



Department of Health
Certification no: C-FILE-21962-026

Certified alternative way (to complying with the Poisons Standard, Part 2) of labelling a package containing a controlled drug, a restricted drug or a poison (labelling exemption)

Health (Drugs and Poisons) Regulation 1996 - section 11

I, Suzanne Turner, Acting Director, Healthcare Approvals and Regulation Unit and delegate of the Chief Executive, Queensland Health, do hereby certify the following alternative way of labelling a package containing a controlled drug, a restricted drug or a poison:

The Alternative Way

In Queensland, the exemption granted on 12 August 2021 by John Skerritt, Deputy Secretary Health Products Regulation Group, Department of Health (Cwlth), being an appropriate authority as defined in the Poisons Standard, part 1, in the instrument named the *Therapeutic Goods (Poisons Standard) (COVID-19 Treatment-GlaxoSmithKline) (Sotrovimab) Labelling Exemption 2021* is certified as an alternative way of labelling the Schedule 4 treatment described in that exemption.

Conditions of certification

1. This certification is effective on the day COVID-19 Treatment sponsored by GlaxoSmithKline is approved to be entered into the Australian Register of Therapeutic Goods in accordance with the Commonwealth *Therapeutic Goods Act 1989*.
2. This certification expires in accordance with the expiry of the exemption granted by the appropriate authority in the instrument named the Therapeutic Goods (Poisons Standard) (COVID-19 Treatment-GlaxoSmithKline) (Sotrovimab) Labelling Exemption 2021.

Certified at Brisbane this 26th day of August 2021 by Suzanne Turner
Delegate of the Chief Executive
Healthcare Approvals and Regulation Unit
Queensland Health
Certification number: C-FILE-21962-026

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