Therapeutic Goods (Authorised Supply of Specified Medical Devices) Rules March 2018

Therapeutic Goods Act 1989

I, LARRY KELLY, a delegate of the Minister for Health for the purposes of subsection 41HC(6) of the *Therapeutic Goods Act 1989*, revoke the Therapeutic Goods (Authorised Supply of Specified Medical Devices) Rules September 2017 that was registered on 29 September 2017, and make the following Rules.

Dated 20 March 2018

(Signed by)

LARRY KELLY
Delegate of the Minister for Health

1 Name

These Rules are the *Therapeutic Goods (Authorised Supply of Specified Medical Devices) Rules March 2018*.

2 Commencement

These Rules commence the day after they are registered.

3 Authority

These Rules are made under subsection 41HC(6) of the *Therapeutic Goods Act 1989*.

4 Authorisation to supply medical devices

(1) A health practitioner of the class specified in column 3 in an item in table 1 is authorised to supply a medical device of the kind specified in column 1 in the item to a person if:

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

(b) the supply is for the purpose specified in column 2 in the item; and

(c) the following conditions are satisfied:

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

(ii) the health practitioner must ensure that the medical device 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 medical device 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 medical device, the health practitioner must notify the Therapeutic Goods Administration, and the sponsor of the medical device, about the adverse event, in accordance with subsection (3);

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

(2) A health practitioner is authorised to supply a medical device of the kind 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 the class specified in column 3 in the item; and

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

(d) the supply is for the purpose specified in column 2 in the item; and

(e) the following conditions are satisfied:

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

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

(3) For the purposes of subparagraphs (1)(f)(iv) and (v) and (2)(h)(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 medical devices

Item	Column 1 Kind of medical device	Column 2 Purpose	Column 3 Authorised health practitioner
1	Biodesign Enterocutaneous Fistula Plug	For repair of enterocutaneous fistulae.	Medical practitioner
2	BlastGen (Product No. 1205)	Culture of embryos from the 4-8 cell stage through to the blastocyst stage; or Embryo transfer.	Medical practitioner
3	CollaCote Dressing	For haemostasis or to protect the wound surface during dental procedures.	Dental practitioner
4	CollaPlug Absorbable Collagen Wound Dressing	For haemostasis or to protect the wound surface during dental procedures.	Dental practitioner
5	CollaTape Absorbable Collagen	For haemostasis or to protect the wound surface during dental procedures.	Dental practitioner
6	EmbryoGen (Product No. 1203)	Fertilisation and culture until the 2-8 cell stage; or Embryo transfer at day 2 or 3.	Medical practitioner
7	EmbryoGen & BlastGen (Product No. 1206)	Culture of embryos until the 2-8 cell stage (Embryogen) and culture of embryos from the 4-8 cell stage through to the blastocyst stage (Blastgen); or Embryo transfer.	Medical practitioner

8	EmbryoGen V2 (Product No. 1204)	Culture of human embryos until the 2-8 cell stage; or Embryo transfer at day 2 or 3.	Medical practitioner
9	Endotine Forehead	For use in subperiosteal browplasty surgery.	Medical practitioner
10	Endotine Midface	For use in subperiosteal midface suspension surgery.	Medical practitioner
11	GM508 CultActive	For investigation of fertilization failure after previous ICSI-cycles.	Medical practitioner
12	Ilex Skin Protectant	For use on a variety of dermal wounds and stomal irritations as a topical skin barrier.	Medical practitioner; Nurse practitioner
13	Jupiter Sternal Protection Device	For use following median sternotomy incisions to add a protective layer over the entire cut surfaces of the sternal bone.	Medical practitioner
14	Matriderm® Acellular Dermal Substitute	For the treatment of all deep dermal defects in combination with a split-thickness skin graft.	Medical practitioner
15	Pro Osteon® Bone Graft Substitute 200R	For use as a bone graft substitute only for bony voids or gaps that are not intrinsic to the stability of the bony structure.	Medical practitioner; Dental practitioner
16	Pro Osteon® Bone Graft Substitute 500R	For use as a bone graft substitute only for voids or gaps that are not intrinsic to the stability of the bony structure.	Medical practitioner
17	Quintip Individual Skin Test System	For allergy skin testing using puncture to apply the test extract.	Medical practitioner
18	Vicryl tape V152G	For the approximation of parenchymal tissue; or For reconstruction of the collateral ligaments of the knee.	Medical practitioner