REGULATION OF NICOTINE E-LIQUIDS FOR VAPING IN AUSTRALIA

DISCUSSION PAPER
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Australian Tobacco Harm Reduction Association

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Executive summary

Nicotine vaping is widespread in Australia but remains unregulated without safety standards. This discussion paper provides a framework for a national approach to regulating vaping liquids which balances the considerable benefits for public health while minimising potential risks to the community.

The decline in Australian smoking rates has slowed considerably since 2013, despite strict tobacco control policies, plain packaging and the highest tobacco prices in the world. However, the decline in smoking rates has accelerated in other countries like the US and UK where nicotine vaping is legal.

Nicotine vaping is the most effective and most popular quitting aid globally. There is overwhelming scientific agreement that vaping nicotine is far safer than smoking. However, Australia remains the only western democracy to ban the sale and use of nicotine for vaping. The public health benefits are well recognised and countries like the UK and New Zealand cautiously promote it as a safer alternative to smoking.

There is a compelling case for Australia to ease restrictions and implement carefully balanced regulations that protect consumers without compromising the considerable potential benefits.

Nicotine vaping is a form of 'tobacco harm reduction'. Vaping is not risk-free, but it is a far less harmful alternative for smokers who are unable to quit and would otherwise continue to smoke. Almost all the harm from smoking is caused by the thousands of toxic chemicals released when tobacco is burned, while most of these toxins are either absent or are present at very low levels in e-liquid vapour. The UK Royal College of Physicians and Public Health England estimated that long-term vaping is unlikely to be more than 5% of the risk of smoking. Modelling and simulation studies have predicted a significant net long-term public health benefit. Much has been made of a recent outbreak of serous lung injuries (EVALI) in the US. However, this was found to have been caused by vitamin E contamination in unregulated black-market e-liquids containing THC.

Tobacco addiction is very difficult to treat due to the addictive properties of nicotine as well as the social and ritualistic aspects of smoking. Nicotine replacement products (patches, sprays, inhalers, lozenges) and prescription therapies (Champix, Zyban) have low success rates. Research has found that smokers who vape nicotine have higher quit rates.

Nicotine vaping provides the nicotine smokers are addicted to as well as the hand-to-mouth ritual and sensations of smoking. This makes it a satisfying alternative for smokers who are unable to quit using other methods. Vaping is almost exclusively used by smokers and ex-smokers, with little credible evidence that it serves as a gateway to smoking among adults or youths. Fewer than 1.3% of Australian 14-17-year-olds non-smokers vaped once or more in the past year. Most youth consumption is experimental and short lived. Regular vaping is rare among those who have never smoked, regardless of age.

Many smokers have successfully quit by substituting tobacco with nicotine vaping products. However, vaping has proven highly controversial in Australia, attracting considerable support as well as criticism among health professionals and throughout society. Australian medical professional associations are gradually acknowledging the benefits of legalised vaping as a public health measure, including the Royal Australian and New Zealand College of Psychiatrists, The Royal Australian College of General Practitioners and the Royal Australasian College of Physicians. The Australian Medical Association (AMA) does not currently favour legalised vaping, however the support of the British Medical Association, the UK Royal College of Physicians and the New Zealand Medical Association suggest the AMA's position no longer reflects best-practice.

History teaches us prohibition is rarely effective and risks new, dangerous supply chains being established by criminal gangs. The Australian Government established an Illicit Tobacco Taskforce in 2018 to combat an illegal tobacco trade with an estimated value of $1.6-3.8 billion a year.

Smoking is far more prevalent among low income and disadvantaged Australians. For this cohort, the punitive effect of excessive prices is harder to justify when a far safer and cheaper alternative to smoking is restricted from sale. New regulations proposed by the Department of Health include a disproportionate penalty of $220,000 for vapers who import nicotine liquid from 1 January 2021. Vapers currently face harsh fines of up to $45,000 and jail terms of up to 2 years for possessing nicotine liquid to quit smoking without a prescription.

Making a safer and far less costly nicotine option will help low income people at a time of great financial and emotional stress.

An estimated 522,000 Australians currently vape using nicotine e-liquids purchased online from overseas retailers and the black market. The supply and sale of these products is not currently subject to product safety and consumer protection laws. This creates a heightened risk of consumers being exposed to unsafe products, as well as putting children at risk from unsafe containers (although serious poisoning is extremely rare).

However, Australia does not have to choose between banning nicotine e-liquid sales and allowing their unregulated use. By drawing on the experiences of countries like the UK and New Zealand, we can address legitimate concerns about legalised vaping while simultaneously allowing smokers to receive the considerable health benefits associated with making the switch. The recommendations outlined below are proposed as the basis of a regulatory framework to achieve this. Regulations should be reviewed at regular intervals as more evidence emerges from research and experience

We emphasise that legalised nicotine vaping is not a silver bullet that will rid Australia of tobacco smoking. Nicotine vaping is a harm reduction measure that will complement existing tobacco control and smoking cessation measures and enhance their effectiveness.

With careful management and proportionate regulation, legalised nicotine vaping provides an opportunity to improve the lives of millions of Australians. It is an opportunity that, with care, we should take.

List of recommendations

1. Exempt nicotine e-liquid in concentrations ≤ 5% for vaping from the Poisons Standard
2. Regulate nicotine in concentrations ≤5% as a consumer product
3. Minimise youth access by strict age verification, prohibited youth-friendly packaging, restricted advertising and public health messaging
4. Introduce laws and guidelines specifying minimum standards for the manufacture and safety of vaping liquids
5. Introduce mandatory standards for labelling, refill containers and health warnings
6. Prohibit descriptive flavour names that specifically appeal to youth and unsafe flavouring chemicals
7. Establish a notification scheme for pre-market registration
8. Regulate the sale of nicotine e-liquids in vape shops, other retail outlets and online
9. Permit vaping in specified public spaces and allow owners and managers of premises to set their own regulations
10. Use public health messaging to raise awareness of the health risks relative to smoking tobacco
11. Establish a system for reporting harmful effects and recall of unsafe products

About ATHRA

The Australian Tobacco Harm Reduction Association (ATHRA) is a registered health promotion charity established to help reduce the harm from tobacco smoking in Australia. ATHRA's aim is to provide smokers and health professionals with evidence-based information on safer alternatives to smoking. ATHRA's broader goal is to encourage the complete cessation of tobacco smoking in Australia.

ATHRA was established by medical practitioners with a special interest in tobacco, harm reduction and public health. The Board Members have special expertise in this field and play an active role in evidence-based education of the public and health professionals and policy advice in Australia.

ATHRA is funded by public donations. ATHRA does not accept donations from tobacco companies, their subsidiaries or the vape industry. ATHRA accepted financial support from the small retail vape sector to help establish the charity in 2017 but has not accepted any industry funding since March 2019.

Board members do not receive any financial payments. None have ever received funding or payments of any kind from the vaping or tobacco industry and have no commercial relationships with those industries. Board members do not have any pecuniary interest whatsoever in the promotion of nicotine vaping.

