

**DRAFT FOR CONSULTATION WITH RELEVANT RACP COLLEGE BODIES, AFFILIATED
SPECIALTY SOCIETIES AND MEMBERS**

**Draft Statement on Vapourised Nicotine Products development by the RACP's
Australasian Chapter of Addiction Medicine (AChAM) Committee**

Statement of the issue

The use of vapourised nicotine ("vaping") sets a challenge to public health and policy. On the one hand, its use is an important and evidence-based treatment to help people who are tobacco-dependent cease smoking. On the other hand, it has emerged in recent years as a primary addiction, especially in young people, and has the potential to lead to tobacco smoking.

Regulatory approaches in Australia and Aotearoa New Zealand

The Australian and Aotearoa New Zealand Governments have taken distinctly different approaches to regulating vapourised nicotine with the aim of balancing the potential benefits of vaping as a smoking cessation tool with the need to protect public health, and particularly young people:

- In Australia, the use of vapourised nicotine is regulated through the [*Therapeutic Goods and Other Legislation Amendment \(Vaping Reforms\) Act 2024*](#). Import controls on all vapes were introduced on 1 January 2024 and 1 March 2024, together with changes to the regulations for therapeutic vapes. Only vapes that have been notified to the TGA as meeting TGA requirements can be imported and as of 1 October 2024, therapeutic vapes containing nicotine or a zero-nicotine substance are available for supply in pharmacy settings to patients 18 years or over with or without a prescription depending on the jurisdiction.¹
- In Aotearoa New Zealand, the use of vapourised nicotine is regulated through the [*Smokefree Environments and Regulated Products \(Vaping\) Amendment Act 2020*](#) which allows the sale of vaping products, including nicotine-containing e-cigarettes, in designated retail outlets, subject to strict marketing and safety regulations.

1. Role of vapourised nicotine to assist people in tobacco cessation

a. Facts

- i. People with tobacco dependence are at significant risk of harm from their dependence (including COPD, many cancers, and vascular disease, among other harms). In Australia, deaths from tobacco use exceed 20,000 per annum.² Approximately 1.8 million Australians (~8.3% of the population) smoke daily (down from 2.3 million or 11% in 2019)³ - however among patients of Australian Alcohol and other Drug (AoD) Treatment services, it is estimated that approximately 84% smoke tobacco.⁴ As such, AoD patients represent a population likely to disproportionately benefit from tobacco cessation treatment and harm reduction strategies.

¹ Australian Government, Department of Health and Aged Care, Therapeutic Goods Administration (TGA). *Changes to the regulation of vapes*. 1 October 2024. Available from:

<https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/changes-regulation-vapes>

² Australian Institute of Health and Welfare (AIHW). *Australian Burden of Disease Study: Impact and causes of illness and death in Australia 2018*, Australian Burden of Disease Study series no. 23. Cat. no. BOD 29.

Canberra: Australian Institute of Health and Welfare; 2021. Available from:

<https://www.aihw.gov.au/reports/burden-of-disease/abds-impact-and-causes-of-illness-and-death-in-aus/summary>

³ Australian Institute of Health and Welfare (AIHW). *National Drug Strategy Household Survey 2022-2023*.

Canberra: Australian Institute of Health and Welfare; 2024. Available from: <https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey/contents/about>

⁴ Guydish J, Passalacqua E, Pagano A, Martinez C, Le T, Chun J, et al. *An international systematic review of smoking prevalence in addiction treatment*. *Addiction*. 2016;111(2):220–30. doi:10.1111/add.13099.

DRAFT FOR CONSULTATION WITH RELEVANT RACP COLLEGE BODIES, AFFILIATED SPECIALTY SOCIETIES AND MEMBERS

- ii. Vapourised nicotine is an effective tool to assist in the cessation of tobacco consumption, being more effective than conventional forms of nicotine replacement therapy (NRT)⁵ and comparable in effectiveness to varenicline.⁶

b. Recommendations

- i. Vapourised nicotine should be an option for tobacco dependent people wanting to cease consumption, either as first or second line treatment and should be available, affordable, and easily accessible. It is appropriate for there to be concerted efforts to make vapourised nicotine products available to AoD patients who smoke tobacco.
- ii. We support the Australian Federal Government's decision to make vapourised nicotine available through sale at pharmacies with or without prescriptions depending on the jurisdiction.

