

Therapeutic Goods (Medicines and OTG— Authorised Supply Notification Form) Approval 2023

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

Dated 21 December 2023

Chris Bedford Acting First Assistant Secretary Regulatory Practice and Support Division Health Products Regulation Group Department of Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods (Medicines and OTG—Authorised Supply Notification Form) 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	1 January 2024.	1 January 2024		
Note:	This table relates only to the provisions of the	his instrument as originally made. It will		

te: This table relates only to the provisions of this instrument as originally made.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 subsection 19(7D) 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;
- (b) supply.

In this instrument:

Act means the Therapeutic Goods Act 1989.

Supply Rules means the *Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022.*

Note: The Supply Rules are a legislative instrument published on the Federal Register of Legislation at www.legislation.gov.au.

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.

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

5 Approved form

For the purposes of subsection 19(7C) of the Act, the approved form for notifying the Secretary of the supply of goods in accordance the Supply Rules is the online form titled *New SAS submission*, accessed via the *SAS Dashboard* in the SAS and AP Online System, as in force or existing on 1 January 2024.