



Therapeutic Goods (Authorised Supply) Amendment (SAS Guidance) Rules 2024

I, Nicholas Henderson, as delegate of the Minister for Health and Aged Care, make the following rules.

Dated 4 June 2024

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

Contents

1 Name	1
2 Commencement.....	1
3 Authority	1
4 Schedules.....	1
Schedule 1—Amendments	2
<i>Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022</i>	2
<i>Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022</i>	2
<i>Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022</i>	2

1 Name

This instrument is the *Therapeutic Goods (Authorised Supply) Amendment (SAS Guidance) Rules 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Note: This table relates only to the provisions of this instrument as originally made.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 subsections 19(7A), 32CM(7A) and 41HC(6) of the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022

1 Section 4 (definition of SAS guidance)

Repeal the definition, substitute:

SAS Guidance means the document titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 2.0, March 2024) published by the Therapeutic Goods Administration, as in force or existing on 1 April 2024.

Note: The SAS Guidance is published at www.tga.gov.au.

Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022

2 Section 4 (definition of SAS guidance)

Repeal the definition, substitute:

SAS Guidance means the document titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 2.0, March 2024) published by the Therapeutic Goods Administration, as in force or existing on 1 April 2024.

Note: The SAS Guidance is published at www.tga.gov.au.

Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022

3 Section 4 (definition of SAS guidance)

Repeal the definition, substitute:

SAS Guidance means the document titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 2.0, March 2024) published by the Therapeutic Goods Administration, as in force or existing on 1 April 2024.

Note: The SAS Guidance is published at www.tga.gov.au.

4 Schedule 1 (table item 36)

Repeal the item.