



# **Therapeutic Goods (Medicines—Authorised Supply) Rules 2020**

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I, Jane Cook, as delegate of the Minister for Health, make the following rules.

Dated 15 September 2020

Dr Jane Cook  
First Assistant Secretary  
Medicines Regulation Division  
Health Products Regulation Group  
Department of Health

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## 1 Name

This instrument is the *Therapeutic Goods (Medicines—Authorised Supply) Rules 2020*.

## 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Note: This table relates only to the provisions of this instrument as originally made.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) listed goods;
- (c) medicine;
- (d) Register;
- (e) registered goods;
- (f) sponsor; and
- (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](http://www.tga.gov.au).

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*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

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(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.

<b>Specified therapeutic goods</b>				
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>	<b>Column 5</b>
<b>Item</b>	<b>Active ingredient</b>	<b>Dosage form</b>	<b>Route of administration</b>	<b>Indication</b>
1	aciclovir	eye ointment	ophthalmic	treatment of herpes simplex keratitis
2	allergens—multiple, various (including control solutions)	drops	intradermal	confirmation of suspected allergic reactions
3	allergens – multiple, various (including control solutions)	drops	skin prick	confirmation of suspected allergic reactions
4	amifampridine (3,4-diaminopyridine)	tablet	oral	treatment of Lambert-Eaton Myasthenic Syndrome
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 <i>Helicobacter Pylori</i> infection
7	buspirone	tablet	oral	treatment of generalised anxiety disorders
8	calcitriol	liquid	oral	prevention of hypophosphatemic rickets in children; or treatment of hypoparathyroidism (with severe hypocalcaemia)
9	carbidopa	tablet	oral	premedication for F-18 DOPA imaging
10	cholecalciferol	capsule	oral	treatment of severe vitamin D deficiency and prevention of osteoporosis
11	cholecalciferol	injection	intramuscular	treatment of severe vitamin D deficiency and prevention of osteoporosis
12	cinnarizine	tablet	oral	treatment of vestibular disorders such as vertigo, tinnitus, nausea and vomiting (including Meniere's disease)
13	clobetasol propionate 0.05%	cream	topical	treatment, or prolongation of flare-free intervals, of

<b>Specified therapeutic goods</b>				
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<b>Item</b>	<b>Active ingredient</b>	<b>Dosage form</b>	<b>Route of administration</b>	<b>Indication</b>
				dermatitis/eczema where other treatments have failed
14	clobetasol propionate 0.05%	lotion	topical	treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed
15	clobetasol propionate 0.05%	ointment	topical	treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed
16	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, drug resistant tuberculosis, non-tuberculosis mycobacterial infections or other infections as recommended by an infectious diseases specialist
17	cyclopentolate, 0.2%, and phenylephrine, 1%	eye drops	ophthalmic	production of mydriasis
18	cyclosporin, 0.05%	eye drops, emulsion	ophthalmic	treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca (dry eye syndrome)
19	deflazacort	tablet	oral	treatment of Duchenne muscular dystrophy
20	dehydrated ethanol (alcohol) 96% - 100%	ampoule	topical	treatment of progressive keratoconus and intra-operative use in superficial keratectomy (single use per procedure)
21	dexamethasone (preservative free)	eye drops	ophthalmic	treatment of inflammatory conditions of the eye that are non-infected and steroid responsive in patients

<b>Specified therapeutic goods</b>				
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>	<b>Column 5</b>
<b>Item</b>	<b>Active ingredient</b>	<b>Dosage form</b>	<b>Route of administration</b>	<b>Indication</b>
				sensitive to preservative-containing formulations
22	diazoxide	capsule	oral	treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome or insulinoma
23	diazoxide	suspension	oral	treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome or insulinoma
24	diazoxide	tablet	oral	treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome or insulinoma
25	diflunisal	tablet	oral	treatment of amyloidosis
26	dimethyl sulfoxide (DMSO)	solution	intravesical	symptomatic relief of interstitial cystitis
27	doxycycline	injection	intralesional	sclerotherapy of 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 <i>Helicobacter Pylori</i> 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	injection	intravenous	prostate cancer imaging