Board members

Dr Joe Kosterich (Chairman)

Dr Colin Mendelsohn

Dr Alex Wodak AM

Mr Ean Alexander

Contents

Smoking and quitting rates in Australia

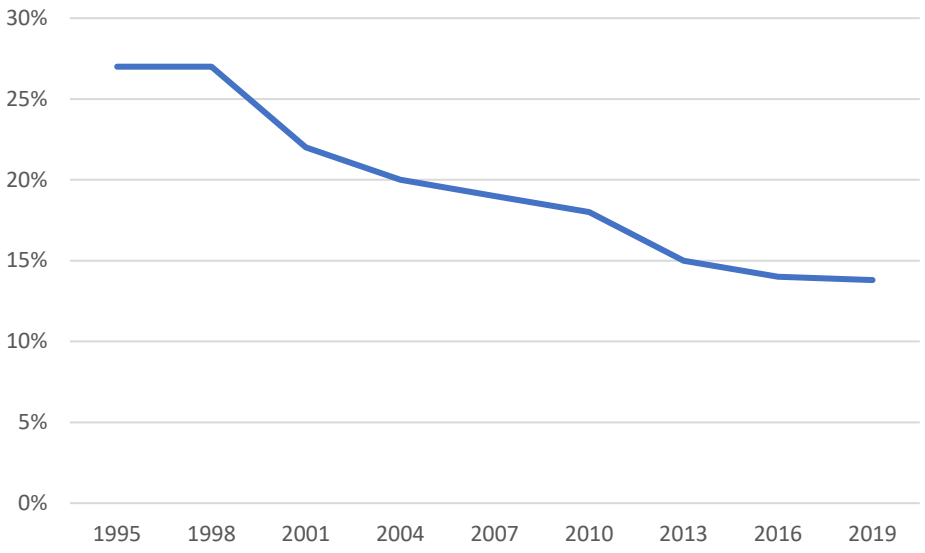
Smoking rates in Australia have declined steadily since the 1970s, but the decline has slowed considerably since 2013 despite plain packaging rules, strict tobacco control and the highest cigarette prices in the world (Figure1). The decline has primarily been driven by reduced uptake rather than successful quitting efforts. [3]

In 2019, 14% of Australians aged 14+ were current daily or non-daily smokers. [4] Smoking remains the leading cause of preventable death and illness in Australia. It accounts for 21,000 deaths annually, [5] 9.3% of the burden of disease [6] with a total annual cost to the community (tangible and intangible) of AUD$136.9 billion [7]. Around two out of three long-term Australian smokers will die prematurely due to smoking, losing an average of 10 years of life. [8]

Smoking rates are higher and quitting rates lower in low-socio-economic groups and remote and rural communities, making smoking a leading cause of health and financial inequalities. [9] These populations are disproportionately affected by smoking-related disease and have higher mortality rates than more wealthy and metropolitan cohorts. Vaping nicotine has the potential to reduce smoking rates and health inequalities. [10]

The high cost of smoking causes considerable financial distress in low income groups and is contributing to financial inequalities. [11] A pack-a-day smoker spends $12,500 per year on smoking ($35 per pack). Vaping is 90% cheaper than smoking and would result in substantial financial savings for the average smoker who switches to vaping.

Figure1: Smoking rates in Australia 1995-2019
ages 14+, daily and non-daily



Source: Australian Bureau of Statistics, July 2020

Success rates in treating tobacco addiction

Tobacco smoking is a powerful addiction and the currently available strategies have very modest long-term success rates of 2-15% after 6-12 months. [12] Treatments include nicotine replacement products, prescription medication, counselling and support. Most smokers want to quit but try and fail repeatedly.

- Forty percent of Australian smokers try quitting at least once a year [13]
- By the age of 40, the average smoker has unsuccessfully tried to quit on 20 occasions [13]
- Ninety-six percent of unaided attempts to quit (no medication or professional support) end in failure [14]

The above data shows that new strategies are urgently needed to help the 2.9 million Australians who continue to smoke tobacco. Careful legalisation and regulation of nicotine vaping represents an opportunity to do so.

Nicotine vaping as a tobacco harm reduction strategy

"Harm reduction is a strategy used in medicine and social policy to minimise harm to individuals and/or wider society from hazardous behaviours or practices that cannot be completely avoided or prevented"

- *UK Royal College of Physicians [1]*

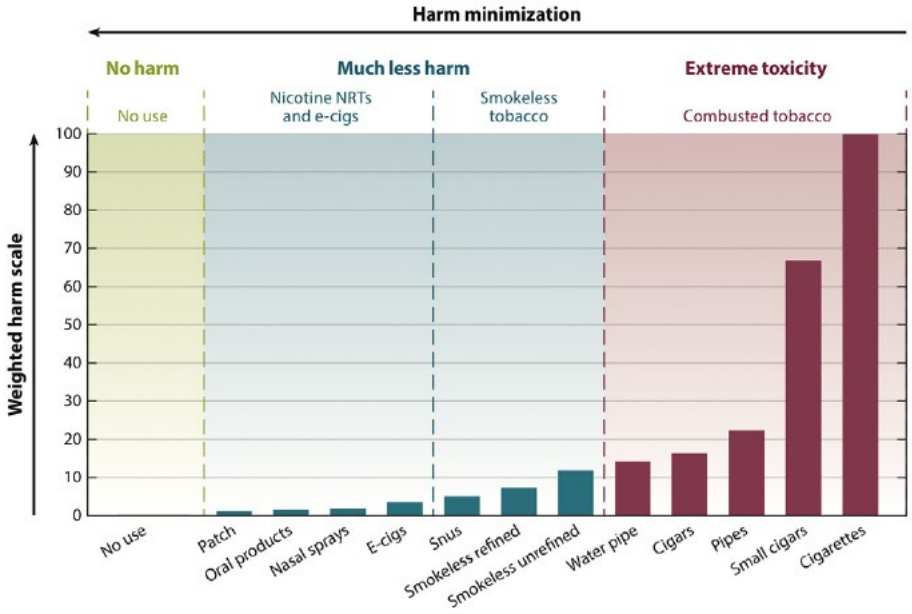
Complete cessation of all tobacco and nicotine is always the ideal goal. However, a large proportion of smokers are unable or unwilling to quit, either unaided or with conventional therapies. This cohort remains at high risk of tobacco-related harm.

Tobacco harm reduction (THR) aims to reduce the health risks in continuing smokers. This involves switching from combustible tobacco to a lower-risk smokeless alternative that delivers the nicotine smokers are addicted to, but without combustion and smoke. Smokeless products are not risk-free but are much safer than smoking.

The focus of THR is to reduce (not eliminate) harm in smokers who would otherwise continue to smoke. It is not intended to prevent the use of nicotine, which has been shown to cause minimal harm to health in the doses used in vaping. Short term vaping is preferred, but some need to vape long-term to prevent relapse to smoking.

Nicotine-containing products exist on a continuum of risk. The health risks depend on how nicotine is delivered. Combustible products such as cigarettes and cigars represent a very high risk, while non-combustible products like nicotine vaporisers, heated tobacco products (HTPs) and snus (oral tobacco pouches) carry a much lower risk (see Figure 2). This discussion paper focuses on vaping products only (e-cigarettes).

Figure 2: Nicotine product risk continuum [15]



Tobacco harm reduction is a supplementary strategy, rather than a substitute for traditional tobacco control measures. THR is one of the three pillars of Australia's National Tobacco Strategy, along with demand and supply reduction. [16] THR is mandatory under the World Health Organisation (WHO) Framework Convention of Tobacco Control to which Australia is a signatory [17].

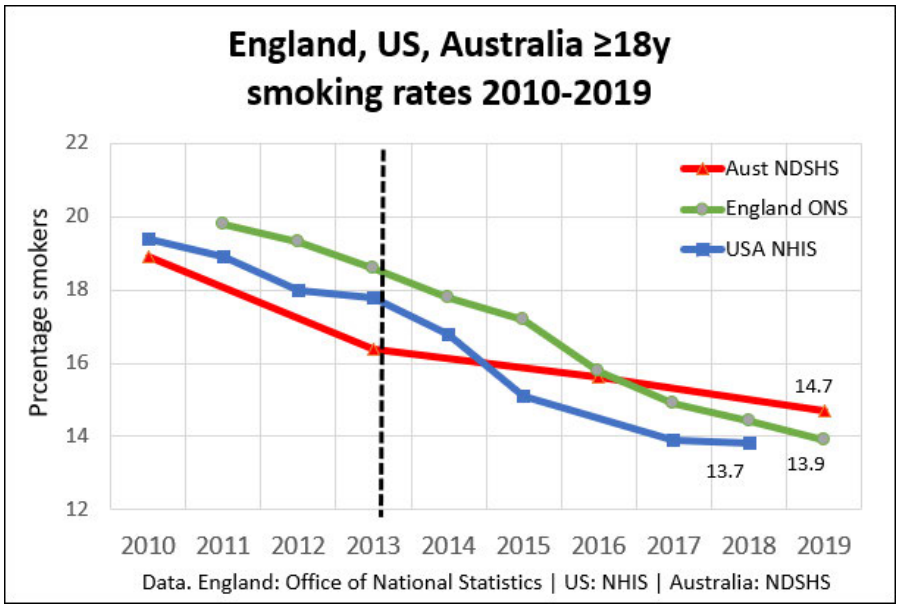
Harm reduction has already been successfully deployed in Australia with great success. Examples include needle exchange programmes and prescription methadone to reduce harm among street heroin users. It is an established public health approach and is an integral principle of the Australian National Drug Strategy. [18]

