



Therapeutic Goods (Six Monthly Report Form—Sponsor) Approval 2026

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

Dated 25 May 2026

Debra Phillips
Director
International Regulatory Branch
Health Products Regulation Group
Department of Health, Disability and Ageing

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1 Name

This instrument is the *Therapeutic Goods (Six Monthly Report Form—Sponsor) Approval 2026*.

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.	26 May 2026

Note: This table relates only to the provisions of this instrument as originally made.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 TG Regulations, including the following:

- (a) Therapeutic Goods Administration.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

MD Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

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

- (a) an approval under paragraph 19(1)(a), 32CK(1)(d) or 41HB(1)(d) of the Act;

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- (b) an authority under section 19, 32CM or 41HC of the Act;
 - (c) an exemption under regulation 12A of the TG Regulations or regulation 7.2 of the MD Regulations.

TG Regulations means the *Therapeutic Goods Regulations 1990*.

5 Approved form

The approved form for providing a report to the Secretary by a relevant sponsor under paragraph 47B(1)(c) of the TG Regulations is:

- (a) for reports provided to the Secretary before 1 January 2027—either:
 - (i) the form titled *Six monthly report – supply of unapproved therapeutic goods by a sponsor* (V1.0 June 2024) that was available on the Therapeutic Goods Administration website immediately before 13 May 2026, as in force or existing on that date; or
 - (ii) the form titled *Six monthly report – supply of unapproved therapeutic goods by a sponsor* (V2.0 April 2026) available on the Therapeutic Goods Administration website on 13 May 2026, as in force or existing on that date; or
- (b) for reports provided to the Secretary from 1 January 2027—the form titled *Six monthly report – supply of unapproved therapeutic goods by a sponsor* (V2.0 April 2026) available on the Therapeutic Goods Administration website on 13 May 2026, as in force or existing on that date.

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

Note: See section 6.

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1 The whole of the instrument

Repeal the instrument.