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	specific membrane antigen (PSMA)			study
37	glycopyrronium bromide	tablet	oral	treatment of excessive salivation in patients with neurological conditions
38	hyoscine hydrobromide	patch	transdermal	treatment of excessive salivation
39	hypertonic sodium chloride, 5%	eye drops	ophthalmic	temporary relief of corneal oedema (hypertonicity)
40	hypertonic sodium chloride, 5%	eye ointment	ophthalmic	temporary relief of corneal oedema (hypertonicity)
41	indigo carmine	injection	intravenous	intraoperative detection of suspected urethral injuries during abdominal and pelvic surgical procedures
42	indocyanine green dye	injection	intravenous	intra-operative diagnostic use
43	ketotifen	tablet	oral	treatment of allergic conditions
44	levofloxacin	tablet	oral	treatment of resistant <i>Helicobacter Pylori</i> infection or drug resistant tuberculosis
45	levomepromazine	injection	subcutaneous	treatment of nausea and vomiting or agitation
46	levomepromazine	tablet	oral	treatment of nausea and vomiting or agitation
47	lorazepam	injection	parenteral	treatment of acute severe behavioural episodes in the hospital setting
48	melatonin	capsule	oral	treatment of sleep disorders
49	melatonin	immediate release tablet	oral	treatment of sleep disorders
50	melatonin	lozenge	oral	treatment of sleep disorders
51	melatonin	syrup	oral	treatment of sleep disorders
52	mexiletine	capsule	oral	treatment of ventricular arrhythmia or myotonic disorders
53	mexiletine	tablet	oral	treatment of ventricular arrhythmia or myotonic disorders
54	moxifloxacin 0.5%	eye drops	ophthalmic	treatment of refractory bacterial conjunctivitis

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55	nadolol	tablet	oral	treatment of ventricular tachycardia or long QT Syndrome
56	natamycin 5%	eye drops	ophthalmic	treatment of refractory fungal blepharitis, conjunctivitis or keratitis
57	neomycin	tablet	oral	sepsis prevention for colorectal operation
58	nitazoxanide	suspension	oral	treatment of giardiasis, cryptosporidiosis or blastocystis
59	nitazoxanide	tablet	oral	treatment of giardiasis, cryptosporidiosis or blastocystis
60	paromomycin	capsule	oral	antiprotozoal treatment of any of the following amoebic infections: (a) <i>blastocystis hominis</i> ; (b) <i>dientamoeba fragilis</i> ; (c) <i>entamoeba histolytica</i> ; (d) parasite infection
61	pimozide	tablet	oral	treatment of schizophrenia, chronic psychosis or Tourette syndrome
62	pristinamycin	tablet	oral	treatment of confirmed methicillin-resistant <i>Staphylococcus aureus</i> or 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; or treatment of refractory or resistant <i>mycoplasma genitalium</i> infections; or treatment of other infections as prescribed by an infectious disease specialist
63	pyrazinamide	tablet	oral	treatment of tuberculosis
64	riboflavin, 0.1% in 1.1% hydroxypropyl	eye drops	ophthalmic	intraoperative use in corneal collagen

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	methylcellulose (HPMC)			crosslinking (CXL) procedures for the treatment of progressive keratoconus
65	riboflavin, 0.1% in 20% dextran	eye drops	ophthalmic	intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus
66	riboflavin, 0.1% in sodium chloride	eye drops	ophthalmic	intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus
67	riboflavin, 0.22% in sodium chloride	eye drops	ophthalmic	intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus
68	ripasudil 0.4%	eye drops	ophthalmic	treatment of refractory corneal oedema or refractory glaucoma
69	sodium benzoate	tablet	oral	treatment of urea cycle disorders
70	tacrolimus 0.03%	ointment	topical	treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in children
71	tacrolimus 0.1%	ointment	topical	treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in adults
72	tetracycline	capsule	oral	treatment of resistant <i>Helicobacter Pylori</i> infection
73	tetracycline	tablet	oral	treatment of resistant <i>Helicobacter Pylori</i> infection
74	tick-borne encephalitis vaccine	injection	intramuscular	prevention of tick-borne encephalitis
75	tinidazole	tablet	oral	treatment of <i>trichomonas</i>

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<b>Item</b>	<b>Active ingredient</b>	<b>Dosage form</b>	<b>Route of administration</b>	<b>Indication</b>
				<i>vaginalis</i> 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 prevention of infection of the surgical site
76	tizanidine	capsule	oral	treatment of spasticity where other treatments have failed
77	tizanidine	tablet	oral	treatment of spasticity where other treatments have failed
78	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)
79	verteporfin	powder for injection	intravenous infusion	photosensitisation for photodynamic therapy
80	yttrium-90 (Y-90) Citrate	injection	intraarticular	radiosynovectomy treatment

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## **Schedule 2—Repeals**

Note: See section 6.

### ***Therapeutic Goods (Authorised Supply of Medicines) Rules 2019***

#### **1 The whole of the instrument**

Repeal the instrument.