



Therapeutic Goods (Medicine Shortages and Discontinuations—Notification Forms) Approval 2023

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

Dated 8 November 2023

A handwritten signature in black ink, appearing to be 'N. Henderson', written over a horizontal line.

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 (Medicine Shortages and Discontinuations—Notification Forms) Approval 2023*.

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Note: This table relates only to the provisions of this instrument as originally made.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 paragraphs 30EF(4)(a), 30EFA(3)(a) and 30EG(4)(a) 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) medicine;
- (b) reportable medicine;
- (c) Secretary;
- (d) shortage;
- (e) supply.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

TGA Business Services means the TGA Business Services portal, accessed via the Therapeutic Goods Administration website.

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

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

5 Approved notification form – medicine shortage

For the purposes of notifying the Secretary of a shortage of a reportable medicine in Australia under subsection 30EF(1) of the Act, the approved form is the online form titled *New Medicine Shortage Notification*, accessed via the *Notification* item under the *Medicine Shortages* heading within the *Create Applications & Submissions* section of the sponsor portal within the *Medicines Shortages* link in the *Your TGA* tab in TGA Business Services.

6 Approved notification form – medicine shortage change and resolution

For the purposes of notifying the Secretary of a change to the period of a shortage, or resolution of a shortage, of a reportable medicine in Australia under subsections 30EFA(1) and (2) of the Act, the approved form is the online form titled *New Medicine Shortage Notification*, accessed via the *Notification* item under the *Medicine Shortages* heading within the *Create Applications & Submissions* section of the sponsor portal within the *Medicines Shortages* link in the *Your TGA* tab in TGA Business Services.

7 Approved notification form – discontinuation of supply of medicine

For the purposes of notifying the Secretary of a decision to permanently discontinue the supply of a reportable medicine in Australia under subsection 30EG(1) of the Act, the approved form is the online form titled *New Medicine Shortage Notification*, accessed via the *Notification* item under the *Medicine Shortages* heading within the *Create Applications & Submissions* section of the sponsor portal within the *Medicines Shortage* link in the *Your TGA* tab in TGA Business Services.

8 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 8.

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1 The whole of the instrument

Repeal the instrument.