



# **Therapeutic Goods (Special Access Scheme— Application and Notification Forms) Approval (No. 2) 2024**

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

Dated 16 December 2024

Nicholas Henderson  
First Assistant Secretary  
Medicines Regulation Division  
Health Products Regulation Group  
Department of Health and Aged Care

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## 1 Name

This instrument is the *Therapeutic Goods (Special Access Scheme—Application and Notification Forms) Approval (No. 2) 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.	

Note: This table relates only to the provisions of this instrument as originally made.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

- (a) subparagraph 12A(2)(a)(iii) of the *Therapeutic Goods Regulations 1990*;
- (b) paragraph 7.2(1A)(b) of the *Therapeutic Goods (Medical Devices) Regulations 2002*;
- (c) paragraph 19(2)(a) of the *Therapeutic Goods Act 1989*;
- (d) subsection 32CK(3) of the *Therapeutic Goods Act 1989*;
- (e) subsection 41HB(4) of the *Therapeutic Goods Act 1989*;
- (f) subsection 19(7D) of the *Therapeutic Goods Act 1989*;
- (g) subsection 32CM(7D) of the *Therapeutic Goods Act 1989*;
- (h) subsection 41HC(6C) of the *Therapeutic Goods Act 1989*.

## 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.

In this instrument:

**Act** means the *Therapeutic Goods Act 1989*.

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

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**TG Regulations** means the *Therapeutic Goods Regulations 1990*.

**SAS and AP Online System** means the TGA Special Access Scheme and Authorised Prescriber Scheme Online System, accessed via the Therapeutic Goods Administration website.

Note: The Therapeutic Goods Administration website can be accessed at [www.tga.gov.au](http://www.tga.gov.au).

**Therapeutic Goods Administration**, or **TGA**, means the part of the Department known as the Therapeutic Goods Administration.

## 5 Approved forms

*Special Access Scheme Category A—use in life-threatening cases*

- (1) For the purposes of:
- (a) subparagraph 12A(2)(a)(iii) of the TG Regulations; and
  - (b) subregulation 7.2(1A) of the MD Regulations;
- the following forms are approved for the statement mentioned in those provisions:
- (c) the online form titled *New SAS submission*, accessed via the *SAS Dashboard* in the SAS and AP Online System, as in force or existing at the commencement of this instrument;
  - (d) the form titled *Special Access Scheme Category A form*, available upon request from the TGA, as in force or existing at the commencement of this instrument.

*Special Access Scheme Category B—approval for special uses*

- (2) For the purposes of:
- (a) paragraph 19(2)(a) of the Act; and
  - (b) subsection 32CK(3) of the Act; and
  - (c) subsection 41HB(4) of the Act;
- the following forms are approved for an application under those provisions:
- (d) the online form titled *New SAS submission*, accessed via the *SAS Dashboard* in the SAS and AP Online System, as in force or existing at the commencement of this instrument;
  - (e) the form titled *Special Access Scheme Category B form*, available upon request from the TGA, as in force or existing at the commencement of this instrument.

*Special Access Scheme Category C—authorised supply*

- (3) For the purposes of:
- (a) subsection 19(7C) of the Act; and
  - (b) subsection 32CM(7C) of the Act; and
  - (c) subsection 41HC(6B) of the Act;
- the following forms are approved for notifying the Secretary of the supply of goods:

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- (d) the online form titled *New SAS submission*, accessed via the *SAS Dashboard* in the SAS and AP Online System, as in force or existing at the commencement of this instrument;
  - (e) the form titled *Special Access Scheme Category C form*, available upon request from the TGA, as in force or existing at the commencement of this instrument.