Therapeutic Goods (Authorised Supply of Medicines) Rules 2019

I, Adrian Bootes, as delegate of the Minister for Health, make the following rules.

Dated 13 September 2019

Adrian Bootes
Acting First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods (Authorised Supply of Medicines) Rules 2019*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 19(7A) of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:
(a) health practitioner;
(b) medicine;
(c) Register; and
(d) supply.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

listed means included in the part of the Register for goods known as listed goods.

medical practitioner has the same meaning as in section 19 of the Act.

registered means included in the part of the Register for goods known as registered goods or provisionally registered goods.

Regulations means the *Therapeutic Goods Regulations 1990*.

SAS Guidance means the document titled *Special Access Scheme Guidance for health practitioners and sponsors* (Version 1.1, September 2017) published by the Therapeutic Goods Administration, as in force or existing immediately before the commencement of this instrument.

Note: The SAS Guidance is published at www.tga.gov.au.

Therapeutic Goods Administration has the same meaning as in the Regulations.

5 Authorisation

Supply by, or to a patient of, a medical practitioner

(1) A medical practitioner is authorised to supply a medicine that contains an active ingredient specified in column 2 of an item in the table in Schedule 1, to a patient of that practitioner, in circumstances where:

(a) the medicine only contains the active ingredient in the strength and concentration specified (if any) in column 2 of that item; and

(b) the medicine is in the dosage form specified in column 3 of that item; and

(c) the medicine is administered by the route specified in column 4 of that item; and

(d) the supply is for the indication specified in column 5 of that item; and

(e) the conditions specified in subsection (2) are satisfied.

(2) The medical practitioner must:

(a) inform the patient, or a parent or guardian of the patient, that the medicine is not registered or listed; and

(b) obtain informed consent from the patient, or a parent or guardian of the patient, in relation to, and before, the supply of the medicine; and

(c) supply the medicine in accordance with good medical practice; and

(d) if the medical practitioner becomes aware that the patient has suffered an adverse event in relation to the medicine—notify the Therapeutic Goods Administration and the sponsor of the medicine about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance; and

(e) if the medical practitioner becomes aware of a defect in the medicine—notify the Therapeutic Goods Administration and the sponsor of the medicine in accordance with the reporting guidelines set out in the SAS Guidance.

(3) A health practitioner is authorised to supply a medicine that contains an active ingredient specified in column 2 of an item in the table in Schedule 1, to a patient of a medical practitioner (***the treating practitioner***), in circumstances where:

(a) the medicine only contains the active ingredient in the strength and concentration specified (if any) in column 2 of that item; and

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

(c) the medicine is in the dosage form specified in column 3 of that item; and

(d) the medicine is administered by the route specified in column 4 of that item; and

(e) the supply is for the indication specified in column 5 of that item; and

(f) the conditions specified in subsection (4) are satisfied.

(4) The health practitioner supplying the medicine must:

(a) if the health practitioner becomes aware that the patient has suffered an adverse event in relation to the medicine—notify the Therapeutic Goods Administration and the sponsor of the medicine about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance; and

(b) if the health practitioner becomes aware of a defect in the medicine—notify the Therapeutic Goods Administration and the sponsor of the medicine in accordance with the reporting guidelines set out in the SAS Guidance.

6 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Medicines authorised for supply

Note: See section 5.

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
1	allergens—multiple, various (including control solutions)	drops	intradermal	confirmation of suspected allergic reactions
2	allergens – multiple, various (including control solutions)	drops	skin prick	confirmation of suspected allergic reactions
3	amifampridine (3,4-diaminopyridine)	tablet	oral	treatment of Lambert-Eaton Myasthenic Syndrome
4	bifidobacterium bifidum and Lactobacillus acidophilus	capsule	oral	prevention of necrotising enterocolitis
5	betaxolol 0.25% (preservative free)	eye drops	ophthalmic	treatment of elevated intraocular pressure where other treatments are inappropriate
6	bismuth subcitrate	tablet	oral	treatment of resistant *Helicobacter Pylori* infection
7	buspirone	tablet	oral	treatment of generalised anxiety disorders
8	calcitriol	liquid	oral	prevention of hypophosphatemic rickets in children; treatment of hypoparathyroidism (with severe hypocalcaemia)
9	cholecalciferol	capsule	oral	treatment of severe vitamin D deficiency and prevention of osteoporosis
10	cholecalciferol	injection	intramuscular	treatment of severe vitamin D deficiency and prevention of osteoporosis
11	cinnarizine	tablet	oral	treatment of vestibular disorders such as vertigo, tinnitus, nausea and vomiting (including Meniere's

