

Proposed amendments referred for scheduling advice to
the Joint ACMS-ACCS #25
2.1 Nicotine
CAS Number 54-11-5

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Australian Tobacco Harm Reduction Association

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Executive summary

- The proposed amendment misses the opportunity to correct a glaring inconsistency in nicotine regulation
- Scheduling nicotine liquid as S7 and S4 while specifically exempting deadly ‘tobacco prepared and packed for smoking’ is unscientific and unethical and amounts to a de facto ban
- We recommend that low concentrations of nicotine liquid for vaping be exempt from the Poisons Standard, regulated proportionately to risk and available as a consumer product to assist in smoking cessation
- The exemption of nicotine liquid would allow it to be regulated to improve product quality and safety and provide a range of consumer protections
- Nicotine in the low doses used for vaping is low risk and is substantially less harmful than smoking tobacco
- Nicotine vaping is an effective quitting aid for smokers who are otherwise unable or unwilling to quit and is more effective than nicotine replacement therapy
- The restriction of access to nicotine liquid is inconsistent with the growing evidence for nicotine vaping and the support of the Royal Australasian College of Physicians, the Royal Australian and New Zealand College of Psychiatrists and the Royal Australian College of General Practitioners
- Nicotine vaping has been associated with higher quit rates and falling population smoking rates in other countries. It is likely to help reduce Australia’s stagnant smoking rate and avert the premature deaths of hundreds of thousands of Australian smokers
- Exempting nicotine from the Poisons Standard will decriminalise vapers, eliminate the black market and allow regulation of safety and quality standards for nicotine liquids
- The evidence so far does not support concerns about the use of nicotine liquid - youth uptake, renormalising smoking, uptake by non-smokers and significant harms from vaping
- **We do NOT support the amendment.** Instead we propose the following rescheduling:

Schedule 7

NICOTINE **except:**

- a) in preparations for human therapeutic use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use.; or
- b) in tobacco prepared and packed for smoking; or
- c) in preparations for use as a substitute for tobacco when packed and labelled:
 - (i) for use in an electronic vaporiser (e-cigarette)
 - (ii) nicotine concentration up to 6%
 - (iii) maximum nicotine per container: 180mg (30ml of 6% nicotine)
 - (iv) in a child resistant container
 - (v) labelled with the concentration of nicotine and other ingredients
 - (vi) labelled with the statement ‘Keep out of reach of children’
 - (vii) labelled with the statement ‘Not to be sold to a person under the age of 18 years’

What is ATHRA?

The [Australian Tobacco Harm Reduction Association](#) (ATHRA) is a registered health promotion charity established by doctors in 2017 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 is funded by public donations. We do not accept donations from tobacco companies or their subsidiaries or the vape industry. ATHRA accepted financial support from the small vape retail sector to establish the charity in 2017 but has not accepted any industry funding since March 2019.

Introduction

The amendment for nicotine in the Poisons Standard misses the opportunity to **correct a glaring inconsistency in nicotine regulation**.

Nicotine in its most lethal form (tobacco prepared and packed for smoking) is exempt from the Poisons Standard and is freely available, while the far safer substitute (liquid nicotine for vaping) is restricted to prescription-only access. This amounts to a de facto ban. Most doctors are unwilling to provide prescriptions as vaping is discouraged by health authorities. **This inconsistency is unscientific and unethical.**

Smoked tobacco is the leading cause of preventable illness and death in Australia. [1] Smoking is responsible for 21,000 premature deaths each year [2] and 9.3% of the burden of disease. [3] Up to two out of three continuing smokers will die prematurely from the habit, losing on average 10 years of life. [4]

Tobacco products are widely available in supermarkets, petrol stations, general stores with very little restrictions to access except for a poorly enforced age limit.

In contrast, low concentrations of nicotine liquid for vaping are effectively banned and cannot be purchased in Australia. Nicotine vaping is far less harmful than tobacco smoking and is the most popular quitting aid globally. It is an effective quitting aid, more effective than nicotine replacement therapy.

