



Therapeutic Goods (Poisons Standard) (COVID-19 Treatment—GlaxoSmithKline) (Sotrovimab) Labelling Exemption 2022

I, John Skerritt, as the appropriate authority, grant the following labelling exemption.

Dated 3 August 2022

Adjunct Professor John Skerritt
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 Treatment—GlaxoSmithKline) (Sotrovimab) Labelling Exemption 2022*.

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.	4 August 2022

Note: This table relates only to the provisions of this instrument as originally made.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 labelling exemption is granted under section 1.5.5 of Part 2 of the current Poisons Standard.

4 Definitions

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

- (a) current Poisons Standard;
- (b) medicine;
- (c) Register;
- (d) registered goods.

Note 2: A number of expressions used in this labelling exemption are defined in section 1 of Part 1 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 medicine, and that:

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

5 Exemption

The specified products are exempt from the labelling requirements in:

- (a) section 1.3(1)(a) of Part 2 of the current Poisons Standard; and
- (b) section 1.3(1)(c) of Part 2 of the current Poisons Standard; and
- (c) section 1.3(1)(k) of Part 2 of the current Poisons Standard; and
- (d) section 1.4(1)(a) of Part 2 of the current Poisons Standard.

Note 1: Under section 1.1(1) of Part 2 of the current Poisons Standard, a scheduled substance or preparation must not be supplied unless labelled in accordance with section 1 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 section 1 of Part 2 of the current Poisons Standard:

- (a) labelling of the primary pack and immediate container with signal words, as required by section 1.3(1)(a);
- (b) labelling of the primary pack and immediate container with the cautionary statement 'KEEP OUT OF REACH OF CHILDREN', as required by section 1.3(1)(c);
- (c) labelling of the primary pack and immediate container with the approved name and a statement of the quantity, proportion or strength, as required by sections 1.3(1)(k) and 1.4(1)(a).

6 Repeals

Each instrument that is specified in Schedule 1 is repealed as set out in the applicable items in that Schedule.

Schedule 1—Repeals

Note: See section 6.

Therapeutic Goods (Poisons Standard) (COVID-19 Treatment— GlaxoSmithKline) (Sotrovimab) Labelling Exemption 2021

1 The whole of the instrument

Repeal the instrument.