smoking Uptake among Non-Smokers, Including Relapse in Former Smokers: Umbrella Review, Systematic Review and Meta-Analysis." *Obesity, Fitness, & Wellness Week*, 2020, p. 1192.

²⁶ Please see Banks E, Beckwith K, Joshy G. Summary report on use of e-cigarettes and impact on tobacco smoking uptake and cessation, relevant to the Australian context. Commissioned Report for the Australian Government Department of Health, September 2020. Available at <http://hdl.handle.net/1885/211618>.

There is no evidence that e-cigarettes provide a mechanism for ending nicotine addiction that is safer or more effective than the current medicines and services.

E-cigarettes are not a harm reduction smoking cessation method.

The tobacco industry has a history of making harm reduction claims about their products. In particular, they have argued that e-cigarettes are a harm reduction product that provides an alternative pathway for smokers who are unable or unwilling to quit²⁷.

There is no evidence that there are large numbers of Australian smokers who are unwilling or unable to quit. In fact, there is emerging evidence that Australian smokers want to quit and need more mental health support to do so²⁸. The concept of 'hard-core' smokers arises from the hardening hypothesis. This hypothesis predicts that as smoking prevalence declines, remaining smokers will be more heavily addicted to nicotine and/or less interested in quitting. These remaining smokers are labelled 'hard-core' or 'hardened' smokers. The hardening hypothesis, as it is commonly formulated, is **largely unsupported** by the evidence, at least from high-income countries with advanced tobacco control programmes and low smoking prevalence²⁹.

Current Australian evidence points to smokers softening, changing their habits and expressing a stronger desire to quit³⁰.

We note that the Pharmaceutical Benefits Advisory Committee is currently undertaking a post-market review of smoking cessation medicines and that this, in conjunction with emerging research and advice on improving the current availability of subsidised nicotine replacement therapy, medical and psychological support, provides an opportunity for the Australian Government to enhance and strengthen current safe and evidence-based services to better support smokers wishing to quit. We encourage the Committee to focus on improving the current system and ensuring that those Australians wishing to end nicotine addiction have access to evidence-based information, and best-practice subsidised services and support.

Currently, the best way to support Australians to quit smoking is by improving knowledge of current, safe and effective methods and providing timely and subsidised access to best-practice services and approved medical interventions.

The established evidence on the uptake of e-cigarettes amongst non-smokers and the potential gateway effect onto traditional products.

Despite a decrease in the prevalence of smoking across Australia, the prohibition on the sale of nicotine e-cigarettes and the restricted sale of flavoured e-cigarettes, the most recent Australian National Drug Strategy Household Survey revealed an increase in use of e-cigarettes (both nicotine and flavoured) for Australians:

- aged 14-19 - lifetime use rose from 12.6% in 2016 to 14.5% in 2019
- aged 18-24 - lifetime use rose from 19.2% in 2016 to 26% in 2019
- aged 25-29 - lifetime use rose from 14.8% in 2016 to 20% in 2019³¹.

²⁷ See Therapeutic Goods Administration final decision on an application to allow nicotine for use in e-cigarettes to be commercially sold in Australia, dated 23 March 2017, at <https://www.tga.gov.au/book-page/21-nicotine-0>.

²⁸ Brennan, Emily, et al. "Hardening or Softening? An Observational Study of Changes to the Prevalence of Hardening Indicators in Victoria, Australia, 2001–2016." *Tobacco Control*, vol. 29, no. 3, 2020, pp. 252–257

²⁹ Edwards, Richard. "Hardening Is Dead, Long Live Softening: Time to Focus on Reducing Disparities in Smoking." *Tobacco Control*, vol. 29, no. 3, 2020, pp. 250–251.

³⁰ Ibid 28.

³¹ Australian Institute of Health and Welfare. National Drug Strategy Household Survey 2019. AIHW, 2020.

While young Australians are generally not trying or taking up conventional cigarettes, they are trying and taking up e-cigarettes.

Firstly, as noted above, e-cigarettes create known and unknown harms to human health, as they contain chemicals known to cause cancer, heart disease and other illnesses. Flavoured e-cigarettes, which are popular among young Australians contain chemicals used to create flavours which are harmful to health – diacetyl which has been found in 75% of flavoured e-cigarettes has been linked to severe respiratory disease³².

Secondly, research demonstrates that e-cigarettes act as a gateway to conventional cigarettes. ANU's systematic review of data from current reviews and primary research studies concludes that never smokers who have used e-cigarettes were, on average, around **three times as likely** as those who have not used e-cigarettes to try smoking conventional cigarettes and transition to regular tobacco smoking³³.

Lung Foundation Australia members and supporters are acutely aware of the dangers of introducing unknown and unproven products to Australians. In a survey conducted by Lung Foundation Australia in February 2020 (pre-COVID-19) on nicotine products, 80% of respondents believed that Australian Governments **have not learned lessons** from past public health disasters (e.g. allowing mass produced tobacco products into Australia and the sale and use of asbestos).

