

Therapeutic Goods (Poisons Standard) (Paracetamol) Labelling Exemption (No. 2) 2024

I, Tracey Duffy, as the appropriate authority, grant the following labelling exemption.

Dated 12 November 2024

Tracey Duffy
Acting 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) (Paracetamol) Labelling Exemption (No. 2) 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 Provisions	Column 2 Commencement	Column 3 Date/Details

Note: This

This table relates only to the provisions of this instrument as originally made.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) medicine;
- (c) 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.

5 Exemption—Schedule 2 medicines

(1) In this section:

specified products means medicines containing paracetamol:

(a) included in Schedule 2 to the current Poisons Standard; and

- (b) that was not included in a Schedule to the current Poisons Standard immediately before 1 February 2025.
- (2) The specified products are exempt from the labelling requirements in section 16 of the current Poisons Standard.
 - Note 1: Under section 13 of the current Poisons Standard, a scheduled substance or preparation must not be supplied unless labelled in accordance with Division 2 of Part 2 of the current Poisons Standard.
 - Note 2: This subsection exempts specified products from the requirement to have signal words.
- (3) The exemption in subsection (2) remains in force until 31 January 2026.

6 Exemption—Schedule 3 medicines

(1) In this section:

specified products means medicines:

- (a) containing paracetamol:
 - (i) included in Schedule 3 to the current Poisons Standard; and
 - (ii) that was included in Schedule 2 to the current Poisons Standard immediately before 1 February 2025; and
- (b) labelled, in accordance with the requirements in section 16 of the current Poisons Standard, with the signal words 'PHARMACY MEDICINE'.
- (2) The specified products are exempt from the labelling requirements in section 16 of the current Poisons Standard that apply to poisons included in Schedule 3 to the current Poisons Standard.
 - Note 1: Under section 13 of the current Poisons Standard, a scheduled substance or preparation must not be supplied unless labelled in accordance with Division 2 of Part 2 of the current Poisons Standard.
 - Note 2: This subsection exempts medicines containing paracetamol in Schedule 3 to the current Poisons Standard from the requirement to have signal words 'PHARMACIST ONLY MEDICINE' written on the label where the medicine instead has the signal words 'PHARMACY MEDICINE' written on the label.
- (3) The exemption in subsection (2) remains in force until 31 January 2026.

7 Repeals

Unless repealed earlier, this instrument is repealed at the start of 1 February 2026.