Australia remains the only western democracy to effectively ban the sale and use of nicotine for vaping. Nicotine for vaping is widely and legally available in the UK, US, New Zealand, Canada and the European Union and has been associated with increasing quit rates and accelerated declines in smoking.

However in Australia, for the first time in decades there was no statistically significant fall in the rate of adult smoking in two consecutive national surveys covering the period 2013-2016 and 2014/5-2017/8.[5, 6]

Increased availability of nicotine as a consumer product like cigarettes would improve access for smokers and help smokers to quit and would lead to substantial improvements in public health.

Vaping nicotine is increasingly being accepted by Australian medical associations. The Royal Australasian College of Physicians [7] and the Royal Australian and New Zealand College of Psychiatrists [8] support the use of vaping for smokers who are unable to quit.

The Royal Australian College of General Practitioners acknowledges a valid role for vaping for smokers who are unable to quit with other methods and who ask their GP about it. [9]

Nicotine liquid

1 Purpose

The purpose of this submission is to propose the exemption of low concentrations of nicotine liquids (6% or less) for use in vaping products for smokers who are unable or unwilling to quit smoking with conventional treatments.

Nicotine vaping is used as a short-term aid for quitting or as a long-term safer substitute for smoking (tobacco harm reduction). Switching to vaping helps to reduce the harm in those who would otherwise continue to smoke by providing nicotine in a cleaner form, without the products of combustion which cause almost all the harm to health from smoking. Nicotine is the main addictive chemical in tobacco smoke, but it has only minor adverse effects on health. [10, 11]

Australian studies show that the main reasons for vaping are to quit smoking, to reduce the harm from smoking and to cut down on cigarettes. [12]

2 Risks of exempting nicotine liquid

- Uptake by youth

Although teens who try vaping are more likely to later try smoking, there is no compelling evidence available that one causes the other. A more likely explanation for this association is 'common liability'; i.e. young people who are impulsive, rebellious and sensation-seeking are more likely to try both behaviours. [13]

Most use in young people is experimental and infrequent and is much more common in smokers. Regular vaping by never-smokers is rare, generally 1% or less in international surveys. [14]

In Australia in 2017, only 0.3% of 12–17 year old never-smokers had vaped on 3 or more days in the last month according to the ASSTAOS study. [15] Even in the US with the so-called youth vaping epidemic, only 0.4% of never-smokers vaped regularly (≥ 20 days in the last 30 days). [16]

The evidence suggests that vaping is diverting young people from smoking and reducing smoking rates. [17] Youth smoking rates have declined faster than ever in the UK [18] and US [19] since the introduction of vaping.

A recent study found that only 1% of US teens who vape FIRST go on to become established smokers, and some of these would have smoked anyway. [20]

- Safety of vaping nicotine

As vaping is almost exclusively used as an alternative by smokers, the key question is the relative risk compared to smoking.

Vaping is not risk-free but the scientific consensus is that it is far safer than smoking. Almost all the harm from cigarettes is due to the tar, CO and thousands of other toxins produced from burning tobacco. Vaping products heat a nicotine liquid into a liquid aerosol without combustion or smoke.

According to the UK Royal College of Physicians [21]

"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"

A comprehensive review by Public Health England concluded (p12) [22]

“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.”

A review by the US National Academies of Sciences, Engineering and Medicine found [23]

Conclusion 5-3. There is substantial evidence that except for nicotine, under typical conditions of use, exposure to potentially toxic substances from e-cigarettes is significantly lower compared with combustible tobacco cigarettes.

Conclusion 18-2. There is 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.

The risk of cancer has been independently estimated to be <0.5% of the risk from smoking. [24]

Numerous biomarker studies have demonstrated substantially lower levels of toxic markers in vapers compared to continuing smokers. [25, 26]

Substantial health improvements have been demonstrated in smokers who switch to vaping. Cardiovascular health improves [27], blood pressure drops [28], asthma [29] and emphysema [30] improve and people just feel a lot better.

All the modelling studies (except one [31]) indicate a substantial net public health benefit for vaping, taking into account the risks of youth uptake, harm from vaping, uptake by non-smokers etc [32-34]

- Unknown long-term effects

Like all new products, the precise long-term risk of vaping will not be known for another 20-30 years. It is possible that some harms may emerge over time and we need to keep monitoring vaping for any new side-effects.

