



Therapeutic Goods (Six Monthly Report Form - Sponsor) Approval 2022

I, Petra Bismire, as delegate of the Secretary of the Department of Health, make the following approval.

Dated 30 March 2022

Petra Bismire
Director, Experimental Products Section
Medicines Regulation Division
Health Products Regulation Group
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Six Monthly Report Form—Sponsor) Approval 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.	31 March 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Note: This table relates only to the provisions of this instrument as originally made.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 instrument is made under regulation 47B of the *Therapeutic Goods Regulations 1990*.

4 Definitions

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

- (a) Secretary;
- (b) sponsor;
- (c) therapeutic goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

Regulations means the *Therapeutic Goods Regulations 1990*.

relevant sponsor means a sponsor of therapeutic goods in relation to which any of the following applies:

- (a) an exemption under section 18, 32CA or 41HA of the Act;
- (b) an approval under section 19, 32CK or 41HB of the Act;
- (c) an authority under section 19, 32CM or 41HC of the Act.

Therapeutic Goods Administration means that Part of the Department known as the Therapeutic Goods Administration.

5 Approved form

The approved form for providing a report to the Secretary by a relevant sponsor under paragraph 47B(1)(c) of the Regulations is the form titled *Six monthly report – supply of unapproved therapeutic goods by a sponsor* (March 2022) published on the Therapeutic Goods Administration website.

Note: The Therapeutic Goods Administration website can be accessed at <https://www.tga.gov.au>.

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

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2021***

1 The whole of the instrument

Repeal the instrument.