



Therapeutic Goods (Poisons Standard) (COVID-19 Vaccine—Pfizer) (SARS-CoV-2 Spike Protein (mRNA) LP.8.1) Labelling Exemption 2025

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

Dated 7 October 2025

Professor Anthony Lawler
Deputy Secretary
Health Products Regulation Group
Department of Health, Disability and Ageing

Contents

1 Name.....	1
2 Commencement.....	1
3 Authority.....	1
4 Definitions.....	1
5 Exemption.....	2

1 Name

This instrument is the *Therapeutic Goods (Poisons Standard) (COVID-19 Vaccine—Pfizer) (SARS-CoV-2 Spike Protein (mRNA) LP.8.1) Labelling Exemption 2025*.

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.	8 October 2025

Note: This table relates only to the provisions of this instrument as originally made.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 SARS-CoV-2 spike protein (mRNA) LP.8.1; 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 in, imported into, or supplied in, Australia by Pfizer Australia Pty Ltd.

5 Exemption

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.

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 intermediate container with signal words, as required by section 16;
- (b) labelling of the primary pack and intermediate container with the cautionary statement 'KEEP OUT OF REACH OF CHILDREN', as required by section 18.