We will only find out exactly how risky nicotine vaping is over time. It may be 90% safer or 99% safer. The exact figure doesn't matter. Based on the chemistry, toxicology and clinical improvements it is certain to be much safer than smoking.

The Royal College of Physicians estimates the **long-term risk** is likely to be no more than 5% of the risk of smoking, which takes into account the possibility of unknown issues that may arise in the future. [21]

- Secondhand vapour

Unlike secondhand smoke, the risk to bystanders from ‘passive vaping’ appears to be minimal. According to Public Health England’s review in 2018, ‘to date there have been no identified health risks of passive vaping to bystanders’. [35]. The report of the Royal College of Physicians states ‘There is, so far, no direct evidence that such passive exposure is likely to cause significant harm’. [21]

This is because only a small percentage of the vapour is exhaled (15% or less), there is no ‘sidestream’ vapour (which accounts for at least 80% of secondhand smoke), the chemicals in exhaled vapour are at very low levels and the vapour evaporates rapidly, much faster than smoke.

- Uptake by non-smokers

Surveys in many countries have shown that current use by adult non-smokers is rare, generally <1%. [35] For example England 0.5%, NZ No regular use; US 0.3%, EU current daily use by never smokers 0.08%, Germany 0.3%, Iceland 0.4%, Greece 0.2%.

- Dual use

A temporary period of smoking and vaping (dual use) is common as smokers transition to quitting and studies have found that dual users are more likely to quit smoking than other smokers.

Dual users usually reduce their cigarette intake, often to very low levels because they are getting some of their nicotine from vaping. Most studies of dual users show a substantial reduction of toxins and carcinogen biomarkers [25] and many studies show health improvements. [28, 30]

However, the greatest health benefits are from complete cessation of smoking and vaping and that is always the preferred goal.

- Nicotine addiction

Almost all vapers are already addicted to nicotine from previous smoking. Studies have consistently shown that vaping is less addictive than smoking based on self-reports, withdrawal symptoms, 'Time to First Cigarette', cigarette dependence scales and laboratory studies. [36, 37] This makes it easier to transition off nicotine later.

Nicotine per se is less addicting than tobacco smoke which contains other chemicals such as Monoamine Oxidase Inhibitors which enhance nicotine's effect. [38] Smoking is also the most addictive delivery system as it delivers nicotine to the brain much faster than vaping and other delivery systems.

- Renormalisation of smoking

Vaping critics fear that widespread vaping could make smoking appear more socially acceptable again and undermine decades of successful tobacco control efforts. However, the evidence is that the opposite is occurring. [39]

According to Public Health England, 'There is no evidence that ENDS are undermining the long-term decline in cigarette smoking among adults and youth and may in fact be contributing to it'. [22]

Smoking rates in countries where vaping is readily available are declining faster than in Australia, in some cases faster than ever.

- EVALI

There was a recent outbreak of serious lung injury in the US. We now know that the cause in almost all (if not all) cases was blackmarket THC or cannabis oils contaminated with Vitamin E Acetate purchased from street dealers. Not a single case has been linked to nicotine vaping. [40]

- The role of 'Big Tobacco'

There are concerns that vaping is another plot by the tobacco industry to keep people smoking, hook youth or undermine tobacco control. This concern is understandable as a result of the past dishonesty and appalling behaviour of the industry. However, modern vaping was invented by a Chinese pharmacist in 2003 and has been developed by small to medium businesses. Vaping is a disruptive innovation which the tobacco industry later recognised as a major threat to its business model. [41]

Tobacco companies control 20% or less of the global vaping market. Tobacco companies sell no e-cigarettes in Australia. After decades of soaring tobacco company stock prices, steep falls in stock prices occurred after July 2017 when the FDA announced its plan to encourage vaping and reduce nicotine levels in cigarettes. There was a huge

rally in the tobacco stock price in September 2018 when the US Federal Drug Administration announced a crackdown on vaping.

