



Therapeutic Goods (Six Monthly Report Form—Sponsor) Approval 2024

I, Debra Phillips, as delegate of the Secretary of the Department of Health and Aged Care, make the following approval.

Dated 19 June 2024

Debra Phillips
Acting Director
International Regulatory Branch
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name.....	1
2 Commencement	1
3 Authority	1
4 Definitions	1
5 Approved form.....	2
6 Repeals.....	2
Schedule 1—Repeals	3
<i>Therapeutic Goods (Six Monthly Report Form—Sponsor) Approval 2022</i>	3

1 Name

This instrument is the *Therapeutic Goods (Six Monthly Report Form—Sponsor) Approval 2024*.

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.	20 June 2024

Note: This table relates only to the provisions of this instrument as originally made.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 1: 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.

Note 2: A number of expressions used in this instrument are defined in regulation 2 of the Regulations, including the following:

- (a) Therapeutic Goods Administration.

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.

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 online form titled *Six monthly report – supply of unapproved therapeutic goods by a sponsor* (V1.0 June 2024), as in force or existing on 13 June 2024, and accessible via the Therapeutic Goods Administration website.

Note: The Therapeutic Goods Administration website can be accessed at 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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1 The whole of the instrument

Repeal the instrument.