2. Problems of vapourised nicotine dependence

a. Facts

- i. There are rising rates of primary dependence to vapourised nicotine either in combination with tobacco smoking or alone, particularly in young people.³
- ii. The amount of nicotine consumed by people who “vape” can be significantly higher than that associated with tobacco consumption.
- iii. This population experiences significant dependence and may therefore need higher than usual doses of NRT to manage withdrawal symptoms.
- iv. Traditional screening questionnaires (e.g. Fagerström test for nicotine dependence) are not necessarily valid in this group, and tools to assess vapourised nicotine dependence are in their infancy.⁷
- v. There is a lack of clear evidence on how to treat dependence to vapourised nicotine. Currently, guidelines for the management of vapourised nicotine dependence are based on limited evidence, expert consensus and analogy with cigarette smoking and estimated dose of nicotine.^{8,9}

b. Recommendations

- i. People at risk of nicotine dependence should be identified by school health programmes, primary care practitioners or specialist services including hospitals through systematic screening processes and diagnosed (or risk stratified) through further questions at that time.
- ii. People identified as nicotine dependent (or high risk for dependence) should be treated initially in primary care, with referral to specialist services for more complex treatment as a back-up.

⁵ Lindson N, Butler AR, McRobbie H, Bullen C, Hajek P, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Livingstone-Banks J. *Electronic cigarettes for smoking cessation*. Cochrane Database of Systematic Reviews. 2024; (1).

⁶ Lindson N, Theodoulou A, Ordóñez-Mena JM, Fanshawe TR, Sutton AJ, Livingstone-Banks J, Hajizadeh A, Zhu S, Aveyard P, Freeman SC, Agrawal S. *Pharmacological and electronic cigarette interventions for smoking cessation in adults: component network meta-analyses*. Cochrane Database of Systematic Reviews. 2023; (9).

⁷ Piper ME, Baker TB, Benowitz NL, Smith SS, Jorenby DE. *E-cigarette dependence measures in dual users: reliability and relations with dependence criteria and e-cigarette cessation*. Nicotine and Tobacco Research. 2020 May;22(5):756-63.

⁸ Bittoun R. *Managing Vaping Cessation: A Monograph for Counselling Adult and Adolescent Vapers*. 2021.

⁹ The Royal Australian College of General Practitioners (RACGP). *Supporting smoking & vaping cessation: A guide for health professionals*. Melbourne: RACGP; 2024. Available from: <https://www.racgp.org.au/getmedia/924ba55d-dc47-41f9-bf5b-7a4cf9e19963/RACGP-NVP-and-Vaping-Cessation-September-2024.pdf.aspx>

**DRAFT FOR CONSULTATION WITH RELEVANT RACP COLLEGE BODIES, AFFILIATED
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- iii. Further work on validating screening, diagnostic and treatment pathways for nicotine dependence is needed.¹⁰