To prevent another outbreak of respiratory disease in the next generation of Australians, we urge the Committee to dispassionately review the evidence, listen to the advice of health experts and maintain the momentum of lessons learned during the COVID-19 pandemic; **strong respiratory health is essential for a strong, socially cohesive and economically prosperous Australia.**

Evidence of the impact of legalising nicotine vaping products on youth smoking and vaping rates and measures Australia could adopt to minimise youth smoking and vaping.

Young Australians 14-19 years of age.

In the most recent Australian National Drug Strategy Household Survey, an increase in use of e-cigarettes was reported for Australians aged 14-19; lifetime use of e-cigarettes rose from 12.6% in 2016 to 14.5% in 2019³⁴. Yet, 96% were never smokers.

The rise in the use of novel nicotine and flavoured e-cigarettes to almost 15% of this population cohort is concerning because:

- i. E-cigarettes are addictive and harmful to health (see above). Early initiation of nicotine is highly likely to lead to life-time use, and nicotine exposure during adolescence may have neurobiological consequences that persist into adulthood. Long-term effects of adolescent nicotine use include deficits in learning and memory³⁵. Animal studies have found persistent cellular damage in the midbrain, hippocampus, and cerebral cortex following adolescent

³² J.G. Allen, *et al.* Flavoring chemicals in e-cigarettes: diacetyl, 2, 3-pentanedione, and acetoin in a sample of 51 products, including fruit-, candy-, and cocktail-flavored e-cigarettes
Environ. Health Perspect. (2015)

³³ *Ibid* 13.

³⁴ *Ibid*.

³⁵ The Wiley Handbook on the Cognitive Neuroscience of Addiction, edited by Stephen J. Wilson, John Wiley & Sons, Incorporated, 2015.

nicotine exposure³⁶. Furthermore, it is likely that long-term use of e-cigarettes will lead to significant adverse health outcomes, such as cancer and heart disease;

- ii. There is strong emerging evidence that e-cigarettes act as gateway to combustible cigarettes (see above).

In addition, to the evidence cited in the ANU review above, the Irish Health Research Board, on 12 October 2020, published a report which had very similar findings demonstrating that teenagers are between three and five times more likely to start smoking if they have used e-cigarettes previously.

Lung Foundation Australia believe that Australian governments need to examine a variety of policy responses to prevent the next generation of Australians from experiencing preventable lung disease. These policy options include:

- Educating young Australians on the health, well-being, social and economic impacts of nicotine or chemical addiction,
- Raising the age at which individuals can purchase tobacco or e-cigarette products, in order to phase out the sale of combustible cigarettes,
- Prohibiting the purchase of combustible cigarettes to people born in certain years (to phase out their sale),
- Restricting the sale of combustible cigarettes to limited licenced outlets or specific authorities in each state and territory,
- Prohibiting the importation of nicotine e-cigarettes,
- Prohibiting the importation of flavoured e-cigarettes,
- Enforcing consumer law through robust monitoring and testing of nicotine products and prosecutions,
- Assisting Australians impacted by addiction and false and misleading health claims to pursue legal actions against the manufacturers of novel nicotine or chemical products,
- Legislating to ban political donations and representations from tobacco or e-cigarette industry groups or individuals, and
- Legislating to ensure media outlets, do not publish false and misleading claims about tobacco, nicotine or chemical products, either as opinion pieces or journalistic content, and
- Supporting Australians to take action against media companies that publish false and misleading information leading to addiction and disease.

Access to e-cigarettes products under Australia's current regulatory frameworks.

As outlined above, flavoured e-cigarettes are freely available for purchase by any Australian over the age of 18 as a consumer item. Lung Foundation does not support the sale of flavoured e-cigarettes as a consumer item and calls on the Government to end this practice to protect the lung health of all Australians.

Nicotine e-cigarettes are legally available via the TGA's personal importation scheme. We understand that individuals can source nicotine e-cigarettes online and have the items posted to their home address.

The TGA has proposed to reschedule nicotine in the *Poisons Schedule*, to in effect, require that a legal prescription must be issued by a medical practitioner for lawful possession and use of all nicotine

³⁶ *Ibid.*

products, other than those exempted (combustible cigarettes and over the counter oromucosal and transdermal nicotine replacement therapies). Most of these nicotine products will **not** be assessed for safety, toxicity and health impacts, as this scheduling, and the listing of nicotine as a “medicine of established use” means e-cigarettes, heat-not-burn products, snuff, chewing tobacco and other novel nicotine products will be available as “unapproved therapeutic products” via prescription.

Lung Foundation Australia does not support this amendment as it stands.

At this stage, introducing new, untested and unknown nicotine products to Australians trying to quit tobacco and nicotine addictions is not supported by Lung Foundation Australia members and supporters. It is an approach that exposes vulnerable Australians to an unnecessary health risk placing them effectively in a risky, speculative population-level experiment.

