Therapeutic Goods (Authorised Supply of Specified Medicines) Rules 2017

Therapeutic Goods Act 1989

I, LARRY KELLY, a delegate of the Minister for Health for the purposes of subsection 19(7A) of the *Therapeutic Goods Act 1989*, make the following Rules.

Dated 28 June 2017

(signed by)

LARRY KELLY
Delegate of the Minister for Health

1 Name

These Rules are the *Therapeutic Goods (Authorised Supply of Specified Medicines) Rules 2017*.

2 Commencement

These Rules commence on 3 July 2017.

3 Authority

These Rules are made under subsection 19(7A) of the *Therapeutic Goods Act 1989*.

4 Authorisation to supply medicines

(1) A health practitioner of the class specified in column 5 in an item in table 1 is authorised to supply a medicine that:

(a) contains only the active ingredient or ingredients, in the strength or concentration (if any), specified in column 1 in the item; and

(b) is in the dosage form specified in column 2 in the item;

to a person if:

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

(d) the medicine is to be administered through the route of administration specified in column 3 in the item; and

(e) the supply is for an indication specified in column 4 in the item; and

(f) the following conditions are satisfied:

(i) the health practitioner must inform the patient, or a parent or guardian of the patient, that the medicine is not registered or listed;

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

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

(2) A health practitioner is authorised to supply a medicine that:

(a) contains only the active ingredient or ingredients, in the strength or concentration (if any), specified in column 1 in an item in table 1; and

(b) is in the dosage form specified in column 2 in the item;

to a person if:

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

(d) the treating practitioner is a health practitioner of the class specified in column 5 in the item; and

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

(f) the medicine is to be administered through the route of administration specified in column 3 in the item; and

(g) the supply is for an indication specified in column 4 in the item; and

(h) the following conditions are satisfied:

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

(ii) if the health practitioner supplying the medicine becomes aware of any defect in the medicine, the health practitioner must notify the Therapeutic Goods Administration, and the sponsor of the medicine, 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 1.0, published by the Therapeutic Goods Administration in June 2017.

Table 1: Authorised supply of medicines

Item	Column 1 Active ingredient(s) and strength or concentration	Column 2 Dosage form	Column 3 Route of administration	Column 4 Indication(s)	Column 5 Authorised health practitioner
1	Triamcinolone acetonide	Suspension for injection	Ophthalmic	Treatment of inflammatory ocular conditions	Medical practitioner
2	Triamcinolone acetonide	Suspension for injection	Ophthalmic	Visualization during vitrectomy.	Medical practitioner
3	Melatonin	Syrup	Oral	Treatment of sleep disorders	Medical practitioner
4	Melatonin	Modified release tablet	Oral	Treatment of sleep disorders	Medical practitioner
5	Melatonin	Capsule	Oral	Treatment of sleep disorders	Medical practitioner
6	Melatonin	Tablet	Oral	Treatment of sleep disorders	Medical practitioner
7	Bismuth subcitrate	Tablet	Oral	Treatment of resistant *H.Pylori* infection	Medical practitioner
8	Tetracycline	Capsule	Oral	Treatment of resistant *H.Pylori* infection	Medical practitioner
9	Riboflavin, 0.1% in 20% dextran	Eye drops	Ophthalmic	Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment for progressive keratoconus.	Medical practitioner
10	Riboflavin, 0.1% in sodium chloride (hypotonic)	Eye drops	Ophthalmic	Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment for progressive keratoconus.	Medical practitioner
11	Flunarizine	Tablet	Oral	Prophylactic treatment of migraine	Medical practitioner
12	Cyclosporin, 0.05%	Eye drops, emulsion	Ophthalmic	Treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca.	Medical practitioner
13	Cinnarizine	Tablet	Oral	Treatment of vestibular disorders such as vertigo, tinnitus, nausea and vomiting (including Meniere's disease).	Medical practitioner

Item	Column 1 Active ingredient(s) and strength or concentration	Column 2 Dosage form	Column 3 Route of administration	Column 4 Indication(s)	Column 5 Authorised health practitioner
14	Hypertonic sodium chloride, 5%	Eye drops	Ophthalmic	Temporary relief of corneal oedema (hypertonicity)	Medical practitioner
15	Hypertonic sodium chloride	Eye ointment	Ophthalmic	Temporary relief of corneal oedema (hypertonicity)	Medical practitioner
16	Dexamethasone, 0.1%	Eye drops	Ophthalmic	Treatment of non-infected, steroid responsive, inflammatory conditions of the eye	Medical practitioner
17	Buspirone	Tablet	Oral	Treatment of generalised anxiety disorders	Medical practitioner
18	Paromomycin	Capsule	Oral	Antiprotozoal treatment of the following amoebic infections: (a) *blastocystis hominis*; (b) *dientomoeba fragilis*; (c) *entamoeba histolytica*; (d) parasite infection	Medical practitioner
19	Allergens – multiple, various	Skin prick test	Intradermal	Confirmation of suspected allergic reactions	Medical practitioner
20	Cyclopentolate, 0.2%, & phenylephrine, 1%	Eye drops	Ophthalmic	Production of mydriasis.	Medical practitioner
21	Verteporfin	Powder for injection	Intravenous infusion	Photosensitisation for photodynamic therapy	Medical practitioner
22	Pyrazinamide	Tablet	Oral	Treatment of resistant tuberculosis	Medical practitioner
23	Furazolidone	Tablet	Oral	Treatment of resistant *H.Pylori* infection	Medical practitioner
24	Pristinamycin	Tablet	Oral	Treatment of confirmed methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant *Enterococci* infection where there is history of failed therapy with the other available antibiotics, at sites in relation to bone/joint/prosthesis Treatment of other infections as prescribed by an infectious disease specialist	Medical practitioner

Item	Column 1 Active ingredient(s) and strength or concentration	Column 2 Dosage form	Column 3 Route of administration	Column 4 Indication(s)	Column 5 Authorised health practitioner
25	Glycopyrronium bromide	Tablet	Oral	Treatment of excessive salivation in patients with neurological conditions	Medical practitioner
26	Cholecalciferol	Capsule	Oral	Treatment of severe vitamin D deficiency and prevention of osteoporosis	Medical practitioner
27	Cholecalciferol	Injection	Intramuscular	Treatment of severe vitamin D deficiency and prevention of osteoporosis	Medical practitioner