Therapeutic Goods (Authorised Supply of Specified Medicines) Rules September 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*, revoke the Therapeutic Goods (Authorised Supply of Specified Medicines) Rules 2017 that was registered on 3 July 2017, and make the following Rules.

Dated 27 September 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 September 2017*.

2 Commencement

These Rules commence the day after they are registered.

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 1.1, published by the Therapeutic Goods Administration in September 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	Allergens – multiple, various (including control solutions)	Drops	Intradermal	Confirmation of suspected allergic reactions	Medical Practitioner
2	Allergens – multiple, various (including control solutions)	Drops	Skin prick	Confirmation of suspected allergic reactions	Medical Practitioner
3	Bismuth subcitrate	Tablet	Oral	Treatment of resistant *Helicobacter Pylori* infection	Medical Practitioner
4	Buspirone	Tablet	Oral	Treatment of generalised anxiety disorders	Medical Practitioner
5	Calcitriol	Liquid	Oral	Prevention of hypophosphatemic rickets in children; Treatment of hypoparathyroidism (with severe hypocalcaemia)	Medical Practitioner
6	Cholecalciferol	Capsule	Oral	Treatment of severe vitamin D deficiency and prevention of osteoporosis	Medical Practitioner
7	Cholecalciferol	Injection	Intramuscular	Treatment of severe vitamin D deficiency and prevention of osteoporosis	Medical Practitioner
8	Cinnarizine	Tablet	Oral	Treatment of vestibular disorders such as vertigo, tinnitus, nausea and vomiting (including Meniere's disease).	Medical Practitioner
9	Clofazimine	Capsule	Oral	Treatment of Leprosy granulomatous cheilitis, Melkersson Rosenthal Syndrome, confirmed *mycobacterium avium* paratuberculosis in immunocompromised patients recommended by an infectious disease specialist, erythema nodosum leprosum	Medical Practitioner
10	Cyclopentolate, 0.2%, & phenylephrine, 1%	Eye drops	Ophthalmic	Production of mydriasis	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
11	Cyclosporin, 0.05%	Eye drops, emulsion	Ophthalmic	Treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca	Medical Practitioner
12	Dehydrated ethanol (alcohol) 96% - 100%	Ampoule	Topical	Treatment of progressive keratoconus and intra-operative use in superficial keratectomy (single use per procedure).	Medical Practitioner
13	Dexamethasone	Implant	Intravitreal	Treatment of macular oedema, retinal vein occlusion and non-infectious uveitis	Medical Practitioner
14	Dexamethasone, 0.1%	Eye drops	Ophthalmic	Treatment of non-infected, steroid responsive, inflammatory conditions of the eye	Medical Practitioner
15	Diazoxide	Tablet	Oral	Treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome and insulinoma	Medical Practitioner
16	Diazoxide	Capsule	Oral	Treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome and insulinoma	Medical Practitioner
17	Diazoxide	Suspension	Oral	Treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome and insulinoma	Medical Practitioner
18	Dimethyl sulfoxide (DMSO)	Solution	Intravesical	Symptomatic relief of interstitial cystitis	Medical Practitioner
19	Flunarizine	Tablet	Oral	Prophylactic treatment of migraine	Medical Practitioner
20	Flunarizine	Capsule	Oral	Prophylactic treatment of migraine	Medical Practitioner
21	Fosfomycin	Sachet	Oral	Treatment of uncomplicated urinary tract infections Treatment of *pseudomonas aeruginosa* infections in Cystic Fibrosis patients	Medical Practitioner
22	Furazolidone	Tablet	Oral	Treatment of resistant *Helicobacter Pylori* infection	Medical Practitioner
23	Glycopyrronium bromide	Tablet	Oral	Treatment of excessive salivation in patients with neurological conditions	Medical Practitioner
24	Hyoscine hydrobromide	Patch	Transdermal	Treatment of excessive salivation	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	Hypertonic sodium chloride, 5 %	Eye ointment	Ophthalmic	Temporary relief of corneal oedema (hypertonicity)	Medical Practitioner