The role of nicotine vaping for THR is overwhelmingly supported by research that shows it is far less harmful than smoking. [19] It is also the most effective quitting aid and is the most popular quitting aid in countries where it is available. [20]

Nicotine e-liquids are widely and legally available in the UK, USA, New Zealand, Canada and the European Union. This level of access correlates with increasing quit rates and accelerated declines in smoking across those regions. [21] These trends do not appear to be caused by other factors such as tax rises and public health marketing campaigns. [21]

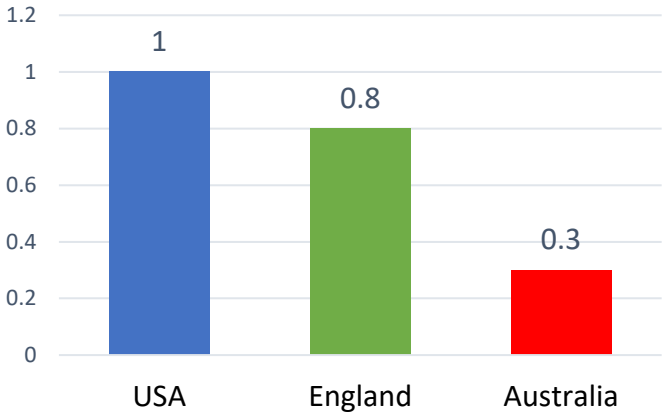
The USA and UK have reported accelerating declines in smoking rates since around 2013, when vaping began gaining popularity. [21, 22] The smoking rates in these countries have fallen substantially faster than in Australia, where progress has significantly slowed in recent years (see Figure3).

Figure3: Smoking rates in England, USA and Australia



Since 2013, the adult smoking rate in Australia has declined by 0.3% per year compared to 0.8% per year in England (2013-2019) and 1% per year in the USA (2013-2018) [4, 22, 23] (see Figure 4).

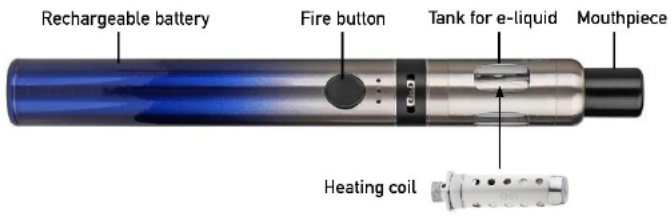
Figure 4: Annual average per cent decline in smoking rate since 2013



The vaping process explained

Nicotine vaping involves heating a liquid solution (e-liquid) to produce a liquid aerosol that the user inhales and exhales as a visible mist. Vaping devices (vaporisers or e-cigarettes) consist of a battery, a tank or reservoir to hold the e-liquid, and a coil or heating element to heat the liquid. The four main categories of vaporiser are outlined in Appendix 1.

Components of a vaporiser



Vaping is unique because it delivers the nicotine smokers are addicted to, while replicating the hand-to-mouth ritual and the sensations and social aspects of smoking. However, vaping does not involve tobacco, combustion or smoke. The toxins in tobacco smoke that cause almost all of the harm to health from smoking are almost entirely absent from nicotine vapour. Those that are present exist in far lower doses.

E-liquid generally consists of four ingredients: flavourings, nicotine, propylene glycol and vegetable glycerine (see Figure 5).

Figure 5: Typical e-liquid ingredients

Flavouring	▪ Food flavourings
Nicotine	▪ The main addictive substance present in tobacco ▪ Considered relatively low-risk in the low doses used in vaping
Propylene glycol	▪ A colourless, odourless organic compound with a light, syrupy consistency ▪ Commonly used in foods, cosmetics and pharmaceuticals ▪ Delivers the 'throat hit' when inhaled
Vegetable glycerine	▪ Viscous liquid with a slightly sugary taste ▪ Commonly used in foods, cosmetics and pharmaceuticals ▪ Primary source of the exhaled vapour

E-liquids commonly come in ready-to-use solutions with a typical nicotine concentration of 0.3-5%. Some more experienced consumers prefer to purchase highly concentrated nicotine (10-20%) that they manually mix with their choice of flavoured e-liquid. These high concentration products cause most cases of accidental poisoning (although extremely rare) and are often sold in large bottles that are not child-proof.

Purchasing nicotine e-liquid in Australia

The sale of e-liquids containing nicotine is banned in Australia. Consumers purchase nicotine e-liquid from overseas websites and some products are procured via the black market.

The Therapeutic Goods Administration (TGA) Personal Importation Scheme allows individuals to legally import 3 months' supply of nicotine e-liquid for personal use to quit smoking or prevent relapse. The scheme requires the user to have a prescription from a registered Australian medical practitioner. Very few consumers have a prescription (ATHRA estimates <1%).

Popularity in Australia

Vaping nicotine is the most popular aid for quitting or reducing smoking in Australia in spite of harsh restrictions on access. [4] According to the National Drug Strategy Household Survey, 522,000 Australians aged 14+ (2.5%) vaped in 2019, an increase from 239,000 vapers in 2016. [4] Vaping's rising popularity represents an opportunity to achieve significant public health benefits.

Flavourings

Flavours are an integral component of vaping which make vaping more appealing as an alternative to smoking. Flavours play an important role in the initiation of vaping for current smokers and in reducing the likelihood of relapse. [24, 25]. Studies show that the use of flavours increases quit rates compared to non-flavoured or tobacco flavours. [26] Banning flavours will have a negative effect overall on public health.

Almost all flavouring chemicals are substances Generally Recognized As Safe (GRAS) for ingestion by the US Flavor Extracts Manufacturers Association. [link] According to Public Health England, "To date, there is no clear evidence that specific flavourings pose health risks but there are suggestions that inhalation of some could be a source of preventable risks". [2]

Certain chemical flavourings have been identified as potentially harmful and should be subject to regulatory control. These flavourings include diacetyl, cinnamaldehyde and benzaldehyde.

Analysis of public health risk

Vaping is not risk-free, but it is beyond reasonable doubt that it is a much less harmful alternative to smoking. Almost all the harm from cigarettes is due to the tar, carbon monoxide and thousands of other toxins produced from burning tobacco.

Research comparing the toxicity of tobacco smoke and nicotine vapour has found:

- a substantial reduction in the number and dose of chemicals in vapour
- a dramatic reduction in toxins and carcinogens in the blood, urine or when tobacco smokers switch to vaping
- improvements in the health of smokers after switching to vaping.

A recent review by the US National Academies of Sciences, Engineering and Medicine found 'substantial evidence that completely switching from regular use of combustible tobacco cigarettes to e-cigarettes results in reduced short-term adverse health outcomes in several organ systems'. [27]

Certain chemical flavourings have been identified as potentially harmful and should be subject to regulatory control. These flavourings include diacetyl, cinnamaldehyde and benzaldehyde.

Common concerns

There is a range of legitimate concerns about vaping. Most risks are small compared to the risk of smoking and some can be mitigated by appropriate risk-proportionate regulation. The key public health issue is the net public health impact after taking into account the magnitude of all the risks and benefits.