It is better for public health if tobacco companies switch to making less harmful alternatives rather than lethal cigarettes. The focus of policy makers should be on reducing smoking-related death and disease, not on destroying the tobacco companies.

3 Benefits of exempting nicotine liquid

- Helping smokers quit

Nicotine vaping is a legitimate smoking cessation method which should be available to Australian smokers.

Randomised controlled trials have demonstrated that vaping is more effective than conventional nicotine replacement therapy. In a trial of 886 smokers, Hajek found abstinence rates at 12 months were 18% for smokers randomised to vaping and 9.9% for those randomised to nicotine replacement therapy. [42] Ninety per cent of NRT users used combination NRT, which is current best practice.

In an RCT of 1,124 smokers, Walker found that combining nicotine vaping with the nicotine patch was more effective than using the patch alone at 6 months (17% vs 10%). [43]

RCT findings are supported by comprehensive analyses of the better quality observational studies that found that vaping facilitates quit attempts and increases cessation. [44, 45]

Evidence from population studies supports a benefit from vaping. The decline in smoking in both the USA and UK has accelerated over the period that vaping has become widespread and population quit rates have increased. [46] [47] In contrast, smoking rates in Australia have not declined significantly since 2013. [5, 6]

The population impact of vaping is amplified because of its popularity with smokers. Vaping devices are now the most popular quitting aid in the UK [18], the USA [48] and the European Union [49].

Australia has a low rate of current vaping. [5] A recent Australian review concluded that greater uptake of vaping nicotine has the potential to substantially reduce smoking rates in Australia. [50]

- Decriminalisation of vapers

There are currently approximately 300,000 vapers in Australia, most of whom illegally import nicotine liquid without a prescription. Vapers face harsh fines and jail terms for quitting smoking with a method that works for them. Exempting nicotine liquid from the Poisons Standard would allow these and other smokers to access nicotine and vape legally without the fear of prosecution.

- Elimination of the black market

There is also a black market for nicotine liquid in Australia which puts users at risk. Back-yard suppliers sell unregulated products without quality or safety standards, without child-resistant closures or appropriate and accurate labelling. [51]

- Allowing product regulation

The ban on the sale and use of nicotine liquid precludes regulation of vaping products. Most purchases are made on the internet and through an unregulated black market and there is no effective regulatory control. [12] Regulation under consumer law will improve product safety and quality: it will facilitate high quality manufacturing practice,

quality control, enforcement of safety standards, accurate labelling, restricted sales to minors, child resistant containers etc. Regulation would reduce the risk of child poisoning.

An Australian study of 'nicotine-free e-liquids' found many contained nicotine and a range of potentially harmful non-disclosed chemicals, highlighting the need for regulation and quality standards for vaping liquids and labelling. [52]

- Reduced use of concentrated nicotine

In jurisdictions where vaping is legal, most vapers purchase and use premixed nicotine liquid at low concentrations, typically 0.6-1.8% freebase nicotine or 2-6% nicotine salt. In Australia however, most vapers import highly concentrated nicotine 100mg/ml (10%) or 200mg/ml (20%) to mix with locally purchased nicotine-free vaping liquid. Concentrated nicotine is highly toxic and is a special risk to small children.

There was an Australian case 2 years ago in which a toddler died from drinking concentrated nicotine (100mg/ml). [53] Making nicotine liquid available in Australia will reduce the importation of highly concentrated nicotine preparations and the risk of accidental or deliberate overdose.

- Positive effects of nicotine

Nicotine has many positive effects and some smokers continue to smoke for these effects:

- Enhances fine motor skills, attention and concentration, arousal and working memory [54]
- Increased alertness
- Produces pleasure, and relief of anxiety and negative affect [11]
- Has positive effects on Parkinson's disease, schizophrenia, ulcerative colitis and attention deficit disorder
- Assists with weight control
- Possible protective effect on COVID-19 [55, 56]

- Benefits to the Australian vaping industry

Many Australian vape shops are setting up businesses in New Zealand to sell nicotine to Australian customers. Legal access to vaping in Australia would boost the Australian vaping industry, resulting in increased employment and the collection of sales tax and GST on vaping products worth many millions of dollars annually.

