Therapeutic Goods (Biologicals—Authorised Supply) Rules 2020

I, Jane Cook, as delegate of the Minister for Health, make the following rules.

Dated 15 September 2020

Dr Jane Cook
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods (Biologicals—Authorised Supply) Rules 2020*.

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 registered.	

Note: This table relates only to the provisions of this instrument as originally made.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 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; and
(f) supply.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

SAS Guidance means the document titled *Special Access Scheme Guidance for health practitioners and sponsors* (Version 1.1, September 2017) published by the Therapeutic Goods Administration, as in force or existing at the commencement of this instrument.

Note: The SAS Guidance is published at 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
  (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.

6 Repeals

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

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	Puros Cancellous Particulate Allograft (human bone tissue)	intra-oral graft	ridge and sinus augmentation, extraction socket grafting, or bony defects	dental practitioner
9	Puros Cortical Particulate	intra-oral graft	ridge and sinus augmentation, extraction	dental practitioner

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Biological**	**Route of administration**	**Indication**	**Health practitioner**
	Allograft (human bone tissue)		socket grafting, or bony defects	
10	Tutoplast Pericardium (sterilised human tissue allograft)	topical	soft tissue graft	medical practitioner

Schedule 2—Repeals

Note: See section 6.

Therapeutic Goods (Authorised Supply of Specified Biologicals) Rules April 2018

1 The whole of the instrument

Repeal the instrument.