



Therapeutic Goods (Authorised Supply of Specified Medicines) Rules March 2018

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 September 2017 that was registered on 29 September 2017, and make the following Rules.

Dated 12 March 2018

(Signed by)

LARRY KELLY

Delegate of the Minister for Health

1 Name

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

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

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- (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	Amifampridine (3,4- diaminopyridine)	Tablet	Oral	Treatment of Lambert-Eaton Myasthenic Syndrome	Medical Practitioner
4	Bifidobacterium bifidum & Lactobacillus acidophilus	Capsule	Oral	Prevention of necrotising enterocolitis	Medical Practitioner
5	Betaxolol 0.25% (preservative free)	Eye drops	Ophthalmic	Treatment of elevated intraocular pressure where other treatments are inappropriate	Medical Practitioner
6	Bismuth subcitrate	Tablet	Oral	Treatment of resistant <i>Helicobacter Pylori</i> infection	Medical Practitioner
7	Buspirone	Tablet	Oral	Treatment of generalised anxiety disorders	Medical Practitioner
8	Calcitriol	Liquid	Oral	Prevention of hypophosphatemic rickets in children; Treatment of hypoparathyroidism (with severe hypocalcaemia)	Medical Practitioner
9	Cholecalciferol	Capsule	Oral	Treatment of severe vitamin D deficiency and prevention of osteoporosis	Medical Practitioner
10	Cholecalciferol	Injection	Intramuscular	Treatment of severe vitamin D deficiency and prevention of osteoporosis	Medical Practitioner
11	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
12	Clobetasol propionate 0.05%	Cream	Topical	Treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed	Medical Practitioner
13	Clobetasol propionate 0.05%	Lotion	Topical	Treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed	Medical Practitioner
14	Clobetasol propionate 0.05%	Ointment	Topical	Treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed	Medical Practitioner
15	Clofazimine	Capsule	Oral	Treatment of Leprosy, granulomatous cheilitis, Melkersson Rosenthal Syndrome, confirmed <i>mycobacterium avium</i> paratuberculosis in immunocompromised patients recommended by an infectious disease specialist, erythema nodosum leprosum	Medical Practitioner
16	Cyclopentolate, 0.2%, & phenylephrine, 1%	Eye drops	Ophthalmic	Production of mydriasis	Medical Practitioner
17	Cyclosporin, 0.05%	Eye drops, emulsion	Ophthalmic	Treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca	Medical Practitioner
18	Deflazacort	Tablet	Oral	Treatment of Duchenne muscular dystrophy	Medical Practitioner
19	Dehydrated ethanol (alcohol) 96% - 100%	Ampoule	Topical	Treatment of progressive keratoconus and intra- operative use in superficial keratectomy (single use per procedure).	Medical Practitioner
20	Diazoxide	Tablet	Oral	Treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome and insulinoma	Medical Practitioner
21	Diazoxide	Capsule	Oral	Treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome and insulinoma	Medical Practitioner
22	Diazoxide	Suspension	Oral	Treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome and insulinoma	Medical Practitioner
23	Diflunisal	Tablet	Oral	Treatment of amyloidosis	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
24	Dimethyl sulfoxide (DMSO)	Solution	Intravesical	Symptomatic relief of interstitial cystitis	Medical Practitioner
25	Flunarizine	Tablet	Oral	Treatment of vestibular disorders	Medical Practitioner
26	Flunarizine	Capsule	Oral	Treatment of vestibular disorders	Medical Practitioner
27	Furazolidone	Tablet	Oral	Treatment of resistant <i>Helicobacter Pylori</i> infection	Medical Practitioner
28	Glycopyrronium bromide	Tablet	Oral	Treatment of excessive salivation in patients with neurological conditions	Medical Practitioner
29	Hyoscine hydrobromide	Patch	Transdermal	Treatment of excessive salivation	Medical Practitioner
30	Hypertonic sodium chloride, 5 %	Eye ointment	Ophthalmic	Temporary relief of corneal oedema (hypertonicity)	Medical Practitioner
31	Hypertonic sodium chloride, 5%	Eye drops	Ophthalmic	Temporary relief of corneal oedema (hypertonicity)	Medical Practitioner
32				For intraoperative detection of suspected urethral injuries during abdominal and pelvic surgical procedures	Medical Practitioner
	Indigo Carmine	Injection	Intravenous		
33	Indocyanine green dye	Injection	Intravenous	For intra-operative diagnostic use	Medical Practitioner
34	Insulin Neutral- concentrated (Humulin R U-500)	Solution for injection	Subcutaneous	Treatment of diabetes	Medical Practitioner
35	Levofloxacin	Tablet	Oral	Treatment of resistant <i>Helicobacter Pylori</i> infection	Medical Practitioner