3. Public health impact of vaping availability

a. Facts

- i. The long-term health effects of tobacco consumption are well known.
- ii. At this stage there is still some uncertainty about the long-term health consequences of vapourised nicotine consumption.
- iii. There are harms identified from the consumption of vapourised nicotine, although on the current evidence these harms are far less severe than for long term tobacco consumption/dependence.^{11,12}
- iv. The availability of vaping devices in Australia and Aotearoa New Zealand has seen an increase in the number of young people consuming nicotine and/or tobacco, albeit with a reduction in the amount of tobacco consumed in recent years.^{13,14,15} It is unclear how these trends will continue in the longer term.
- v. The majority of vaping devices in Australia are currently sold and used illicitly.¹⁶ These illicit devices are manufactured in Australia and overseas in an unregulated fashion and are often unlabelled with unknown and potentially toxic constituents. It is, thus, very difficult to describe the risk associated with using illicit and unregulated devices - as compared with the use of pharmaceutical-grade, regulated nicotine products, where contents are known and effects predictable.
- vi. Given the uncertainties around the long-term health impacts of vaping and the longer-term trends in their use, it is possible that the availability of pharmaceutical grade vapourised nicotine may lead to either net public health benefits or alternatively public health harm if there is a concomitant reduction in tobacco smoking.
- vii. Now the Australian Government has taken the decision to ban vapourised nicotine apart from medical prescriptions, or through pharmacies, there are a number of levers that are available to it to further modify the risks and patterns of uptake. These include the nature of the enforcement of the legal status and regulation of manufacture and labelling of vapourised nicotine products. They also include the range of tobacco policy responses, and the possibility to link vaping and tobacco cessation policies (i.e. the phase out of

¹⁰ Note: Bittoun R, Anderson P, Kahler CW, Cioe PA, Miyata H, and Zwar N. *Tobacco and nicotine* (Chapter 11) includes information about Combination NRT for adolescents who vape. In: Saunders JB, Nutt DJ, Higuchi S, Assanangkornchai S, Bowden- Jones H, van den Brink W, Bonomo Y, Poznyak V, Saxon AJ, and Strang J, eds. *Oxford Handbook of Addiction Medicine 3rd ed.* Oxford: Oxford University Press; 2024: p.279- 322. doi: 10.1093/med/9780192844088.001.0001. ISBN: 9780 92844088.

¹¹ UK Office for Health Improvement and Disparities, *Nicotine vaping in England: 2022 evidence update main findings*. Published 29 September 2022. Available from: <https://www.gov.uk/government/publications/nicotine-vaping-in-england-2022-evidence-update/nicotine-vaping-in-england-2022-evidence-update-main-findings>

¹² Marques P, Piqueras L, Sanz MJ. *An updated overview of e-cigarette impact on human health*. Respiratory research. 2021 May 18;22(1):151.

¹³ Australian Institute of Health and Welfare (AIHW), *Young people's use of vapes and e-cigarettes*, Figure 5: Dual use of regular cigarettes and e-cigarettes, people aged 15 to 24, 2016 to 2022-2023. Canberra: Australian Institute of Health and Welfare; 2024. Available from: <https://www.aihw.gov.au/reports/smoking/young-peoples-vapes-e-cigarettes>

¹⁴ Edwards R, Hoek J, Waa A, Ball J., Public Health Communication Centre Aotearoa, *What is happening with vaping amongst adolescents and young adults in Aotearoa?* 2023.

¹⁵ Manatū Hauora Minister of Health, *Smoking status of daily vapers: New Zealand Health Survey 2017/18 to 2021/22*. 2023. Available from: https://www.health.govt.nz/system/files/2023-05/smoking_status_of_daily_vapers.pdf

¹⁶ Australian Institute of Health and Welfare (AIHW). *Vaping and e-cigarette use in the NDSHS*. Canberra: Australian Institute of Health and Welfare; 2024. Available from: <https://www.aihw.gov.au/reports/smoking/vaping-e-cigarette-use>

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tobacco in combination with an increased availability of vapourised nicotine). There is significant variability in policies taken by different jurisdictions around the world and there is not a consensus at this point of time on the optimal policy mix.

- viii. While a purely prohibitionist or highly restrictive model for vapourised nicotine may seem appealing, past experiences with prohibition have shown many unforeseen problems and the use of illicit, unregulated and potentially hazardous vaping devices continues.

b. Recommendations

- i. Policies should be developed that focus on health as the primary outcome, i.e. reducing the harm from vaping and tobacco while maximising the potential therapeutic value of availability of vapourised nicotine
- ii. More work on the optimal policy mix to maximise health is needed.

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