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				disease).
12	clobetasol propionate 0.05%	cream	topical	treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed
13	clobetasol propionate 0.05%	lotion	topical	treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed
14	clobetasol propionate 0.05%	ointment	topical	treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed
15	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
16	cyclopentolate, 0.2%, and phenylephrine, 1%	eye drops	ophthalmic	production of mydriasis
17	cyclosporin, 0.05%	eye drops, emulsion	ophthalmic	treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca
18	deflazacort	tablet	oral	treatment of Duchenne muscular dystrophy
19	dehydrated ethanol (alcohol) 96% - 100%	ampoule	topical	treatment of progressive keratoconus and intra-operative use in superficial keratectomy (single use per procedure).
20	diazoxide	tablet	oral	treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome and insulinoma
21	diazoxide	capsule	oral	treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				Syndrome and insulinoma
22	diazoxide	suspension	oral	treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome and insulinoma
23	diflunisal	tablet	oral	treatment of amyloidosis
24	dimethyl sulfoxide (DMSO)	solution	intravesical	symptomatic relief of interstitial cystitis
25	F-18 myocardial perfusion tracer (18F flurpiridaz)	injection	intravenous	myocardial perfusion study
26	F-18 NaF (sodium fluoride)	injection	intravenous	bone study
27	flunarizine	tablet	oral	treatment of vestibular disorders
28	flunarizine	capsule	oral	treatment of vestibular disorders
29	furazolidone	tablet	oral	treatment of resistant *Helicobacter Pylori* infection
30	Gallium-68 (Ga-68) Galligas	aerosol	inhalation	lung ventilation study
31	Gallium-68 (Ga-68) - MAA	injection	intravenous	lung perfusion study
32	glycopyrronium bromide	tablet	oral	treatment of excessive salivation in patients with neurological conditions
33	hyoscine hydrobromide	patch	transdermal	treatment of excessive salivation
34	hypertonic sodium chloride, 5 %	eye ointment	ophthalmic	temporary relief of corneal oedema (hypertonicity)
35	hypertonic sodium chloride, 5%	eye drops	ophthalmic	temporary relief of corneal oedema (hypertonicity)
36	indigo carmine	injection	intravenous	intraoperative detection of suspected urethral injuries during abdominal and pelvic surgical procedures
37	indocyanine green dye	injection	intravenous	intra-operative diagnostic use
38	insulin neutral-concentrated (Humulin R U-500)	solution for injection	subcutaneous	treatment of diabetes
39	levofloxacin	tablet	oral	treatment of resistant *Helicobacter Pylori* infection

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
40	levomepromazine	tablet	oral	treatment of nausea and vomiting or agitation
41	levomepromazine	injection	subcutaneous	treatment of nausea and vomiting or agitation
42	lorazepam	injection	parenteral	treatment of acute severe behavioural episodes in the hospital setting
43	ketotifen	tablet	oral	treatment of allergic conditions
44	melatonin	syrup	oral	treatment of sleep disorders
45	melatonin	modified release tablet	oral	treatment of sleep disorders
46	melatonin	capsule	oral	treatment of sleep disorders
47	melatonin	immediate release tablet	oral	treatment of sleep disorders
48	melatonin	lozenge	oral	treatment of sleep disorders
49	mexiletine	tablet	oral	treatment of ventricular arrhythmia or myotonic disorders
50	mexiletine	capsule	oral	treatment of ventricular arrhythmia or myotonic disorders
51	midodrine	tablet	oral	treatment of severe orthostatic hypotension
52	moxifloxacin 0.5%	eye drops	ophthalmic	treatment of refractory bacterial conjunctivitis
53	nadolol	tablet	oral	treatment of ventricular tachycardia or long QT Syndrome
54	natamycin 5%	eye drops	ophthalmic	treatment of refractory fungal blepharitis, conjunctivitis or keratitis
55	nitazoxanide	tablet	oral	treatment of giardiasis, cryptosporidiosis and blastocystis
56	nitazoxanide	suspension	oral	treatment of giardiasis, cryptosporidiosis and blastocystis
57	paromomycin	capsule	oral	antiprotozoal treatment of the following amoebic infections: (a) *blastocystis hominis*; (b) *dientomoeba fragilis*;

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				(c) *entamoeba histolytica*; (d) parasite infection
58	pimozide	tablet	oral	treatment of schizophrenia, chronic psychosis and Tourette syndrome
59	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
60	pyrazinamide	tablet	oral	treatment of tuberculosis
61	riboflavin, 0.1% in 20% dextran	eye drops	ophthalmic	intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus
62	riboflavin, 0.1% in sodium chloride	eye drops	ophthalmic	intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus
63	ripasudil 0.4%	eye drops	ophthalmic	treatment of refractory corneal oedema or refractory glaucoma
64	rufinamide	tablet	oral	adjunct treatment of seizures associated with Lennox-Gastaut syndrome in patients over 4 years of age
65	sodium benzoate	tablet	oral	treatment of urea cycle disorders
66	stiripentol	capsule	oral	treatment of intractable epilepsy and Dravet

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				syndrome (severe myoclonic epilepsy of infancy (SMEI))
67	stiripentol	tablet	oral	treatment of intractable epilepsy and Dravet syndrome (severe myoclonic epilepsy of infancy (SMEI))
68	stiripentol	sachet	oral	treatment of intractable epilepsy and Dravet syndrome (severe myoclonic epilepsy of infancy (SMEI))
69	tacrolimus 0.03%	ointment	topical	treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in children
70	tacrolimus 0.1%	ointment	topical	treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in adults
71	tizanidine	capsule	oral	treatment of spasticity where other treatments have failed
72	tizanidine	tablet	oral	treatment of spasticity where other treatments have failed
73	tetracycline	capsule	oral	treatment of resistant *Helicobacter Pylori* infection
74	tetracycline	tablet	oral	treatment of resistant *Helicobacter Pylori* infection
75	tick-borne encephalitis vaccine	injection	intramuscular	prevention of tick-borne encephalitis
76	triamcinolone acetonide	suspension for injection	ophthalmic	treatment of non-infectious uveitis or visualisation during vitrectomy
77	verteporfin	powder for injection	intravenous infusion	photosensitisation for photodynamic therapy
78	yttrium-90 (Y-90) Citrate	injection	intraarticular	radiosynovectomy treatment

Schedule 2—Repeals

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

1 The whole of the instrument

Repeal the instrument