Common concerns include:

- Youth uptake
- Uptake by adult non-smokers
- Renormalisation of smoking
- Dual use
- Nicotine safety
- Nicotine poisoning
- Cancer
- Cardiovascular and lung disease
- Second-hand vapour
- Adolescent brain development
- The tobacco industry

"While vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals which are present pose limited danger. There is a need to publicise the current best estimate that using EC is around 95% safer than smoking." [2]

- Public Health England

Youth uptake

Youth vaping rates are low and most use is experimental and infrequent. Regular youth vaping is mostly confined to smokers or ex-smokers and is rare in never-smokers. [28]

In 2019, only 1.3% of 14-17 year old non-smoking Australian youths had vaped once or more during the past year ('non-smokers' includes ex-smokers). [4] The frequency of vaping was not reported, but international research suggests regular use by non-smokers is likely to be rare. The 2018 US National Youth Tobacco Survey reported that, of non-smokers aged 9-19 who did vape, only 0.4% vaped on ≥20 days. [29]

A legitimate concern is whether vaping acts as a 'gateway' to smoking (i.e. that youth vaping will cause some young people who would not otherwise have smoked to become regular smokers). Numerous studies have found an association between youth vaping and subsequent smoking, but there is little evidence that vaping *causes* smoking uptake. A more likely explanation is that youth who experiment with risky behaviours such as vaping are also more likely to try other risky behaviours (eg. smoking, alcohol, unsafe sex). [30]

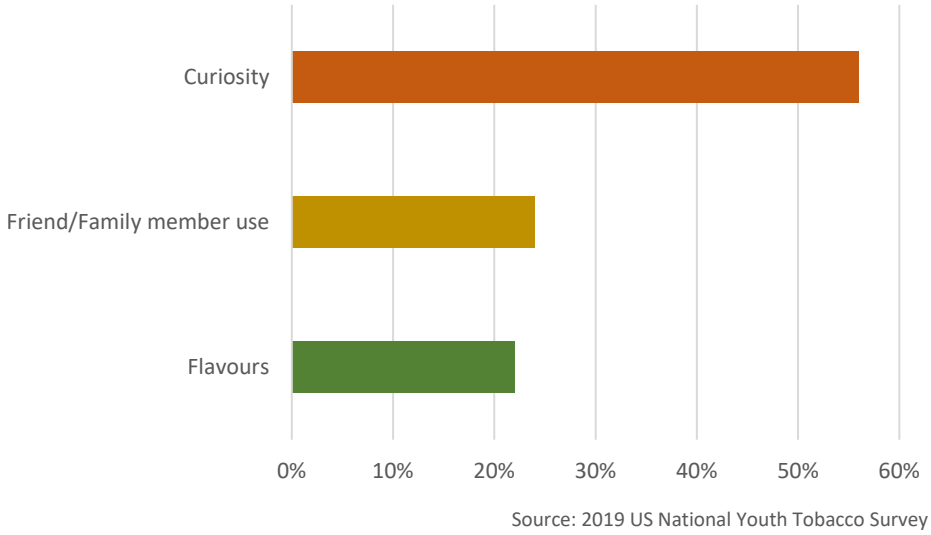
"Despite some experimentation with these devices among never smokers, e-cigarettes are attracting very few young people who have never smoked into regular use."

– Public Health England

The evidence suggests that vaping is diverting some young people from smoking. [31, 32] The decline in youth smoking rates in the US has accelerated during the time that vaping has become popular. [31, 32]

There is some concern that youth-friendly flavours (predominantly sweet flavours) increase youth uptake and for this reason should be banned. However, this argument is not supported by the evidence. [33] Flavours are not the primary reason for youth experimentation with vaping. [4, 34] (See figure 6).

Figure 6: Reasons for youth initiation to vaping (USA)



Source: 2019 US National Youth Tobacco Survey

Flavours preferred by young people are very similar to those preferred by adults, with the exception of tobacco flavours. The most popular flavours used by adults are fruit, dessert, and other sweet flavours. [35]

Restricting flavourings would reduce appeal to adults and would therefore result in a significantly reduced public health benefit. It would also lead to increased black-market supplies and home mixing, with little effect on youth uptake. [36] One large study found that young people who started vaping with non-tobacco flavours were no more likely to go onto smoking than those who started with tobacco flavours. [37]

Uptake by adult non-smokers

Vaping is rare among adult non-smokers and is largely confined to smokers and ex-smokers. In 2019, around 0.7% of Australian never-smokers had vaped at least once in the last 12 months. [4] Less

than 0.3% of these were regular users (weekly or more). Never-smokers who vape are also less likely to use nicotine.

Renormalisation of smoking

Critics fear that widespread vaping could help make smoking more socially acceptable and undermine decades of successful tobacco control efforts. However, the research suggests this is not the case. According to Public Health England, "there is no evidence that ENDS [e-cigarettes] are undermining the long-term decline in cigarette smoking among adults and youth and may in fact be contributing to it". [2]

Dual use

A temporary period of dual use (vaping and smoking) is common as smokers attempt to make a transition to quitting. Fifty four percent of Australian vapers also smoked in 2019. [4] The greatest health benefits from vaping accrue when smokers quit smoking completely, but even dual use offers a relative benefit. Dual users usually reduce their cigarette intake, often to very low levels because they are consuming some of their nicotine through vaping. Most research into dual users shows a substantial reduction in toxins and many studies show improvements in health. [38]

Nicotine safety

Nicotine poisoning

Nicotine poisoning can occur through the accidental or intentional ingestion of nicotine e-liquids. It does not occur through inhalation from vaping.

In the vast majority of cases of ingestion, symptoms are short lived and do not require treatment or evaluation at a health-care facility. [42] In most cases, the individual vomits shortly after ingestion, thereby reducing absorption levels and reducing the risk of serious harm.

Worldwide over the past 15 years, there have been 9 reported deaths due to the ingestion of nicotine e-liquids (4 child fatalities caused by accidental ingestion; 5 adult fatalities caused by intentional ingestion). This represents an extremely low fatality rate given that more than 42 million people are current vapers worldwide. [Source: Eurobarometer]

The Australian Poisons Information Centres reported on national exposures to e-cigarettes and their refills for the period 2009-2016. [43] Over the 8-year period there were 202 calls about nicotine liquid and vaping products, representing less than 0.0002% of calls received. Most patients had mild symptoms and 12 had moderate symptoms, usually gastrointestinal. None were reported to have suffered serious harm.

The Victorian Poisons Information Centre reported 37 calls about nicotine liquid for 2019. Of these only 16 were referred for medical attention. In 2018, there were 26 calls for nicotine liquid out of 33,695 calls, representing 0.077% of total calls. By comparison, there were 280 calls relating to soap and 123 calls for bubble blowing solution. [44]

Cancer

Numerous studies have found substantial reductions of carcinogens in vapour compared to tobacco smoke. The cancer risk from vaping has been estimated to be <0.5% of the cancer risk associated with smoking. [45] Nicotine does not cause cancer, according to the International Agency on Research in Cancer and the US Surgeon-General. [39, 40]

Cardiovascular and lung disease

Vaping poses lower cardiovascular risk than smoking. [41] Clinical studies so far have found improvements in cardiovascular health after switching from smoking to vaping. [46, 47]

Studies in humans have generally found improvements in lung health after smokers switch to vaping. [48] Cell and animal studies have identified potentially harmful pulmonary effects from vaping. It is not known whether these findings translate to disease in humans.

In 2019, there was an outbreak of serious lung injury in the US in people who had recently vaped. This condition was caused by black-market cannabis oils contaminated with Vitamin E Acetate. [49] No cases have been linked to nicotine vaping products. [50]

Concerns have been raised regarding a condition called 'popcorn lung' (bronchiolitis obliterans). This is a serious but rare lung disease caused by inflammation and scarring attributed to the inhalation of diacetyl, a food flavouring used to make popcorn. Diacetyl is also used in some e-liquids, in doses hundreds of times lower than tobacco smoke. There are no known cases of popcorn lung caused by vaping. [51] Diacetyl is no longer used by most reputable manufacturers.

Second-hand vapour

Unlike second-hand smoke, the risk to bystanders from 'passive vaping' appears to be minimal. In 2018 a comprehensive review by Public Health England found 'no identified health risks of passive vaping to bystanders'. [2]

Adolescent brain development

Nicotine has been linked to adolescent brain harm in animal studies. There is no evidence that nicotine vaping causes harmful effects on the human adolescent brain.

Unknown long-term health effects

It is beyond reasonable doubt that the long-term health risks from vaping nicotine are much lower than those of smoking. The UK Royal College of Physicians estimates the long-term risk is likely to be no more than 5% of the risk of smoking. [1] Vapers are exposed to only a small fraction of the toxins found in smoke and experience improved health after switching to vaping.

