



# **Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022**

made under subsection 32CM(7A) of the

*Therapeutic Goods Act 1989*

## **Compilation No. 3**

**Compilation date:** 17 October 2024

**Includes amendments up to:** F2024L01321

Prepared by the Department of Health and Aged Care, Canberra

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## About this compilation

### This compilation

This is a compilation of the *Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022* that shows the text of the law as amended and in force on 17 October 2024 (the **compilation date**).

The notes at the end of this compilation (the **endnotes**) include information about amending laws and the amendment history of provisions of the compiled law.

### Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Register ([www.legislation.gov.au](http://www.legislation.gov.au)). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the Register for the compiled law.

### Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

### Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the Register for the compiled law.

### Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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## 1 Name

This instrument is the *Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022*.

## 3 Authority

This instrument is made under subsection 32CM(7A) 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) biological;
- (b) health practitioner;
- (c) included in the Register;
- (d) Register;
- (e) sponsor;
- (f) supply.

In this instrument:

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

**SAS Guidance** means the document titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 3.0, October 2024) published by the Therapeutic Goods Administration, as in force or existing on 1 October 2024.

Note: The SAS Guidance is published at [www.tga.gov.au](http://www.tga.gov.au).

**Therapeutic Goods Administration** has the same meaning as in the *Therapeutic Goods Regulations 1990*.

## 5 Authorisation

*Supply by a specified health practitioner*

- (1) A health practitioner specified in column 5 of an item in the table in Schedule 1 is authorised to supply a biological to a patient of that practitioner where:
  - (a) the biological is specified in column 2 of that item; and
  - (b) the biological is to be administered by the route specified in column 3 of that item; and
  - (c) the supply is for the indication specified in column 4 of that item; and
  - (d) the conditions specified in subsection (2) are satisfied.
- (2) The health practitioner must:
  - (a) inform the patient, or a parent or guardian of the patient, that the biological is not included in the Register; and

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- (b) obtain informed consent from the patient, or a parent or guardian of the patient, in relation to, and before, the supply of the biological; and
  - (c) supply the biological in accordance with good medical practice or the relevant code of conduct for the health practitioner; and
  - (d) if the health practitioner becomes aware that the patient has suffered an adverse event in relation to the biological—notify the Therapeutic Goods Administration and the sponsor of the biological about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance; and
  - (e) if the health practitioner becomes aware of a defect in the biological—notify the Therapeutic Goods Administration and the sponsor of the biological in accordance with the reporting guidelines set out in the SAS Guidance.

*Supply to a patient of a specified health practitioner*

- (3) A health practitioner is authorised to supply a biological to a patient of a health practitioner specified in column 5 of an item in the table in Schedule 1 (the ***treating practitioner***) where:
  - (a) the biological is specified in column 2 of that item; and
  - (b) the supply is requested by the treating practitioner; and
  - (c) the biological is to be administered by the route specified in column 3 of that item; and
  - (d) the supply is for the indication specified in column 4 of that item; and
  - (e) the conditions specified in subsection (4) are satisfied.
- (4) The health practitioner supplying the biological must:
  - (a) if the health practitioner becomes aware that the patient has suffered an adverse event in relation to the biological—notify the Therapeutic Goods Administration and the sponsor of the biological about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance; and
  - (b) if the health practitioner becomes aware of a defect in the biological—notify the Therapeutic Goods Administration and the sponsor of the biological in accordance with the reporting guidelines set out in the SAS Guidance.

## Schedule 1—Biologicals authorised for supply

Note: See section 5.

