Therapeutic Goods (Medicines—Authorised Supply) Rules 2022

I, Nicholas Henderson, as delegate of the Minister for Health and Aged Care, make the following rules.

Dated 15 December 2022

Nicholas Henderson
Acting First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Medicines—Authorised Supply) Rules 2022*.

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Note: This table relates only to the provisions of this instrument as originally made.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 subsection 3(1) of the Act, including the following:

(a) health practitioner;
(b) listed goods;
(c) medicine;
(d) Register;
(e) registered goods;
(f) sponsor;
(g) supply.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

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 at 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 *Therapeutic Goods Regulations 1990*.

5 Authorisation

Supply by a medical practitioner

(1) A health practitioner who is a medical practitioner is authorised to supply a medicine to a patient of that practitioner where:
  (a) the medicine contains an active ingredient specified in column 2 of an item in the table in Schedule 1 and does not contain any other active ingredient; and
  (b) the medicine only contains the active ingredient in the strength and concentration (if any) specified in column 2 of that item; and
  (c) the medicine is in the dosage form specified in column 3 of that item; and
  (d) the medicine is to be 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 (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 a listed good or registered good; 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.

Supply to a patient of a medical practitioner

(3) A health practitioner is authorised to supply a medicine to a patient of a medical practitioner (the ***treating practitioner***) where:
  (a) the medicine contains an active ingredient specified in column 2 of an item in the table in Schedule 1 and does not contain any other active ingredient; and
  (b) the medicine only contains the active ingredient in the strength and concentration (if any) specified in column 2 of that item; and
  (c) the supply is requested by the treating practitioner; and
  (d) the medicine is in the dosage form specified in column 3 of that item; and
  (e) the medicine is to be administered by the route specified in column 4 of that item; and

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

(g) 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 Repeals

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

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	amiloride	tablet	oral	treatment of hypokalemia
4	betaxolol 0.25% (preservative free)	eye drops	ophthalmic	treatment of elevated intraocular pressure where other treatments are inappropriate
5	bismuth subcitrate	tablet	oral	treatment of resistant *Helicobacter Pylori* infection
6	buspirone	tablet	oral	treatment of generalised anxiety disorders
7	calcitriol	liquid	oral	prevention of hypophosphatemic rickets in children; or treatment of hypoparathyroidism (with severe hypocalcaemia)
8	carbidopa	tablet	oral	premedication for F-18 DOPA imaging
9	ciclosporin, 0.05%	eye drops, emulsion	ophthalmic	treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca (dry eye syndrome)
10	cinnarizine	tablet	oral	treatment of vestibular disorders such as vertigo, tinnitus, nausea and vomiting (including Meniere's disease)

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
11	clobetasol propionate 0.05%	cream	topical	treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed
12	clobetasol propionate 0.05%	lotion	topical	treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed
13	clobetasol propionate 0.05%	ointment	topical	treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed
14	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, drug resistant tuberculosis, non-tuberculosis mycobacterial infections or other infections as recommended by an infectious diseases specialist
15	colecalciferol	capsule	oral	treatment of severe vitamin D deficiency and prevention of osteoporosis
16	colecalciferol	injection	intramuscular	treatment of severe vitamin D deficiency and prevention of

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				osteoporosis
17	cyclopentolate, 0.2%, and phenylephrine, 1%	eye drops	ophthalmic	production of mydriasis
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	dexamethasone (preservative free)	eye drops	ophthalmic	treatment of inflammatory conditions of the eye that are non-infected and steroid responsive in patients sensitive to preservative-containing formulations
21	diazoxide	capsule	oral	treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome or insulinoma
22	diazoxide	suspension	oral	treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome or insulinoma
23	diazoxide	tablet	oral	treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome or insulinoma
24	diflunisal	tablet	oral	treatment of amyloidosis
25	dimethyl sulfoxide (DMSO)	solution	intravesical	symptomatic relief of interstitial cystitis
26	disulfiram	tablet	oral	deterrent to alcohol consumption
27	doxycycline	injection	intralesional	sclerotherapy of

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				lymphatic malformations
28	F-18 DCFPyl (PSMA)	injection	intravenous	prostate cancer imaging study
29	F-18 myocardial perfusion tracer (18F flurpiridaz)	injection	intravenous	myocardial perfusion study
30	F-18 NaF (sodium fluoride)	injection	intravenous	bone study
31	flunarizine	capsule	oral	treatment of vestibular disorders or prophylactic treatment of migraine
32	flunarizine	tablet	oral	treatment of vestibular disorders or prophylactic treatment of migraine
33	furazolidone	tablet	oral	treatment of resistant *Helicobacter Pylori* infection
34	Gallium-68 (Ga-68) Galligas	aerosol	inhalation	lung ventilation study
35	Gallium-68 (Ga-68) - MAA	injection	intravenous	lung perfusion study
36	Gallium-68 prostate specific membrane antigen (PSMA)	injection	intravenous	prostate cancer imaging study; or PET CT gallium 68 PSMA (prostate specific membrane antigen) whole body uptake study
37	ganciclovir	gel	ophthalmic	treatment of cytomegalovirus
38	glycopyrronium bromide	tablet	oral	treatment of excessive salivation in patients with neurological conditions
39	hyoscine hydrobromide	patch	transdermal	treatment of excessive salivation
40	hypertonic sodium chloride, 5%	eye drops	ophthalmic	temporary relief of corneal oedema (hypertonicity)
41	hypertonic sodium chloride, 5%	eye ointment	ophthalmic	temporary relief of corneal oedema (hypertonicity)
42	iloprost	injection	intravenous	treatment of patients