As with any new product, it is possible that some harms may emerge over time. Vaping should continue to be monitored and harmful effects reported.

The role of the tobacco industry

There are concerns that vaping is being used by the tobacco industry to perpetuate people's smoking habits, increase youth uptake or undermine tobacco control. This concern is understandable because of the industry's appalling reputation, but the reality is that vaping is a huge disruptive threat to the tobacco industry and is a direct competitor with tobacco sales. Tobacco companies currently control no more than 20% of the global vapour market. [52]

In 2017, tobacco stocks experienced an unprecedented decline when the US FDA proposed to encourage vaping and reduce nicotine levels in cigarettes. The combined value of the FT500 tobacco companies fell from US$700 billion in July 2017 to US$372 billion in September 2019. Conversely, proposals to restrict vaping are often followed by a rise in tobacco stocks.

Campaigns against vaping on public health grounds have the perverse effect of supporting the tobacco industry.

Nevertheless, the primary focus should be on the improvement of public health. Safer alternatives to smoking will save lives, regardless of who manufactures and sells them.

Risk-benefit analysis

Vaping nicotine is almost exclusively used by smokers and former smokers to reduce harm from smoking. Assessments of public health risk should compare the risks and benefits of vaping with those of smoking. All independent modelling studies except one [53] have estimated a substantial net public health benefit from the introduction of vaping, as measured in life years saved and preventable deaths averted. [54-59]

A recent modelling study estimated that vaping would save between 143,000 and 65 million life-years by 2100 in the US alone, across a range of scenarios. The authors qualified their findings by saying that vaping is not a 'silver bullet'. Rather, it is one of many tools that should be used in a comprehensive public health response to the risks of smoking tobacco. [54]

Another study estimated that replacement of most cigarettes with vaping in the US would yield up to 6.6 million fewer premature deaths with 86.7 million fewer life years lost. [56]

"Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure." [1]

- *UK Royal College of Physicians*

A 2018 review commissioned by Public Health England concluded that the net benefit associated with vaping justified its promotion as a safer alternative to combustible tobacco products. [2]

As with any new product, it is possible that some harms may emerge. It is equally possible that further data will show the relative risk to be even lower. The associated risks should be mitigated through ongoing monitoring.

Australian regulations (current and proposed)

Current regulations

Nicotine vaporisers	
Currently regulated by the Australian Competition and Consumer Commission Not discussed in this document	
Nicotine e-liquid	
Classification	Schedule 7 'dangerous poison' in Poisons Standard It is illegal to possess or use liquid nicotine for vaping without a prescription from a registered Australian medical practitioner
Sale in Australia	Banned
Importation	Nicotine can legally imported from overseas for personal use to quit or reduce smoking under the Therapeutic Goods Administration (TGA) Personal Importation Scheme if the user has a prescription from a registered Australian doctor [link]
Manufacturing and safety standards	Nil
Labelling requirements	Nil
Child safe containers	Nil
Mandatory health warnings	Nil
Notification of product information	Nil
Advertising	Banned
Taxation	Nil
Public use	Banned in smoke-free areas
Post marketing	No surveillance or reporting system for adverse events and no procedure for recalls of harmful products
Penalties	State and territory fines of up to $45,000 and jail terms up to 2 years apply for possessing nicotine without a script [link]

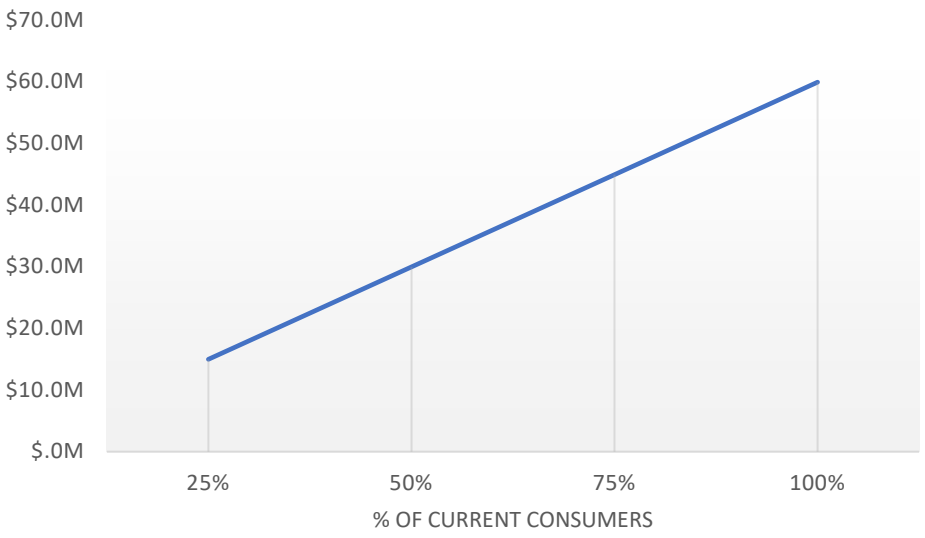
Proposed regulations

Under new regulations to be introduced on 1 January 2021, it will be an offence to import nicotine liquid for personal use with a disproportionate penalty of $220,000. [link]

Under the new guidelines, access to nicotine liquid for vaping involves an onerous and complicated process requiring a doctor's prescription, a special application to the TGA and importation procedures. A survey of 6,500 vapers in August 2020 found that 42% will go back to smoking and 37% will resort to the black market for vaping supplies if these measures are introduced. [link]

These new measures will effectively require nicotine vapers to attend at least two visits to a doctor, most likely a long consultation followed by a standard consultation, costing a total of $112.10 per patient in the form of taxpayer-funded Medicare rebates. For concession holders, an additional $12.50 would be paid to doctors who bulk bill the patient for each visit. Australia currently has an estimated 520,000 vapers. Assuming a modest 25% of these consumers seek permission via the new laws, it will cost an estimated $14.6 million in Medicare rebates per year. Total cost would rise in proportion to patient uptake (see Figure 7).

Figure 7: Estimated annual Medicare costs caused by new laws per annum[1]



[1] Assumptions:

- An initial long consultation will be required for a patient to seek approval from their doctor to use nicotine vaping products. The doctor would then need to apply for permission via the TGA's Special Access Scheme, a process that commonly takes 20–30 minutes.
- An additional appointment will be required to pick up the prescription once approved or receive the nicotine products imported under the Special Access Scheme.
- Medical consultations with GPs priced based on the Medicare Rebate as at 28/08/2020.

International regulations

Australia is the only western democracy to ban the sale and use of nicotine for vaping. Other countries have chosen to promote the health benefits of vaping relative to smoking, while implementing balanced regulations that address the concerns discussed above. The regulations in UK and New Zealand are outlined below (Table 1). The EU has implemented similar requirements.

Table 1: Comparison of UK and NZ regulation of vaping and e-liquids

		
Classification	Dual pathway ▪ Consumer product, or ▪ Medical product if 1) higher nicotine concentration, or 2) making claims of safety or efficacy	Dual pathway ▪ Consumer product, or ▪ Medical product if making claims about safety or efficacy
Nicotine concentration	▪ Max 20mg/ml for consumer products ▪ >20mg/ml for therapeutic products	▪ No limits at present
Minimum age	▪ 18 years	▪ 18 years ▪ Individuals under 18 years not permitted entry to specialist vape shops
Advertising	▪ Prohibited except for outdoor, posters, cinema, side of bus, leaflets, direct hard copy mail, in trade press, blogs, tweets independently compiled	▪ Prohibited
Point of sale display	▪ Allowed	▪ May communicate health information or warnings
Public vaping	▪ Vaping permitted outdoors and not subject to smoke-free legislation ▪ Local proprietors or organisations can decide policy on use in their premises	▪ Prohibited in smoke-free areas ▪ Local authorities can make decisions on vaping in outdoor smoke-free areas

