

# **POSITION STATEMENT**

# Managing Nicotine Dependence and Smoking Cessation in Community Pharmacy

## Position

The Pharmacy Guild of Australia (the Guild) recognises that recreational use of nicotine products poses serious health and social risks to Australians through direct effects (such as dependence and other pharmacological effects on body systems) and indirect effects (such as passive inhalation of smoke or exhalants)<sup>1</sup>. The Guild believes that nicotine products for recreational use should be restricted to adults over 18 years of age and accessed only from licensed premises with licensing details publicly available. The Guild supports Governments at all levels undertaking initiatives in consultation with relevant stakeholders to minimise and prevent nicotine dependence and aid smoking cessation in Australia, including restrictions to limit or reduce recreational use of nicotine products as well as programs to manage and treat nicotine dependence.

The Guild calls for better access to clinical care to increase the success of people breaking their nicotine habit as research has demonstrated that use of cessation medicines accompanied by counselling is more effective. In fact, combining cessation medicines with multisession, intensive group or individual counselling achieves the highest quit rates.<sup>2</sup> With an extensive network of almost 6,000 pharmacies located in most communities of Australia and easy access to clinical care from a highly trained and skilled pharmacist, community pharmacy has an important role to play in assisting the Australian public with nicotine dependence and smoking cessation. Community pharmacy provides the public with access to advice, counselling, support and treatments for smoking cessation, vaping cessation, and cessation from other emerging nicotine-containing products. Pharmacists can also triage and refer to other clinicians when appropriate as well as facilitate enrolment into more intensive support services.

Pharmacists have professional obligations requiring the provision of treatment options to be based on the best available information and without influence of financial gains or incentives. In addition, clinical practice must also be within an evidence-based and patient-centred framework.<sup>3</sup> With this in mind, the Guild believes that the management of nicotine dependence and smoking cessation is best managed by:

- access to approved evidence-based treatments included on the Australian Register of Therapeutic Goods (ARTG)
- interaction with a clinician for a comprehensive assessment, counselling and ongoing clinical support
- enrolment and ongoing attendance in a quality-assured nicotine dependence and/or smoking cessation support program, either in-person or remotely

Recognising the barriers to people wanting to manage their nicotine dependence and/or stop smoking, including the costs of clinical care and treatments as well as access to clinicians, the Guild calls for:



- pharmacists being able to prescribe and supply all approved products, including as a pharmaceutical benefit (i.e. bupropion, nicotine replacement therapy (NRT) and varenicline) for the management of nicotine dependence or smoking cessation
- expanding and expediting PBS listings for approved products for nicotine dependence and smoking cessation, including for a wider range of NRT products such as gum, lozenges, inhalers and mouth sprays
- prescribing and supply of nicotine dependence and smoking cessation treatments consistent with contemporary clinical guidelines

The Guild does not support the supply of unapproved goods without a prescription. The Guild believes that products intended for therapeutic use which are unapproved should only be available as a Schedule 4<sup>4</sup> medicine on prescription from an authorised prescriber consistent with contemporary clinical guidelines and based on empirical evidence.

The Guild believes there needs to be controls in place which limits the supply of unapproved products in preference to approved products to encourage manufacturers or sponsors to accumulate their evidence base and register their products for therapeutic use in Australia. Once registered, scheduling should be determined by the Advisory Committee on Medicine Scheduling (ACMS)<sup>5</sup> involving professional and consumer representatives as well as Commonwealth and state and territory health representatives, and which is open to public consultation.

The Guild understands that some people wishing to stop smoking to reduce the harm to themselves and others may regard the ongoing use of smoking cessation products such as NRT or vapes as a safer alternative. The Guild recognises this approach as a potential harm minimisation strategy but believes that consideration must also be given to the long-term effects of the ongoing use of these products as an alternative to cigarettes.<sup>6</sup>

The Guild supports the National Tobacco Strategy 2023-2030 and recognises its priority area to strengthen regulations on e-cigarettes and novel and emerging products<sup>7</sup>. The Guild as the representative body for community pharmacy must continue to be an active participant in the review and amendment of such strategies.

The Guild welcomes any opportunity to form partnerships and strategic alliances to develop new ideas, practices and directions in relation to nicotine dependence and smoking cessation interventions delivered in the primary health care system so that we all effectively respond to the needs of the population and achieve better public health outcomes.

### **Pharmacist Prescribing of treatments**

The Guild believes that expanding the current evidence-based treatment options through PBS prescribing by community pharmacists as part of an in-pharmacy nicotine-dependence consultation will provide people with more accessible options and help reduce the burden of nicotine dependence in Australia.