26	Hypertonic sodium chloride, 5%	Eye drops	Ophthalmic	Temporary relief of corneal oedema (hypertonicity)	Medical Practitioner
27	Indigo Carmine	Injection	Intravenous	For intraoperative detection of suspected urethral injuries during abdominal and pelvic surgical procedures	Medical Practitioner
28	Indocyanine green dye	Injection	Intravenous	For intra-operative diagnostic use	Medical Practitioner
29	Ketotifen	Tablet	Oral	Treatment of allergic conditions	Medical Practitioner
30	Mannitol	Capsules	Inhalation	Treatment of bronchiectasis Treatment of cystic fibrosis (adjunct to dornase alpha or for patients intolerant to dornase alpha)	Medical Practitioner
31	Melatonin	Syrup	Oral	Treatment of sleep disorders	Medical Practitioner
32	Melatonin	Modified release tablet	Oral	Treatment of sleep disorders	Medical Practitioner
33	Melatonin	Capsule	Oral	Treatment of sleep disorders	Medical Practitioner
34	Melatonin	Immediate Release Tablet	Oral	Treatment of sleep disorders	Medical Practitioner
35	Melatonin	Lozenge	Oral	Treatment of sleep disorders	Medical Practitioner
36	Midodrine	Tablet	Oral	Treatment of severe orthostatic hypotension	Medical Practitioner
37	Nitazoxanide	Tablet	Oral	Treatment of giardiasis, cryptosporidiosis and blastocystis	Medical Practitioner
38	Nitazoxanide	Suspension	Oral	Treatment of giardiasis, cryptosporidiosis and blastocystis	Medical Practitioner
39	Paromomycin	Capsule	Oral	Antiprotozoal treatment of the following amoebic infections: (a) *blastocystis hominis*; (b) *dientomoeba fragilis*; (c) *entamoeba histolytica*; (d) parasite infection	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
40	Pimozide	Tablet	Oral	Treatment of schizophrenia, chronic psychosis and Tourette syndrome	Medical Practitioner
41	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 refractory or resistant *mycoplasma genitalium* infections Treatment of other infections as prescribed by an infectious disease specialist	Medical Practitioner
42	Pyrazinamide	Tablet	Oral	Treatment of tuberculosis	Medical Practitioner
43	Riboflavin, 0.1% in 20% dextran	Eye drops	Ophthalmic	Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus.	Medical Practitioner
44	Riboflavin, 0.1% in sodium chloride	Eye drops	Ophthalmic	Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus.	Medical Practitioner
45	Rufinamide	Tablet	Oral	Adjunct treatment of seizures associated with Lennox-Gastaut syndrome in patients over 4 years of age	Medical Practitioner
46	Stiripentol	Capsule	Oral	Treatment of intractable epilepsy and Dravet syndrome (severe myoclonic epilepsy of infancy (SMEI))	Medical Practitioner
47	Stiripentol	Tablet	Oral	Treatment of intractable epilepsy and Dravet syndrome (severe myoclonic epilepsy of infancy (SMEI))	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
48	Stiripentol	Sachet	Oral	Treatment of intractable epilepsy and Dravet syndrome (severe myoclonic epilepsy of infancy (SMEI))	Medical Practitioner
49	Tacrolimus 0.1%	Ointment	Topical	Treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis in adults	Medical Practitioner
50	Tetracycline	Capsule	Oral	Treatment of resistant *Helicobacter Pylori* infection	Medical Practitioner
51	Tetracycline	Tablet	Oral	Treatment of resistant *Helicobacter Pylori* infection	Medical Practitioner
52	Tick-borne Encephalitis Vaccine	Injection	Intramuscular	Prevention of tick-borne encephalitis	Medical Practitioner
53	Triamcinolone acetonide	Suspension for injection	Ophthalmic	Treatment of inflammatory ocular conditions	Medical Practitioner
54	Triamcinolone acetonide	Suspension for injection	Ophthalmic	Visualisation during vitrectomy.	Medical Practitioner
55	Verteporfin	Powder for injection	Intravenous infusion	Photosensitisation for photodynamic therapy	Medical Practitioner
56	Yttrium-90 (Y-90) Citrate	Injection	Intraarticular	Radiosynovectomy treatment	Medical Practitioner