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
			infusion	with severe disabling Raynaud's phenomenon; or treatment of peripheral ischaemia
43	indigo carmine	injection	intravenous	intraoperative detection of suspected urethral injuries during abdominal and pelvic surgical procedures
44	indocyanine green dye	injection	intravenous	intra-operative diagnostic use
45	interferon alpha-2b	eye drops	ophthalmic	treatment of ocular surface squamous neoplasia
46	ketotifen	tablet	oral	treatment of allergic conditions
47	levofloxacin	tablet	oral	treatment of resistant *Helicobacter Pylori* infection or drug resistant tuberculosis
48	levomepromazine	injection	subcutaneous	treatment of nausea and vomiting or agitation
49	levomepromazine	tablet	oral	treatment of nausea and vomiting or agitation
50	lifitegrast	eye drops	ophthalmic	treatment of dry eye disease
51	melatonin	capsule	oral	treatment of sleep disorders
52	melatonin	immediate release tablet	oral	treatment of sleep disorders
53	melatonin	lozenge	oral	treatment of sleep disorders
54	melatonin	syrup	oral	treatment of sleep disorders
55	metolazone	tablet	oral	treatment of fluid overload
56	mexiletine	capsule	oral	treatment of ventricular arrhythmia or myotonic disorders
57	mexiletine	tablet	oral	treatment of ventricular

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				arrhythmia or myotonic disorders
58	moxifloxacin 0.5%	eye drops	ophthalmic	treatment of refractory bacterial conjunctivitis
59	nadolol	tablet	oral	treatment of ventricular tachycardia or long QT Syndrome
60	natamycin 5%	eye drops	ophthalmic	treatment of refractory fungal blepharitis, conjunctivitis or keratitis
61	neomycin	tablet	oral	sepsis prevention for colorectal operation
62	nitazoxanide	suspension	oral	treatment of giardiasis, cryptosporidiosis or blastocystis
63	nitazoxanide	tablet	oral	treatment of giardiasis, cryptosporidiosis or blastocystis
64	paromomycin	capsule	oral	antiprotozoal treatment of any of the following amoebic infections: (a) *blastocystis hominis*; (b) *dientomoeba fragilis*; (c) *entamoeba histolytica*; (d) parasite infection
65	pimozide	tablet	oral	treatment of schizophrenia, chronic psychosis or Tourette syndrome
66	pristinamycin	tablet	oral	treatment of confirmed methicillin-resistant *Staphylococcus aureus* or vancomycin-resistant *enterococci* infection where there is history of failed therapy with the other available antibiotics, at sites in relation to bone/joint/prosthesis;

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				or treatment of refractory or resistant *mycoplasma genitalium* infections; or treatment of other infections as prescribed by an infectious disease specialist
67	progesterone	injection	subcutaneous	treatment of progesterone deficiency
68	progesterone in oil	injection	intramuscular	treatment of progesterone deficiency
69	pyrazinamide	tablet	oral	treatment of tuberculosis
70	riboflavin, 0.1% in 1.1% hydroxylpropyl methylcellulose (HPMC)	eye drops	ophthalmic	intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus
71	riboflavin, 0.1% in 20% dextran	eye drops	ophthalmic	intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus
72	riboflavin, 0.1% in sodium chloride	eye drops	ophthalmic	intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus
73	riboflavin, 0.22% in sodium chloride	eye drops	ophthalmic	intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				keratoconus
74	ripasudil 0.4%	eye drops	ophthalmic	treatment of refractory corneal oedema or refractory glaucoma
75	sodium benzoate	tablet	oral	treatment of urea cycle disorders
76	tacrolimus 0.03%	ointment	topical	treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in children
77	tacrolimus 0.1%	ointment	topical	treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in adults
78	Technetium-99m (99m Tc) prostate specific membrane antigen (PSMA)-I&S	injection	intravenous	prostate cancer imaging study
79	tetracycline	capsule	oral	treatment of resistant *Helicobacter Pylori* infection
80	tetracycline	tablet	oral	treatment of resistant *Helicobacter Pylori* infection
81	tick-borne encephalitis vaccine	injection	intramuscular	prevention of tick-borne encephalitis
82	tinidazole	tablet	oral	treatment of *trichomonas vaginalis* infections of the genito-urinary tract in female and male patients, giardiasis, amoebic dysentery or amoebic liver abscess; or treatment of acute giardiasis, acute amoebic dysentery or amoebic liver disease in children; or

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				prevention of infection of the surgical site
83	tizanidine	capsule	oral	treatment of spasticity where other treatments have failed
84	tizanidine	tablet	oral	treatment of spasticity where other treatments have failed
85	triamcinolone acetonide	suspension for injection	ophthalmic	treatment of non-infectious uveitis, visualisation during vitrectomy, diabetic macular oedema, cystoid macular oedema secondary to retinal vein occlusion, uveitic macular oedema or post-operative macular oedema (cataract surgery)
86	verteporfin	powder for injection	intravenous infusion	photosensitisation for photodynamic therapy
87	yttrium-90 (Y-90) Citrate	injection	intraarticular	radiosynovectomy treatment

Schedule 2—Repeals

Note: See section 6.

Therapeutic Goods (Medicines—Authorised Supply) Rules 2020

1 The whole of the instrument

Repeal the instrument