There is clear evidence that individuals are more likely to quit smoking successfully when supported and counselled by health professionals.<sup>8</sup> Data has indicated that pharmacy-based services may be more effective for younger smokers and those suffering greater disadvantage (e.g. lower income, chronic illness).<sup>9</sup> To facilitate combining pharmacotherapy with clinical counselling and support, the Guild believes that approved non-prescription NRT should be restricted to sale from a pharmacy, ideally as a Schedule 2 medicine.

The Guild believes that a national community pharmacy program similar to the Queensland scope of practice pilot<sup>10</sup> smoking cessation service should be available to people across the country for the management of nicotine dependence and smoking cessation. Such a program must include proper

remuneration for the pharmacy and allow pharmacists to practice to their full scope to provide people with convenient access to all evidence-based subsidised treatments, including as a pharmaceutical benefit.

### **Access to Vaping Products (vapes)**

The Guild recognises the health risks associated with the recreational use of vapes, particularly for young people.<sup>11</sup> The Guild agrees in principle with the Government's intent of restricting access to vapes in general, and limiting the use of vapes only when indicated as a treatment for nicotine dependence or smoking cessation. However, the Guild does not support the scheduling of vapes as over-the-counter medicines (i.e., Schedule 2 or 3) nor access to unapproved vapes as a nicotine dependence or smoking cessation treatment, unless on prescription from an authorised prescriber and consistent with contemporary clinical guidelines.

If Governments wish to provide greater access to unapproved vapes as a treatment for nicotine dependence or smoking cessation, they should invest in clinical research to evaluate their efficacy and long-term adverse effects.

The Guild believes there needs to be strict regulations in place by all Governments and professional oversight by Ahpra according to their Code of Conduct<sup>12</sup>, to avoid the emergence of telehealth vapedispensary/clinic models or unprofessional and unsafe processes.

## Background

Tobacco is the leading preventable cause of morbidity and mortality in Australia. The Australian Burden of Disease Study 2018 found that tobacco smoking was responsible for 8.6% of the total burden of disease and injury. Estimates of the burden of disease attributable to tobacco use showed that cancers accounted for 44% of this burden.<sup>13</sup> Among Australian adults aged under 25, there was a substantial increase in daily vaping between 2019 and 2022–23 – from about 2% of young men aged 18–24 in 2019 to 8.5% in 2022–23, and from fewer than 1% of young women of the same age in 2019 to 10.3% in 2022–23.<sup>14</sup>

The World Health Organisation (WHO) recommends combining pharmacotherapy and behavioural interventions to support tobacco users to quit, <sup>15</sup> and the additional intervention by a clinician has demonstrated greater success for cessation <sup>16</sup>.

Quitting smoking is beneficial to overall health status and enhances the quality of life. It reduces the risk for many adverse health effects, including cardiovascular diseases, chronic obstructive pulmonary disease (COPD), cancer, and poor reproductive health outcomes. It also reduces the risk of premature death and can add as much as 10 years to life expectancy.<sup>17</sup> Evidence suggests that stopping smoking boosts mental health and reduces anxiety and depression after the withdrawal stage.<sup>18</sup> Quitting also has the benefit of protecting other people from the harmful effects of passive smoking.

### Frameworks for managing nicotine dependence and smoking cessation

The National Tobacco Strategy 2023-2030 is a strategy to improve the health of all Australians by reducing the prevalence of tobacco use and its associated health, social, environmental, and economic costs, and the inequalities it causes.<sup>19</sup>

In February 2005, WHO's Framework Convention on Tobacco Control (FCTC)<sup>20</sup> entered into force. The Australian Government formally ratified the FCTC in October 2004 becoming the 34th Contracting Party to the Convention which requires elimination of all tobacco advertising, promotion and sponsorship; requires prohibition of misleading tobacco product descriptors such as "light" and "mild"; commits nations to protecting non-smokers from tobacco smoke in public places; urges strict regulation of tobacco product contents; and calls for higher tobacco taxes, global coordination to fight tobacco smuggling, and promotion of tobacco prevention, cessation and research programs.

### **Nicotine Vaping Products**

The Australian Government has implemented stronger regulation and enforcement of all vapes to reduce the use by adolescents and adults and minimise the black-market influx of vapes. Under these reforms<sup>21</sup> the personal importation scheme for nicotine vapes was permanently ceased, the Therapeutic Goods Order (TGO 110) was updated, and the Special Access Scheme C pathway was made available to more prescribers and nurse practitioners to prescribe nicotine vapes.

The TGA<sup>22</sup> and the RACGP's clinical guidelines for smoking cessation<sup>23</sup>, recognises the limited evidence available to support the use of vapes for smoking cessation. The RACGP guidelines:

- only recommends their use 'for people who want to quit but have failed to achieve smoking cessation with first-line therapy i.e. a combination of behavioural support and TGA-approved pharmacotherapy
- recognise a lack of evidence for length of therapeutic use of vapes with recommendations for weaning or cessation after 12 weeks, or consideration to switch to NRT or other therapies
- advise a maximum duration of 12 months' use of nicotine vapes is a reasonable consideration.

