



**Australian Government**

**Department of Health and Aged Care**

Therapeutic Goods Administration

# Notice of decision to amend (or not amend) the current Poisons Standard in relation to nicotine

24 May 2024

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# Notice of decision to amend (or not amend) the current Poisons Standard

This web publication comprises:

- a decision made by a delegate<sup>1</sup> of the Secretary of the Department of Health and Aged Care (the **Delegate**) pursuant to section 52D(2) of the Act
- reasons for the decision, and
- the date of effect of the decision.

## **Defined terms**

- In this notice, the following terms are used in addition to those above:
- the *Therapeutic Goods Act 1989* (Cth) (the **Act**)
- the Therapeutic Goods Regulations 1990 (the **Regulations**)
- the [Scheduling Policy Framework](#) 2018 (the **SPF**)
- the Scheduling handbook, [Guidance for amending the Poisons Standard](#) (the **Handbook**)
- the Australian Register of Therapeutic Goods (the **Register**) and
- the Therapeutic Goods Administration (the **TGA**)

Note: additional terms are also defined for individual decisions.

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<sup>1</sup> For the purposes of s 52D of the *Therapeutic Goods Act 1989* (Cth).

# Decision on proposed amendments to the current Poisons Standard

In my capacity as a delegate of the Secretary for the purpose of section 52D(2) of the Act, I have made a decision with respect to nicotine.

## Decision in relation to nicotine

### Decision

Pursuant to section 52D(2) of the Act, a Delegate of the Secretary has made a decision to amend the current Poisons Standard in relation to nicotine as follows:<sup>2</sup>

#### Schedule 7 – Amend entry

NICOTINE **except:**

- (a) when included in Schedule 4; or
- (b) in preparations for oromucosal or transdermal administration for human therapeutic use when included in the Register as an aid in withdrawal either from tobacco smoking or nicotine vaping; or
- (c) in tobacco prepared and packed for smoking.

#### Schedule 4 – Amend entry

# NICOTINE in preparations for human use **except:**

- (a) in preparations for oromucosal or transdermal administration for human therapeutic use when included in the Register as an aid in withdrawal either from tobacco smoking or nicotine vaping; or
- (b) in tobacco prepared and packed for smoking.

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#### NICOTINE

Schedule 7

Schedule 4

Appendix D, clause 5

Appendix F, clause 4

Appendix J, clause 1

#### Appendix D, clause 5 – Poisons for which possession without authority is illegal.

Item	Poison
24	NICOTINE

<sup>2</sup> Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

**Appendix F, clause 4 – Poisons that must be labelled with warning statements and safety directions.**

Item	Poison	Warning statement item number	Safety direction item number
237	NICOTINE <b>except</b> when in tobacco		1, 4

**Appendix J, clause 1 – Poisons that must be labelled with warning statements and safety directions.**

Item	Poison	Condition
65	NICOTINE <b>except</b> when in tobacco	

**Materials considered**

In making this decision, the Delegate considered the following material:

- subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (f) any other matters considered necessary to protect public health.
- paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

**Reasons for the decision (including findings on material questions of fact)**

In exercising my power under section 52D(2) of the Act, I have taken into account the information provided in the materials listed above. I have made a decision to amend the Schedule 4 and 7 entries for nicotine in the Poisons Standard to restrict the exemptions of oromucosal or transdermal nicotine preparations to those that are used as an aid in withdrawal from tobacco smoking or nicotine vaping and are entered on the Australian Register of Therapeutic Goods (the Register).

In relation to my decision to include reference to oromucosal or transdermal nicotine preparations that are used for nicotine vaping withdrawal in the exemption, under s 52E(1)(a) and (b) of the Act, I acknowledge that at present there is a significant prevalence of nicotine vaping in Australia. There is a need in the community for aids to manage nicotine withdrawal associated with nicotine vaping. Nicotine preparations indicated for withdrawal from nicotine vaping are currently classified as Schedule 4 (prescription only) medicines. I consider enabling greater accessibility to nicotine vaping cessation aids to support individuals, especially younger people, will provide additional public health benefits. I note the inclusion of nicotine vaping cessation as an indication will require a sponsor to submit an application to the TGA with sufficient evidence to support such use for evaluation by the TGA. Ultimately, the registration of such product will enable consumers to access evidence-based nicotine vaping cessation products that may be readily marketed and available in general sale, such as supermarkets and convenience stores, without a prescription.

In making the decision to restrict the exception in paragraph (b) of the Schedule 4 entry for nicotine to registered preparations included in the Register, I have, under s 52E(1)(b) and (c) of the Act, noted the increasing profile of novel nicotine preparations in Australia, including nicotine pouches and nicotine infused toothpicks. Of particular concern is the promotion of nicotine pouches to young people as an aid to support smoking or nicotine vaping cessation. Nicotine pouches are small pouches or bags containing nicotine and sometimes other ingredients such as sweeteners and flavours that are intended to be placed between the lip and gum, where nicotine is absorbed into the body.

I note at present there is no evidence to support the use of these nicotine pouches or toothpicks for smoking or nicotine vaping cessation, nor the effects of long-term use of these products. Furthermore, exposure to nicotine may lead to increased heart rate, nausea, dizziness, and abdominal cramps, especially to those who do not usually smoke or vape. Evidence also shows nicotine may also have adverse impacts on adolescent brain development.

Regarding the matters in paragraphs 52E(1)(a), (d) and (f) of the Act, currently none of these novel nicotine products are included in the Register, meaning these products have not been evaluated by the TGA for their quality, safety, or efficacy. Of particular concern, these products can be supplied with high levels of nicotine and may also include unspecified materials or ingredients, which present significant safety concerns.

I note that nicotine pouches in particular are being marketed to the community through a range of channels and are easily accessible through the internet, convenience stores and tobacconists. Marketing strategies of these products include unproven health claims, brightly coloured packaging and flavours that appeal to young people. With regard to the matters in s 52E(1)(a) and (d) of the Act, I am also concerned in relation to the risks to the health of children from the packaging and presentation of nicotine pouches. The combination of diverse flavours and sale in small, easily openable plastic and metal containers, means the presentation resembles various confectionary products. This may lead to increased risks of accidental poisoning, especially in children.

Nicotine products, including nicotine pouches, are considered therapeutic goods under Australian law. To lawfully supply or advertise therapeutic goods in Australia, these products must be included in the Register or be covered by an authority or approval under the Act. At present, none of these nicotine products are included in the Register and therefore the supply of these unregistered nicotine products to consumers is unlawful in Australia unless such an approval or authority is in place.

There is an increasing trend in the importation, supply and advertisement of these products in Australia, particularly since 1 January 2024 when the prohibition on importation of disposable vapes commenced. I consider that the supply of these unlawful and unregistered nicotine products poses significant public health risks. I find urgent control under the current Poisons Standard is necessary to regulate the supply of such novel nicotine products and to protect public health. This scheduling change will not affect existing lawful nicotine products that are already included in the Register. It is my view that this additional restriction will support Commonwealth, state and territory authorities to identify unlawful nicotine products and carry out relevant law enforcement activities more effectively. It will also ensure consumers are accessing safe and efficacious nicotine cessation products that are supported by evidence.

### ***Implementation date***

**1 June 2024**

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