



Therapeutic Goods (Poisons Standard) (Therapeutic Vaping Goods) Labelling Exemption 2024

I, Anthony Lawler, as an appropriate authority, make the following labelling exemption.

Dated 27 September 2024

Professor Anthony Lawler
Deputy Secretary
Health Products Regulation Group
Department of Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods (Poisons Standard) (Therapeutic Vaping Goods) Labelling Exemption 2024*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

| Commencement information | | |
|---------------------------------|-----------------|----------------|
| Column 1 | Column 2 | Column 3 |
| Provisions | Commencement | Date/Details |
| 1. The whole of this instrument | 1 October 2024. | 1 October 2024 |

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 39 of the current Poisons Standard.

4 Definitions

Note 1: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

- (a) current Poisons Standard;
- (b) exempt goods;
- (c) Secretary;
- (d) sponsor.

Note 2: A number of expressions used in this instrument are defined in section 6 of the current Poisons Standard, including the following:

- (a) appropriate authority.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

Regulations means the *Therapeutic Goods Regulations 1990*.

specified goods means therapeutic vaping substances or therapeutic vaping substance accessories that:

- (a) are exempt goods under the regulations made for the purposes of subsection 18(1) of the Act in relation to which the sponsor has given the Secretary a sponsor notice; and

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- (b) are not the subject of a determination made by the Secretary in accordance with the relevant item, published on the Department’s website, that the supply of the goods be stopped or should cease because the Secretary is satisfied that the supply of the goods compromises public health and safety or the goods do not conform with a standard applicable to the goods; and
 - (c) contain nicotine as the only active ingredient; and
 - (d) are labelled by the sponsor in accordance with section 16 of the current Poisons Standard for poisons included in Schedule 4 with the signal words ‘PRESCRIPTION ONLY MEDICINE’; and
 - (e) at the time of supply by a medical practitioner, nurse practitioner or pharmacist to another person, or carer of that person—are poisons to which the entry for nicotine in Schedule 3 to the current Poisons Standard applies.

Note: Nicotine in therapeutic vaping goods (within the meaning of the Regulations) in final dosage form for smoking cessation or the management of nicotine dependence is a poison included in Schedule 3 to the current Poisons Standard in specified circumstances, including when supplied to persons aged 18 years or over, the pharmacist requests and sights evidence of the patient’s identity and age, and the concentration of nicotine in the goods does not exceed 20 mg/mL.

sponsor notice means a notice given to the Secretary in compliance with the requirements of item 15 in the table in Schedule 5A to the Regulations.

therapeutic vaping substance has the same meaning as in the Regulations.

therapeutic vaping substance accessory has the same meaning as in the Regulations.

5 Exemption

- (1) The specified goods are exempt from the requirement in section 16 of the current Poisons Standard to include the signal words ‘PHARMACIST ONLY MEDICINE’.
- (2) The exemption remains in force until 30 September 2025.

6 Repeals

This instrument is repealed at the start of 1 October 2025, unless repealed earlier.