Importantly, scheduling all nicotine products, such as e-cigarettes and heat-not-burn devices as prescription only medicines and listing nicotine as a medicine with a well-established history of use:

- Provides implicit approval to the manufacturers and consumers of nicotine products, through the “unapproved therapeutic goods” pathway, that their products, are in fact *therapeutic* products, **in the absence** of strong, credible evidence to this effect and **in the absence** of an application by manufacturers to the TGA to test the safety and efficacy of those products before providing them to Australians as therapeutic goods, **and**
- Transfers responsibility for the safety, efficacy and physical impact of these products to the medical professionals prescribing, and possibly, dispensing the unapproved therapeutic nicotine products. That responsibility may also be shared with the consumer. We note that there is no standardised e-cigarette liquid; ingredients vary, are often not described accurately or at all on labels, and consumers can create their own mixtures and modify doses and heating of liquids dependent on the e-cigarette device used. We do not believe that such modifiable, “free-form” products should be characterised as medicines.

We believe that any manufacturer of a nicotine product who claims that their product can *end nicotine addiction*, must have that product **assessed for safety and efficacy** according to Australian law and prove that the usage regime **ends** nicotine addiction. The interim decision and established use listing relieves a manufacturer of this obligation, thus exposing medical practitioners, importers and individual Australians to unseen, unmeasured and unknown impacts and liabilities.

We maintain the view that all nicotine products for use as smoking cessation aids should be submitted to the TGA to review their safety and efficacy before they can be prescribed to Australians.

We believe that all novel nicotine products and flavoured e-cigarettes should be prohibited by import bans and enforced accordingly.

Tobacco industry involvement in the selling and marketing of e-cigarettes.

The creation of the modern e-cigarette device is credited to Hon Lik, a Chinese pharmacist, who commercialised the modern vaping method in 2003. Almost all (90%) e-cigarette products sold globally are made in China, where there are around 1,000 manufacturers.

Transnational tobacco companies have made significant financial investments in acquiring start-up vape companies and developing new commercial e-cigarette lines. British American Tobacco (BAT) owns the global brand Vuse (which consolidates Vype, Ten Motives, Chic, VIP brand) and VELO (BAT has recently acquired Dryft Sciences, LLC (Dryft)). When making the acquisition, markets noted that this acquisition expands BAT's Modern Oral portfolio in the US, from 4 to 28 product variants: “The enhanced portfolio will include a wider range of nicotine strengths and flavours providing adult

nicotine consumers with a greater degree of choice, covering all key consumer preferences. This will significantly strengthen BAT's portfolio in a fast-growing nicotine category in the US"³⁷. Philip Morris International (PMI) own IQOS Mesh and has a significant stake in JUUL. Lorillard own the brand 'blueCig'. Japan Tobacco International own 'Logic' and 'Ploom' and Imperial Tobacco have 'Puritane'.

The tobacco industry fund research and various foundations and lobby groups to prosecute their claims and further their economic interests.

We commend to the Committee, the submissions made by TSANZ and Cancer Council on this matter.

Any other related matter.

The COVID-19 pandemic has led to unprecedented public health policies to protect Australians from respiratory disease. These policies have come at huge economic and social cost yet have been broadly accepted and followed by the public. Unemployment has increased by 228,100 over the year to stand at 937,400³⁸. The most affected industries, such as accommodation, food, arts and recreation and transport have no direct adverse health effects in themselves. So far, Australia has contained COVID19 deaths to less than 1000 people. Globally, the final COVID19 death toll is uncertain but has reached 1.2million. The strongest risk factor for COVID19 fatality is older age, with the highest death rates occurring in those over 70 years old.

In contrast, tobacco use is responsible for more than 8 million deaths globally per annum, including 65,000 children who die from illnesses attributable to second-hand smoke. About half of all tobacco-related deaths occur at ages 35-69 years, making tobacco the most important cause of premature death in developed countries. In Australia, 2015, about one quarter of the estimated 21,000 tobacco-related deaths were in individuals aged between 35 and 69, who lost, on average, 23 years of life each, a total of 443,235 years of healthy life lost. The Australian tobacco industry directly employs fewer than 2000 staff.

Ostensibly hoping to achieve 'harm reduction' through adoption of e-cigarettes will do nothing to alter these stark statistics.

However, the robust Australian response to COVID-19, applauded internationally, proves that public health driven policy to protect the health of the nation is supported by the people. The benefits of ending nicotine as a consumer product in Australia will yield far greater gains than we have seen for COVID-19 at a far lower cost.

Any recommendation from the Select Committee to regulate e-cigarettes, heat-not-burn devices and other novel nicotine delivery systems as consumer products, particularly in response to tobacco industry pressure, would be a significant backwards step for Australian public policy and run counter to the overwhelming support amount Australians to protect and strengthen the nations respiratory health.

³⁷ See: <https://au.advn.com/p.php?pid=nmona&article=83591375>. Accessed 4 November 2020.

³⁸ <https://www.abs.gov.au/statistics/labour/employment-and-unemployment/labour-force-australia/latest-release>