4 Toxicity

- Adverse effects

Nicotine is the main addictive chemical in tobacco smoke, but it has only minor adverse effects on health in the low doses used for smoking and vaping. [10, 11]

With normal use, the risks from vaping nicotine are low and serious side-effects are rare. According to the Cochrane review, 'None of the RCTs or cohort studies reported any serious adverse events (SAEs) that were considered to be plausibly related to ENDS use'. [57, 58] No serious adverse events were found in the two recent large RCTs mentioned above. [42, 43]

Similarly, with nicotine replacement products, a review of 28 studies found that "Typical symptoms indicating nicotine overdose together with high cotinine levels were rare during treatment with NRT. These findings support the safety of NRT for smoking cessation or reduction." [59]

Nicotine vaping has been widely available for over 15 years and there have been negligible serious adverse events from normal use. There has not been one death so far from vaping.

According to the UK Royal College of Physicians, “The long-term effects of nicotine are likely to be minimal”. [21] Nicotine does not cause cancer [60], does not cause respiratory disease [60] and is not a major cause of cardiovascular disease. [61]

There is some evidence from animal studies that nicotine may affect the brain developments of adolescents and harm the developing brain in the fetus. However, it is unclear whether this translates to humans.

- Nicotine intoxication for users

Nicotine intoxication is unlikely to occur in users, since the amount consumed and absorbed is lower than from smoking in most cases and blood nicotine levels rise more slowly than from smoking. [62] Vapers titrate their nicotine intake as smokers do with tobacco cigarettes and NRT. [63, 64] If nicotine levels rise, the user reduces their puffing frequency.

- Nicotine poisoning

According to Public Health England, the “risk of poisoning from ingestion of e-liquids appear to be comparable to ... potentially poisonous household substances.” (p13) [22]

Exposure to poisons is widespread in society and is associated with many products from which society benefits, such as bleach and laundry detergents. These are managed by common-sense, warning labels and child resistant containers.

The classification of all NRT products currently available in Australia (e.g. gums, lozenges, buccal tablets, sprays, inhalations) as unscheduled attests to the safety of nicotine in this context.

The minimum ingested dose limit for fatal outcomes in adults is estimated to be 500–1,000 mg of nicotine. [65]

The maximum dose of nicotine liquid per bottle recommended in this submission is 180mg, ie 30 ml x the maximum suggested strength of 6mg/ml, well below the minimum lethal adult dose.

Risks from nicotine poisoning are mitigated by several factors:

- The low maximum dose of nicotine per bottle (up to 180mg recommended)
- Immediate vomiting. Most cases of deliberate overdose result in prompt vomiting and serious outcomes are rare. [66, 67]
- Poor oral availability. When nicotine is swallowed, it has a low bioavailability. Only 20 to 45% is absorbed into the blood stream and oral bioavailability is also reduced further by the hepatic first-pass metabolism. [68]
- Low nicotine concentration. Standard concentrations of nicotine for vaping are 0.6 - 5%. The most popular strength is 1.8%.

Poisons Centre reports of nicotine liquid exposure suggest that accidental poisoning is rare and is usually mild. Serious events are very rare.

Wylie reviewed 202 cases of exposure to e-cigarettes and liquid nicotine reported to Australian Poisons Centres from 2019-2016. [51]

- Calls about e-cigarettes and nicotine represented only 0.015% of all calls received. That is less than one in five thousand calls.
- Most subjects who had exposure to nicotine had mild, self-limiting symptoms, although twelve had moderate symptoms, usually vomiting and sedation. No cases with severe symptoms were reported and there were no deaths

An analysis of liquid nicotine exposure in the US using National Emergency Injury Surveillance System data in 2018 found [69]

- An estimated 885 cases among children under 5 were treated in US hospitals
- Only 1.1% of cases were treated and admitted to hospital, ie approximately 9 cases

There have been several cases of child death from accidental poisoning globally over the last 10 years.

