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

Therapeutic Goods Act 1989

I, LARRY KELLY, a delegate of the Minister for Health for the purposes of subsection 32CM(7A) of the *Therapeutic Goods Act 1989*, revoke the Therapeutic Goods (Authorised Supply of Specified Biologicals) Rules March 2018 that was registered on 14 March 2018, and make the following Rules.

Dated 27 March 2018

(Signed by)

LARRY KELLY
Delegate of the Minister for Health

1 Name

These Rules are the *Therapeutic Goods (Authorised Supply of Specified Biologicals) Rules April 2018*.

2 Commencement

These Rules commence on 1 April 2018.

3 Authority

These Rules are made under subsection 32CM(7A) of the *Therapeutic Goods Act 1989*.

4 Authorisation to supply biologicals

(1) A health practitioner of a class specified in column 4 in an item in table 1 is authorised to supply a biological specified in column 1 in the item to a person if:

(a) the person is a patient of the health practitioner; and

(b) the biological is to be administered through the route of administration specified in column 2 in the item; and

(c) the supply is for an indication specified in column 3 in the item; and

(d) the following conditions are satisfied:

(i) the health practitioner must inform the patient, or a parent or guardian of the patient, that the biological is not included in the Register;

(ii) the health practitioner must ensure that the biological is supplied only after receiving informed consent from the patient, or a parent or guardian of the patient;

(iii) the health practitioner must ensure that the biological is supplied in accordance with good medical practice;

(iv) if the health practitioner becomes aware that the patient has suffered an adverse event in relation to the biological, the health practitioner must notify the Therapeutic Goods Administration, and the sponsor of the biological, about the adverse event, in accordance with subsection (3);

(v) if the health practitioner becomes aware of any defect in the biological, the health practitioner must notify the Therapeutic Goods Administration, and the sponsor of the biological, about the defect, in accordance with subsection (3).

(2) A health practitioner is authorised to supply a biological specified in column 1 in an item in table 1 to a person if:

(a) the person is a patient of another health practitioner (the ***treating practitioner***); and

(b) the treating practitioner is a health practitioner of a class specified in column 4 in the item; and

(c) the supply is requested by the treating practitioner; and

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(d) the biological is to be administered through the route of administration specified in column 2 in the item; and

(e) the supply is for an indication specified in column 3 in the item; and

(f) the following conditions are satisfied:

(i) if the health practitioner supplying the biological becomes aware that the patient has suffered an adverse event in relation to the biological, the health practitioner must notify the Therapeutic Goods Administration, and the sponsor of the biological, about the adverse event;

(ii) if the health practitioner supplying the biological becomes aware of any defect in the biological, the health practitioner must notify the Therapeutic Goods Administration, and the sponsor of the biological, about the defect.

(3) For the purposes of subparagraphs (1)(d)(iv) and (v) and (2)(f)(i) and (ii), notification must be in accordance with the reporting guidelines set out in the document titled Special Access Scheme Guidance for health practitioners and sponsors, version 1.1, published by the Therapeutic Goods Administration in September 2017.

Table 1: Authorised supply of biologicals

Item	Column 1 Product name Active ingredient	Column 2 Route of administration	Column 3 Indication	Column 4 Health practitioner
1	AlloDerm GBR RTM (human skin tissue matrix)	Intra-oral graft	Graft protection and containment Flap extender to achieve primary closure Gingival augmentation	Dental practitioner
2	AlloDerm RTM (human skin tissue matrix)	Intra-oral graft	Root coverage Gingival augmentation Soft tissue ridge augmentation 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 Filling of periodontal defects	Dental practitioner

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Item	Column 1 Product name Active ingredient	Column 2 Route of administration	Column 3 Indication	Column 4 Health practitioner
5	MinerOss Cancellous (human bone allograft)	Intra-oral graft	Ridge and sinus augmentation Extraction socket grafting Bony defects	Dental practitioner
6	MinerOss Cortical (human bone allograft)	Intra-oral graft	Ridge and sinus augmentation Extraction socket grafting Bony defects	Dental practitioner
7	Puros Cancellous Particulate Allograft (human bone tissue)	Intra-oral graft	Ridge and sinus augmentation Extraction socket grafting Bony defects	Dental practitioner
8	Puros Cortical Particulate Allograft (human bone tissue)	Intra-oral graft	Ridge and sinus augmentation Extraction socket grafting Bony defects	Dental practitioner
9	Tutoplast Pericardium (sterilised human tissue allograft)	Topical	Soft tissue graft	Medical Practitioner

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