36	Levomepromazine	Tablet	Oral	Treatment of nausea and vomiting or agitation	Medical Practitioner
37	Levomepromazine	Injection	Subcutaneous	Treatment of nausea and vomiting or agitation	Medical Practitioner
38	Lorazepam	Injection	Parenteral	Treatment of acute severe behavioural episodes in the hospital setting	Medical Practitioner
39	Ketotifen	Tablet	Oral	Treatment of allergic conditions	Medical Practitioner
40	Melatonin	Syrup	Oral	Treatment of sleep disorders	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
41	Melatonin	Modified release tablet	Oral	Treatment of sleep disorders	Medical Practitioner
42	Melatonin	Capsule	Oral	Treatment of sleep disorders	Medical Practitioner
43	Melatonin	Immediate Release Tablet	Oral	Treatment of sleep disorders	Medical Practitioner
44	Melatonin	Lozenge	Oral	Treatment of sleep disorders	Medical Practitioner
45	Mexiletine	Tablet	Oral	Treatment of ventricular arrhythmia or myotonic disorders	Medical Practitioner
46	Mexiletine	Capsule	Oral	Treatment of ventricular arrhythmia or myotonic disorders	Medical Practitioner
47	Midodrine	Tablet	Oral	Treatment of severe orthostatic hypotension	Medical Practitioner
48	Moxifloxacin 0.5%	Eye drops	Ophthalmic	Treatment of refractory bacterial conjunctivitis	Medical Practitioner
49	Nadolol	Tablet	Oral	Treatment of ventricular tachycardia or long QT Syndrome	Medical Practitioner
50	Natamycin 5%	Eye drops	Ophthalmic	Treatment of refractory fungal blepharitis, conjunctivitis or keratitis	Medical Practitioner
51	Nitazoxanide	Tablet	Oral	Treatment of giardiasis, cryptosporidiosis and blastocystis	Medical Practitioner
52	Nitazoxanide	Suspension	Oral	Treatment of giardiasis, cryptosporidiosis and blastocystis	Medical Practitioner
53	Paromomycin	Capsule	Oral	Antiprotozoal treatment of the following amoebic infections: (a) <i>blastocystis hominis</i> ; (b) <i>dientamoeba fragilis</i> ; (c) <i>entamoeba histolytica</i> ; (d) parasite infection	Medical Practitioner
54	Pimozide	Tablet	Oral	Treatment of schizophrenia, chronic psychosis and Tourette syndrome	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
55				Treatment of confirmed methicillin-resistant <i>Staphylococcus aureus</i> and vancomycin-resistant <i>enterococci</i> infection where there is history of failed therapy with the other available antibiotics, at sites in relation to bone/joint/prosthesis	Medical Practitioner
				Treatment of refractory or resistant <i>mycoplasma genitalium</i> infections	
	Pristinamycin	Tablet	Oral	Treatment of other infections as prescribed by an infectious disease specialist	
56	Pyrazinamide	Tablet	Oral	Treatment of tuberculosis	Medical Practitioner
57	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
58	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
59	Ripasudil 0.4%	Eye drops	Ophthalmic	Treatment of refractory corneal oedema or refractory glaucoma	Medical Practitioner
60	Rufinamide	Tablet	Oral	Adjunct treatment of seizures associated with Lennox-Gastaut syndrome in patients over 4 years of age	Medical Practitioner
61	Sodium benzoate	Tablet	Oral	Treatment of urea cycle disorders	Medical Practitioner
62	Stiripentol	Capsule	Oral	Treatment of intractable epilepsy and Dravet syndrome (severe myoclonic epilepsy of infancy (SMEI))	Medical Practitioner
63	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
64	Stiripentol	Sachet	Oral	Treatment of intractable epilepsy and Dravet syndrome (severe myoclonic epilepsy of infancy (SMEI))	Medical Practitioner
65	Tacrolimus 0.03%	Ointment	Topical	Treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in children	Medical Practitioner
66	Tacrolimus 0.1%	Ointment	Topical	Treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in adults	Medical Practitioner
67	Tizanidine	Capsule	Oral	Treatment of spasticity where other treatments have failed	Medical Practitioner
68	Tizanidine	Tablet	Oral	Treatment of spasticity where other treatments have failed	Medical Practitioner
69	Tetracycline	Capsule	Oral	Treatment of resistant <i>Helicobacter Pylori</i> infection	Medical Practitioner
70	Tetracycline	Tablet	Oral	Treatment of resistant <i>Helicobacter Pylori</i> infection	Medical Practitioner
71	Tick-borne Encephalitis Vaccine	Injection	Intramuscular	Prevention of tick-borne encephalitis	Medical Practitioner
72	Triamcinolone acetonide	Suspension for injection	Ophthalmic	Treatment of non-infectious uveitis or visualisation during vitrectomy	Medical Practitioner
73	Verteporfin	Powder for injection	Intravenous infusion	Photosensitisation for photodynamic therapy	Medical Practitioner
74	Yttrium-90 (Y-90) Citrate	Injection	Intraarticular	Radiosynovectomy treatment	Medical Practitioner