Labelling, packaging	▪ Products contain mandatory leaflet that includes information on: - use and storage - contraindications - possible adverse effects - addictiveness and toxicity - warnings for specific groups - batch number - contact details of manufacturer ▪ Health warnings must cover 30% of label's surface area and must be placed on front and back	▪ To be established after public consultation ▪ It is proposed that NZ will follow the UK model
Restrictions on hardware, bottle sizes	▪ Limit of 2ml for tanks or pods ▪ Limit of 10ml for e-liquids	▪ Nil
Product safety	▪ No vitamins, colourings or prohibited additives (including caffeine and taurine) ▪ Using only ingredients of high purity ▪ Must not include ingredients (except for nicotine) which pose a risk to human health ▪ Deliver a dose of nicotine at consistent levels ▪ Mechanism for ensuring re-filling without leakage	▪ Products will need to comply with any product safety requirements set out in regulations ▪ Requirements will prohibit certain ingredients ▪ Exact requirements will be the subject of public consultation
Child-resistant containers	▪ Nicotine-containing products or their packaging to be child-resistant and tamper evident	▪ To be established after public consultation
Reporting	Side effects and safety concerns can be reported to MHRA through the Yellow Card reporting system	Manufacturers and importers must advise the Director-General of any adverse reaction
Pre-market Notification	▪ 6 months prior to marketing, producers must supply: - A list of all ingredients in the product (liquid) and emissions from the product - Toxicological data, including health and addictive effects	▪ Manufacturers and importers must notify products to the Ministry of Health before they can be sold in New Zealand ▪ A searchable database will be available

	- Nicotine dose and uptake when consumed - Components of the product - Production process details	
Flavours	▪ No flavours prohibited	▪ Specialist vape shops: No flavours prohibited ▪ General retailers: Tobacco, mint and menthol only
Vaping in retail stores	▪ Not restricted	▪ Specialist vape shops: Permitted ▪ General retailers: Prohibited
Legislation	*The Tobacco and Related Products Regulations 2016* (Parts 6, 7 and 8) [link]	*Smokefree Environments and Regulated Products (Vaping) Amendment Bill 2020* [link]
Other references	*E-cigarettes: regulations for consumer products 2019* [link] *E-cigarettes and vaping: policy, regulation and guidance 2020* [link] *UK laws on the advertising of e-cigarettes 2016* [link] *Licensing procedure for electronic cigarettes as medicines* [link]	*Fact sheet: Smokefree Environments and Regulated Products (Vaping) Amendment Bill* [link] *The facts of Vaping* (NZ Ministry of Health website) [link]

Recommendation 1: Poisons Standard

Exempt nicotine e-liquid in concentrations ≤ 5% for vaping from the Poisons Standard

Nicotine liquid for vaping is currently classified as a Schedule 7 'dangerous poison' in the Poisons Standard. This means it is illegal to buy, possess or use liquid nicotine for vaping without a prescription from a registered Australian medical practitioner. Requiring a prescription is a significant barrier to access and amounts to a de facto ban.

However, nicotine in its most lethal form in 'tobacco prepared and packed for smoking' is exempt from the Poisons Standard and is widely available. As a result, it is harder to access a far safer product than its deadly alternative.

Nicotine is addictive but is relatively benign in the low concentrations used for vaping, typically 0.3-5%. The UK Royal College of Physicians report on vaping concludes that "it is widely accepted that any long-term hazards of nicotine are likely to be of minimal consequence in relation to those associated with continued tobacco use." [1]

The concentration of nicotine in e-liquid needs to be sufficient to satisfy a vaper's addiction. A low concentration will not satisfy some users who will return to smoking. Excessively low nicotine concentrations lead to compensatory puffing (more frequent and longer puffs) to deliver adequate nicotine. This creates larger vapour volumes, more toxins and increased health risks. A group of leading authorities concluded that 5% nicotine is necessary to match the nicotine delivery smokers obtain from conventional cigarettes. [link]This is especially true for popular low-power pod devices.

Implementation

Poisons Standard	▪ Exempt nicotine liquid in concentrations ≤5% for vaping for tobacco harm reduction ▪ Exemption subject to appropriate safety standards, packaging and labelling (see Recommendations 4 and 5)
Responsibility	▪ Secretary of the Department of Health

Recommendation 2: Consumer classification

Regulate nicotine in concentrations ≤5% as a consumer product

Under current laws nicotine e-liquid is regulated by the Therapeutic Goods Administration (TGA). The TGA is responsible for regulating medicines and medical devices which make therapeutic (medicinal) claims.

However, low concentrations of nicotine e-liquid are consumer products designed to replace a far more harmful consumer product, combustible tobacco. Subjecting them to TGA approval has the perverse outcome of imposing a significant regulatory burden on the vaping industry, while tobacco – a far more harmful product – remains largely unregulated.

The requirement for TGA approval is onerous and costly. It would drive most small to medium companies out of business and deliver the vaping industry to Big Tobacco. There would be substantial cost increases to consumers, reduced innovation and safety improvements and less diversity in the market. NO product in any country has been assessed by a national regulator and brought to market.

Australia has one of the most robust consumer protection frameworks in the world. Consumer products are regulated by the Australian Competition and Consumer Commission (ACCC), which monitors markets to help ensure consumer products are safe, fit for purpose and comply with other requirements of the *Competition and Consumer Act 2010*.

The UK, EU, Canada and New Zealand use a dual system of regulation with both a consumer and therapeutic pathway:

- Products which do not make therapeutic claims are classified as consumer products and managed under consumer law
- Products which wish to make therapeutic claims can apply for a medicines licence and are regulated by the medicines regulator. These products need to meet a higher standard of evidence and quality. Doctors can prescribe them and some patients may have more confidence in their use

Implementation

Separate regulatory pathways for consumer and therapeutic nicotine products.

Consumer products	ACCC to regulate vaping liquid with low nicotine concentrations (≤5%)
Medicines and therapeutic products	TGA to regulate: ▪ Liquids containing high concentrations of nicotine (>5%) ▪ Nicotine liquids which make therapeutic claims

Recommendation 3: Youth access

Minimise youth access by strict age verification, prohibited youth-friendly packaging, restricted advertising and public health messaging

Vaping and smoking should be discouraged among youth, but some will do both or either – just as they drink alcohol, use illicit drugs, engage in unprotected sex and other risky behaviours. Regulation can minimise the opportunity for youth to access vaping products, but it should be balanced so as not to indiscriminately affect adults (for example through flavour bans, nicotine limits or taxes). Figure 8 outlines the three well-established strategies for regulating youth access.

Figure 8: Regulation of youth access

Access control	Marketing control	Public information
Age limits and restrictions on where and how products can be purchased	Restrictions on marketing, packaging and branding that is specifically targeted at young people	Public messaging that frames vaping as a harm reduction tool for adult smokers

Implementation

Minimum age of sale laws	▪ 18+ nationally
Age verification	▪ Clear requirements for retailers, with enforcement measures and harsh penalties including loss of retail licence, similar to tobacco and alcohol retailers
Vape retailers	▪ Licensing of Australian vape retailers
Brick and mortar vape shops	▪ No admission for individuals under 18
Online retailers	▪ Third-party age verification ▪ Signature and age verification on delivery
Public education	▪ Education campaigns which frame vaping nicotine as a tool for smoking cessation or as a safer alternative for adult smokers
Marketing	▪ Restrictions on branding and packaging that appeal to youth ▪ No advertising of vaping products
Responsibility	▪ State and Territory Health Departments

Recommendation 4: Product safety

Introduce laws and guidelines specifying minimum standards for the manufacture and safety of vaping liquids

The current policy of banning nicotine vaping liquids prevents any regulation of the manufacture and safety of vaping liquids in Australia. As a result, there is little assurance that vaping products being sold to Australians meet minimum safety and quality standards.

Standards for e-liquids have been developed in the UK (BSI), Europe (CEN), France (AFNOR) and USA and are designed to ensure minimum standards for manufacturing and safety. The following recommendations are based mostly on European standards (the most recent guidelines), UK and New Zealand legislation and Australian Work Health and Safety Regulations. See Appendix 2 for details.