#### **Controls for stock-holding and supply**

There are no controls or legislation requiring pharmacists to stock any particular medicine. As far as practicable, a PBS approved pharmacist is expected to keep in stock an adequate supply of drugs and medicinal preparations for which they may be reasonably called upon to supply as a pharmaceutical benefit<sup>24</sup>. This only applies to PBS listed items and remains discretionary according to the pharmacist's knowledge of their local community, local prescribing behaviour and local prescription needs.

A pharmacist may refuse to supply a medicine based on legal, safety or ethical reasons. Under state and territory laws, clinicians are required to only prescribe, dispense and/or supply a medicine based on therapeutic need and which is safe and appropriate for use by the patient concerned.

## **Related Policies**

Community Pharmacy and Harm Minimisation

## **Authority**

#### Endorsed

National Council – August 2024 National Council – November 2020 National Council – March 2015 National Council – March 2011 National Council – June 2007 National Council – November 2003

#### Reviewed

Policy & Regulatory Sub-Committee – August 2024 Policy and Regulation Sub-Committee – October 2020 Policy and Regulation Sub-Committee – January 2015 Government Relations & Policy Committee – February 2011 Policy/Government/Communications Committee – May 2007 Strategic Policy/Rural and Professional Services Committee – November 2003

## References

<sup>1</sup> <u>Pharmacological Approach to Smoking Cessation: An Updated Review for Daily Clinical Practice | High Blood Pressure &</u> Cardiovascular Prevention (springer.com); 2020

<sup>2</sup> Smoking Cessation: A Report of the Surgeon General; US Department of Health and Human Services; 2020; Chapter 6; <u>Smoking</u> Cessation - NCBI Bookshelf (nih.gov)

<sup>3</sup> Ahpra Code of Conduct June 2022; <u>Australian Health Practitioner Regulation Agency - Shared Code of conduct (ahpra.gov.au)</u>

- <sup>4</sup> Schedule 4 of the Poison Standard; The Poisons Standard (the SUSMP) | Therapeutic Goods Administration (TGA)
- <sup>5</sup> Advisory Committee on Medicines Scheduling (ACMS) | Therapeutic Goods Administration (TGA)

- <sup>7</sup> National Tobacco Strategy 2023–2030 | Australian Government Department of Health and Aged Care: Priority Area 9
- <sup>8</sup> National Drug Strategy 2017–2026 | Australian Government Department of Health and Aged Care
- <sup>9</sup> Smoking cessation in community pharmacy practice-a clinical information needs analysis PMC (nih.gov)
- <sup>10</sup> About the pilots | Queensland Health

<sup>11</sup> Vaping – the facts | Youth vaping | Australian Government Department of Health and Aged Care

<sup>12</sup> Australian Health Practitioner Regulation Agency - Regulators come together as one million Australians turn to medicinal cannabis treatments (ahpra.gov.au)

<sup>13</sup> Alcohol, tobacco & other drugs in Australia, Tobacco and e-cigarettes - Australian Institute of Health and Welfare (aihw.gov.au)

<sup>14</sup> <u>18.3 Prevalence of e-cigarette use - Tobacco in Australia</u>

<sup>15</sup> WHO clinical treatment guideline for tobacco cessation in adults; 2024;

<sup>16</sup> Treatment of Tobacco Smoking: A Review | Tobacco and e-Cigarettes | JAMA | JAMA Network; Feb 2022

- <sup>17</sup> Benefits of Quitting Smoking | Smoking and Tobacco Use | CDC
- <sup>18</sup> Benefits of quitting smoking NHS (www.nhs.uk)
- <sup>19</sup> National Tobacco Strategy | Australian Government Department of Health and Aged Care
- <sup>20</sup> WHO Framework Convention on Tobacco Control overview
- <sup>21</sup> New regulation of vapes starting January 2024 | Therapeutic Goods Administration (TGA)
- <sup>22</sup> Vapes: information for prescribers | Therapeutic Goods Administration (TGA)
- <sup>23</sup> RACGP-NVP-and-Vaping-Cessation-Consultation-provisional-draft-Dec2023.pdf.aspx; Recommendation 15
- <sup>24</sup> National Health (Pharmaceutical Benefits) Regulations 2017; clause 62

<sup>&</sup>lt;sup>6</sup> Long-term Nicotine Replacement Therapy: Cancer Risk in Context | Cancer Prevention Research | American Association for Cancer Research (aacrjournals.org); 2011