Specified therapeutic goods				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Biological	Route of administration	Indication	Health practitioner
1	AlloDerm GBR RTM (human skin tissue matrix)	intra-oral graft	graft protection and containment, flap extender to achieve primary closure, or gingival augmentation	dental practitioner
2	AlloDerm RTM (human skin tissue matrix)	intra-oral graft	root coverage, gingival augmentation soft tissue ridge augmentation, or soft tissue augmentation around implants	dental practitioner
3	Amniotic Membrane	ophthalmic	ocular conditions	medical practitioner
4	Grafton DBM Matrix (demineralised human bone tissue)	intra-oral graft	extraction socket grafting, ridge and sinus augmentation, bone augmentation around implants, bony defects, composite grafting, or filling of periodontal defects	dental practitioner
5	MinerOss Cancellous (human bone allograft)	intra-oral graft	ridge and sinus augmentation, extraction socket grafting, or bony defects	dental practitioner
6	MinerOss cortical and cancellous (human bone allograft)	intra-oral graft	ridge and sinus augmentation, extraction socket grafting, or bony defects	dental practitioner
7	MinerOss Cortical (human bone allograft)	intra-oral graft	ridge and sinus augmentation, extraction socket grafting, or bony defects	dental practitioner
8	Ortho-ATI (tenocytes) cell suspension	intratendinous injection	treatment of chronic lateral epicondylitis or gluteal tendinopathy (> 6 months) with or without partial tendon tear, that is	orthopaedic surgeon

Specified therapeutic goods				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Biological	Route of administration	Indication	Health practitioner
			not responsive to conservative treatment	
9	Puros Cancellous Particulate Allograft (human bone tissue)	intra-oral graft	ridge and sinus augmentation, extraction socket grafting, or bony defects	dental practitioner
10	Puros Cortical Particulate Allograft (human bone tissue)	intra-oral graft	ridge and sinus augmentation, extraction socket grafting, or bony defects	dental practitioner
11	Tutoplast Pericardium (sterilised human tissue allograft)	topical	soft tissue graft	medical practitioner



## Endnotes

### Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

### Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

### Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

### Misdescribed amendments

A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and “(md not incorp)” is added to the amendment history.

## Endnotes

### Endnote 2—Abbreviation key

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#### Endnote 2—Abbreviation key

ad = added or inserted	orig = original
am = amended	par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)
amdt = amendment	pres = present
c = clause(s)	prev = previous
C[x] = Compilation No. x	(prev...) = previously
Ch = Chapter(s)	Pt = Part(s)
def = definition(s)	r = regulation(s)/rule(s)
Dict = Dictionary	reloc = relocated
disallowed = disallowed by Parliament	renum = renumbered
Div = Division(s)	rep = repealed
exp = expires/expired or ceases/ceased to have effect	rs = repealed and substituted
F = Federal Register of Legislation	s = section(s)/subsection(s)
gaz = gazette	Sch = Schedule(s)
LA = <i>Legislation Act 2003</i>	Sdiv = Subdivision(s)
LIA = <i>Legislative Instruments Act 2003</i>	SLI = Select Legislative Instrument
(md not incorp) = misdescribed amendment cannot be given effect	SR = Statutory Rules
mod = modified/modification	Sub-Ch = Sub-Chapter(s)
No. = Number(s)	SubPt = Subpart(s)
o = order(s)	<u>underlining</u> = whole or part not commenced or to be commenced
Ord = Ordinance	

## Endnote 3—Legislation history

## Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
<i>Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022</i>	16 Dec 2022 (F2022L01673)	17 Dec 2022	—
<i>Therapeutic Goods (Medicines—Authorised Supply) Amendment (Vaping) Rules 2023</i>	15 Dec 2023 (F2023L01683)	1 Jan 2024	—
<i>Therapeutic Goods (Authorised Supply) Amendment (SAS Guidance) Rules 2024</i>	6 Jun 2024 (F2024L00639)	5 Jun 2024	—
<i>Therapeutic Goods (Authorised Supply) Amendment (SAS Guidance) Rules (No. 2) 2024</i>	16 Oct 2024 (F2024L01321)	17 Oct 2024	—

**Endnotes**

Endnote 4—Amendment history

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**Endnote 4—Amendment history**

Provision affected	How affected
s 2.....	rep LA s 48D
s 4.....	am F2023L01683; F2024L00639; F2024L01321
s 6.....	rep LA s 48C
Schedule 2.....	rep LA s 48C