5 Dose and presentation

Commonly used nicotine concentrations are 3-24mg/ ml (0.3-2.4%) freebase nicotine and 20-60mg/ml (2-6%) for nicotine salt. The suggested maximum dose per bottle is 180mg of nicotine, based on a 30ml bottle of the maximum nicotine concentration used for vaping of 6mg/ml (6%).

There should be mandatory child-resistant containers, accurate labelling and health warnings.

6 Potential for abuse

Studies have consistently shown that vaping is less addictive than smoking based on self-reports, withdrawal symptoms, TTFC, cigarette dependence scales, laboratory studies. [36, 70] This makes it easier to transition off nicotine later.

Nicotine dependence is rare in young people who vape but have never previously smoked. In the 2018 US National Youth Tobacco Survey only 3.8% of never-smokers who vaped in the last 30 days reported cravings and 3.1% wanted to vape within 30 min of waking. [16]

Nicotine on its own is less addicting than smoke which contains other chemicals such as Monoamine Oxidase Inhibitors which enhance nicotine's addictive effect. [38] Smoking is also the fastest delivery system for nicotine and rapid delivery of nicotine to the brain increases dependence.

Nicotine has low dependence potential in NRT. A review of nicotine patch, gum, spray and inhaler concluded "that abuse liability from all four NRT products was low". [71]

Impact of the continuing classification of nicotine liquid as S4 and S7

- Lost opportunity for Public health

A large proportion of smokers are unable or unwilling to quit unaided or with conventional therapies and therefore remain at high risk. Quitting interventions have only a modest effect of 2-15% at 6-12months compared to no intervention. [72] Forty percent of Australian smokers try to quit at least once per year. [73] By the age of forty, the average smoker has tried and failed to quit twenty times.[74]

Vaping provides another exit strategy from deadly smoking for addicted smokers who would otherwise continue to smoke. However, the current scheduling of liquid nicotine has the effect of making nicotine vaping legally unavailable.

Vaping is the most popular and arguably the most effective quitting aid globally. In countries where vaping is widely available such as the US and UK, smoking rates are falling faster than ever, in part due to vaping.

All modelling studies (except one [31]) indicate a substantial net public health benefit from vaping, taking into account the risks of youth uptake, harm from vaping, uptake by non-smokers etc [32-34]. Based on the modelling

study by Levy in the US, vaping has the potential to prevent the premature deaths of hundreds of thousands of Australian smokers. [34]

- Continuing financial stress for smokers

Smoking is increasingly concentrated in low income and disadvantaged groups. The high cost of smoking is causing considerable financial distress and is contributing to health and financial inequalities.

Vaping is 85-90% cheaper than smoking and would result in substantial financial savings for the average smoker. Savings could contribute to better food, accommodation, a healthier lifestyle and considerably less stress.

Recommendations

We recommend that liquid nicotine is exempted from the Poisons Standard and made available as a consumer product. Consumer products are regulated by the Australian Competition and Consumer Commission (ACCC) which provide strong protection for consumers. The ACCC ensures that products are safe, fit for purpose and comply with all legal requirements, in particular under the *Competition and Consumer Act 2010*. Additional regulatory requirements will be needed such as post-market monitoring and surveillance and product recall procedures

Nicotine for vaping should be at least as accessible as combustible tobacco. Allowing widespread access to cigarettes at petrol stations, supermarkets and corner stores, while compelling vapers to get a prescription from a doctor and go to a pharmacy is clearly unworkable.

We propose the following rescheduling

Schedule 7

NICOTINE **except:**

- a) in preparations for human therapeutic use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use.; or
- b) in tobacco prepared and packed for smoking; or
- c) in preparations for use as a substitute for tobacco when packed and labelled:
 - (i) for use in an electronic vaporiser (e-cigarette)
 - (ii) nicotine concentration up to 6%
 - (iii) maximum nicotine per container: 180mg (30ml of 6% nicotine)
 - (iv) in a child resistant container
 - (v) labelled with the concentration of nicotine and other ingredients
 - (vi) labelled with the statement 'Keep out of reach of children'
 - (vii) labelled with the statement 'Not to be sold to a person under the age of 18 years'

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