

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

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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Note: This table relates only to the provisions of this instrument as originally made.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 Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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.