



Therapeutic Goods (Poisons Standard) (COVID-19 Vaccine—Pfizer) (Raxtozinameran) Labelling Exemption 2023

I, Nicholas Henderson, as the appropriate authority, grant the following labelling exemption.

Dated 13 October 2023

Nicholas Henderson
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) (COVID-19 Vaccine—Pfizer) (Raxtozinameran) Labelling Exemption 2023*.

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	The day after this instrument is made.	14 October 2023

Note: This table relates only to the provisions of this instrument as originally made.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) Register;
- (c) registered goods.

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*.

specified products means registered goods that are vaccines, and that:

- (a) contain the active ingredient raxtozinameran; and
- (b) have an indication accepted in relation to their inclusion in the Register that relates to the prevention of coronavirus disease 2019 (COVID-19); and
- (c) are manufactured, imported or supplied by Pfizer Australia Pty Ltd.

5 Exemption

- (1) The specified products are exempt from the labelling requirements in:
 - (a) section 16 of the current Poisons Standard; and
 - (b) section 18 of the current Poisons Standard; and
 - (c) section 26 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: Section 5 of this instrument exempts the specified products from the following labelling requirements in Division 2 of Part 2 of the current Poisons Standard:

- (a) labelling of the primary pack and immediate container with signal words, as required by section 16;
- (b) labelling of the primary pack and immediate container with the cautionary statement 'KEEP OUT OF REACH OF CHILDREN', as required by section 18;
- (c) labelling of the primary pack and immediate container with the approved name and a statement of the quantity, proportion or strength (in accordance with section 34), as required by section 26.

- (2) The exemption in subsection (1) remains in force until 30 September 2024.

6 Repeals

Unless repealed earlier, this instrument is repealed at the start of 1 October 2024.