Implementation

Laboratory standards	
Airborne contamination	▪ A (minimum) ISO 7 cleanroom to minimise product contamination by airborne particles
Dangerous Goods handling certificate	▪ Required for laboratory staff handling nicotine in concentrations ≥10% w/w and volumes > 10L (GHS acute toxicity category 2)
Safety standards	▪ Compliance to standards of safety (Model Work Health and Safety Regulations 2019)
Quality management system	
Regulation of e-liquids	
Nicotine	▪ USP (US Pharmacopeia standard) or equivalent ▪ Certificates of Analysis reflecting % of acceptance on nicotine in dilutions
Base e-liquid	▪ USP or equivalent propylene glycol, vegetable glycerine, purified water or water for injection and ethanol EP or USP Anhydrous Ethanol ▪ Certificates of Analysis for all ingredients
Flavourings	▪ All flavourings (natural or artificial) except tobacco extracts listed as flavouring agents allowed in foods by appropriate regulatory authorities. This would include flavouring agents listed on at least one of the following lists:

	- Annex 1 of European Food Regulation EU 1334/2008 - Substances Added to Food Inventory of the United States - FEMA GRAS listings - IOFI Global Reference List of Natural Complex Substances / Natural Flavouring Complexes ▪ Flavourings required to be in pharmaceutical grade solution
Toxicology	▪ Toxicologically undesirable constituents to be avoided, including: - ingredients posing a material risk to human health from inhalation (eg. essential oils, vitamin E acetate, diacetyl, acetaldehyde, bitter almond oil, acetylpropionyl (i.e. 2/3-pentanedione) - additives with colouring properties added during combustion - additives with CMR properties (mutagenic, carcinogen toxic for reproduction and development or target organs / system without combustion (GHS Category 1 for respiratory tract) (MWHSR) - flavour chemicals classified as toxic for inhalation - psychotropic substances other than nicotine (eg. cannabis, caffeine, analgesics) - Substances implying a health benefit (eg. vitamins, stimulants, taurine)
Safety Data Sheets (SDS)	▪ Safety Data Sheets mandatory for each component used in the manufacturing of the e-liquid, including CAS numbers for all hazardous components
Finished e-liquid standards	▪ Nicotine liquid up to 50mg/ml or 5% w/w ±10% of label claim ▪ Risk assessment of the global toxicity of the final product ▪ Requirement for e-liquids to be non-reactive with the materials of the container used ▪ Safety Data Sheet for each final product manufactured to include pH, flash point and density
Product testing	▪ Mandatory testing for all products intended for vaporisation, including nicotine-free e-liquids ▪ Mandated testing for the harmful and potentially harmful chemicals, including: - formaldehyde - acetaldehyde - acrolein - crotonaldehyde - diacetyl - acetyl propionyl

	▪ For each concentration of nicotine, the nicotine dose uptake to be tested following ISO puffing systems reflected on adapted methods for vaping (CORESTA Recommended Method 84 or equivalent) ▪ Testing to be performed on the highest strength of each PG/VG ratio
Responsibility	▪ Australian Competition and Consumer Commission

Recommendation 5: Product labelling

Introduce mandatory standards for labelling, refill containers and health warnings

Labelling standards, regulation of refill containers and appropriate health warnings are essential for consumer safety and informed decision making.

While plain packaging is justified for combustible tobacco products, the relative risks associated with vaping do not justify this approach. Plain packaging implies the risks of vaping are similar to smoking and may discourage smokers from switching.

Our advice in relation to product labelling are based on:

- European standards
- UK and New Zealand legislation
- Australian Work Health and Safety Regulations
- Input from Australian toxicologists

Implementation

Mandatory labelling requirements	
Ingredients	▪ List of all ingredients in weight order (flavour ingredients can be grouped by flavour descriptor)
Nicotine	▪ Nicotine concentration listed as % w/w, or mg/mL
Volume	▪ Millilitres (mL)
Description	▪ Product purpose to be clearly indicated, eg. "For use in an electronic vaporiser" or similar
Warnings	▪ Compliant with the Model Workplace Health and Safety Regulations, eg. - "Toxic if swallowed" and GHS05 and GHS06 hazard pictograms (red diamonds) - Health warning, eg "Vaping nicotine is not risk-free and may be addictive but is much less harmful than smoking" - "Keep out of reach of children" - Allergy warning if appropriate: "May contain traces of [allergen]"

Mandatory health warnings	
Health warnings	▪ Size, content and position of warnings to be proportionate to risk ▪ Labelling to have prominent warnings communicating health risks relative to smoking ▪ Labels to direct consumers to online resources where they can learn more about the health risks relative to smoking ▪ Risk communications to encourage smokers to make the transition to less harmful products
Mandatory refill container requirements	
Child safety	▪ Child-resistant caps ▪ Protection against breakage
Handling and general safety	▪ Tamper-evidence seals ▪ Leakproof containers ▪ Spillage prevention (delivery spout and no 'open neck' bottles)
Responsibility	▪ Australian Competition and Consumer Commission

Recommendation 6: Flavours

Prohibit descriptive flavour names that specifically appeal to youth and unsafe flavouring chemicals

As discussed, flavours preferred by young people are very similar to those preferred by adults (with the exception of tobacco flavours). Young people enjoy flavours but the evidence does not support the claim that flavours are a major driver of youth uptake.

Restricting flavours will likely have minimal effect on youth uptake but will make vaping less appealing to adult smokers. This will undermine quitting smoking and increase unregulated black-market sales and home mixing and have a negative effect overall on public health. [36]

Appeal to youth could be reduced by banning flavour names that may be especially appealing to young people.

Certain flavour chemicals have been identified as potentially harmful and should be avoided. These include diacetyl, cinnamaldehyde and benzaldehyde.

Implementation

Prohibited flavours	▪ Prohibition of flavours known or suspected to be harmful, including diacetyl, cinnamaldehyde and benzaldehyde ▪ Prohibition of chemical flavourings classified as being toxic when inhaled
Flavour names	▪ Flavour names to be generic descriptions of actual flavour and must not have obvious youth appeal
Responsibility	▪ Australian Competition and Consumer Commission ▪ Food Standards Australia and New Zealand

Recommendation 7: Notification scheme

Establish a notification scheme for pre-market registration

It is recommended that Australia implement a mandatory notification scheme similar to that established in the United Kingdom and proposed for New Zealand. The scheme requires an e-liquid producer to declare the compliance of the product with applicable health and safety standards prior to marketing and sale.

Lists of approved products should be available in a searchable database online so retailers can confirm compliance. In the UK, approved products are listed for companies A to I [link] and J to Z [link]. More information about the UK notification system is available here: *E-cigarettes: regulations for consumer products*. [link] The UK notifications scheme is administered by the Medicines and Healthcare Products Regulatory Agency (MHRA).

A similar notification system will be introduced in New Zealand under the Smokefree Environments and Regulated Products (Vaping) Amendment Bill 2020 [link].

Implementation

Online database	▪ Searchable online database to be established for manufacturers and/or importers to upload the information needed to self-certify regulatory compliance prior to sale ▪ Responsibility: Department of Health
Notification	▪ Prior to sale, manufacturers and/or importers must notify the regulator of each new product and certify that it meets the applicable standards of quality and safety. This would include listing all ingredients, emissions testing, labelling and container requirements. Information should be uploaded to an online database which would be publicly available for consumers and retailers to confirm compliance.
Responsibility	▪ Commonwealth Department of Health

Recommendation 8: Retail

Regulate the sale of nicotine e-liquids in vape shops, other retail outlets and online

Combustible tobacco products (e.g. cigarettes) can be purchased in over 20,000 retail outlets throughout Australia. Vaping products must also be widely available to compete with the more harmful alternative.

Most vape shops are run by former smokers who vape. This positions them to provide support and advice for new vapers, helping to ease the transition from tobacco products. Hygienic sampling of flavours and in-store vaping assists consumers to find the right product that works for them.

Licensing of specialist vape retail outlets will help to ensure compliance with regulations governing sales. Prevention of sale to youth in-store needs to include strict age verification requirements and bans on entry. Breaches of compliance can be managed with the deterrent of sanctions (fines and/or loss of licence).

Vaping products should be available from retail outlets where reliable age verification is available and from retail outlets wherever tobacco is sold, as a safer alternative for smokers. The same restrictions on tobacco sales should apply for the sale of nicotine e-liquid i.e. strict compliance and enforcement measures coupled with harsh penalties including loss of retail licence.

Online access is important given 26% of purchases are currently made this way. [4] Third party online age verification services exist for industries such as online gaming and can be implemented for nicotine vaping purchases. Proof of age can be required when products are delivered.

Implementation

Specialist vape shops	▪ Registration and licensing of vape shops ▪ No entry by under 18-year olds ▪ Vaping to be allowed in-store ▪ Sampling of flavours to be allowed with hygiene measures ▪ Display of products in-store allowed
Other retail outlets	▪ Retail outlets with reliable age verification eg pharmacies, adult stores ▪ Retail outlets where tobacco is sold, eg tobacconists, supermarkets, general stores, petrol stations ▪ No vaping in-store, no flavour sampling; point-of-sale display allowed
Online sales	▪ Permit with strict age verification ▪ Proof of age required on delivery
Responsibility	▪ State and Territory Health Departments

Recommendation 9: Public vaping

Permit vaping in specified public spaces and allow owners and managers of premises to set their own regulations

There is no evidence that vaping poses a material health risk to bystanders and a blanket ban in public places is not justified on public health grounds. Hazardous agents are present at such low concentrations in exhaled vapour that they pose no meaningful risk to bystanders. [60]

Bans on vaping send the misleading message that it is just as harmful (if not more so) than smoking. This makes vaping less appealing compared to smoking and deters tobacco addicts from switching to the less harmful product. Vapers may be more likely to relapse if they are forced to smoking areas with smokers.

Exposure to second-hand vapour represents a nuisance or etiquette issue. This can be managed by public education and appropriate signage. Property owners and managers should be able to make their own decisions about vaping for staff, clients or customers on their premises, as occurs in the UK. Public Health England has produced guidance for employers and organisations to help guide evidence-based policy making [link]. PHE recommends that vaping is not covered by smoke-free legislation and should not routinely be included in an organisation's smoke-free policy.

The UK not-for-profit Action on Smoking and Health produced a set of structured questions to guide employers through vaping policy options [link]. This flexibility allows businesses and other entities to form policies that cater for their clientele and customers. Table 2 lists a number of typical examples of how this flexible policy could be deployed.

Table 2: Examples of flexible onsite regulation of nicotine vaping

1.	A bar wants to have a vape night every Thursday
2.	A bar wants to dedicate one room where vaping is permitted
3.	A corrections facility that is smoke-free wants to support inmates to manage nicotine withdrawal and related tensions by allowing them to vape
4.	In a town with three bars, one decides it will cater for vapers, two decide they will not allow vaping
5.	A bar manager decides on balance that his/her vaping customers prefer it and his/her other clientele are not that bothered, so he decides to allow it.
6.	A hotel wants to allow vaping in a few rooms and in its bar, but not in its restaurant
7.	An office workplace decides to allow vaping breaks near the coffee machine to save on wasted smoking break time and encourage smokers to quit by switching
8.	A care home wants to allow an indoor vaping area to encourage its smoking elderly residents to switch during the coming winter

9. A vape shop is trying to help people switch from smoking and wants to demonstrate products in the shop
10. Vaping might be permitted in railway stations or airport terminals, but not on trains and aircraft
11. Many shops, public buildings and places catering for children decide not to allow vaping at all

Implementation

Restricted locations	▪ Restrict vaping in enclosed public places like hospitals, schools, some public buildings, planes and public transport
Outdoors	▪ Permit vaping in outdoor areas
Workplaces and businesses	▪ Allow owners or managers of workplaces or public premises the right to set their own regulations according to the needs and preferences of their customers and employees
Education	▪ Introduce public information and campaigns that: - educate vapers to consume responsibly by considering others - educate the public that vapour is not smoke and that it is not harmful
Signage	▪ Provide signage alerting clientele and employees where vaping is available ▪ Provide signage to encourage consideration of others and avoiding large clouds
Responsibility	▪ State, Territory and federal Health Departments

Recommendation 10: Public health messaging

Use public health messaging to raise awareness of the health risks relative to smoking tobacco

Health warnings should accurately convey the relative risk compared to smoking. Alarmist health warnings, even if technically correct, can be misleading and misunderstood by the public.

Warnings about nicotine may exacerbate misperceptions about the (minimal) role of nicotine in causing disease. Warnings about addiction play on fears of loss of control or harm to the user that exaggerate the consequences of nicotine use through vaping. The addictiveness of nicotine in smoke is enhanced by the rapid delivery of nicotine to the brain from smoking and other chemicals such as mono-amine oxidase inhibitors. On its own, nicotine is far less addictive.

Health Canada has proposed a set of appropriate warnings, for example, "If you are a smoker, switching completely to vaping is a much less harmful option," and, "Completely replacing your cigarette with a vaping product will significantly reduce your exposure to numerous toxic and cancer-causing substances." [link]

Public health messaging should inform consumers that:

- vaping is not risk-free but is far less harmful than smoking
- vaping is an adult smoking cessation tool for smokers who are unable to quit with the available treatments and would otherwise continue to smoke
- vaping is not for young people or non-smokers
- complete cessation of smoking gives the best health benefits for vapers
- vapers should try to quit vaping but only if they are able to avoid relapse to smoking
- there is no evidence that second-hand vapour is harmful
- vapers should vape considerately and respect the rights of bystanders to fresh air

Implementation

Public messaging to:

- frame vaping as a smoking cessation aid for adult smokers
- educate smokers about the relative risk of vaping and smoking and the benefits of switching to vaping
- educate the public about the minimal risk from secondhand vapour
- educate and encourage vapers to avoid large clouds when in close proximity to bystanders

Responsibility	▪ State and Territory Health Departments

Recommendation 11: Monitoring

Establish a system for reporting harmful effects and recall of unsafe products

A system should be established for reporting products which are unsafe, not of good quality or not compliant with regulations. Consumers and manufacturers and/or importers can contact this service directly.

A procedure for recalling unsafe or non-complaint goods should be established.

In the UK, consumers and healthcare professionals can report side effects and safety concerns with e-cigarettes or refill containers to the MHRA through the Yellow Card reporting system [link].

Implementation

Reporting service	▪ Establish a service for reporting adverse reactions or unsafe products
Recalls	▪ Establish a pathway for recalls when appropriate
Responsibility	▪ Australian Competition and Consumer Commission

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Appendix 1

'Cigalikes'

Cigalikes are designed to look and feel like a cigarette. They consist of a battery and a prefilled cartridge of e-liquid.

Some models are disposable. Others use a rechargeable battery and replaceable cartridges. Cigalikes do not deliver as much nicotine as other models.

Pod devices

Pod models are easy to use and can deliver high levels of nicotine. Most have no buttons and are breath activated. All use a re-chargeable battery. They generally do not create large clouds.

- Prefilled models use sealed pods prefilled with nicotine e-liquid. Pods are replaced when empty.
- Refillable models use refillable pods. When empty, the pod is refilled by the user.

Starter kits

These pen-style tank devices are more complex to use and maintain than cigalikes and pod models. They can deliver high levels of nicotine and create larger clouds.

The tank is refilled as required and the heating coil needs to be replaced every 2-3 weeks when it produces a burnt taste and reduced vapour.

Tank models are best purchased from a local vape shop where you will get advice on correct use and ongoing support.

Advanced tank devices

More advanced devices are larger and more complex to use.

They have larger batteries with LED screens, replaceable parts and adjustable settings.

Advanced devices are not generally recommended for new vapers.

Appendix 2

Standards and references

European Committee for Standardization CEN/TC 437 electronic cigarettes and e-liquid [link]
(An updated CEN is currently under development)

Model Work Health and Safety Regulations 2019, Safe Work Australia [link]

New Zealand Smokefree Environments and Regulated Products (Vaping) Amendment Bill 2020 [link]

The Tobacco and Related Products Regulation 2016 UK (parts 6, 7, 8) [link]