Therapeutic Goods (Medicines—Authorised Supply) Rules 2020

made under subsection 19(7A) of the

Therapeutic Goods Act 1989

Compilation No. 1

Compilation date: 11 February 2022

Includes amendments up to: F2022L00123

Prepared by the Department of Health, Canberra

About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Medicines—Authorised Supply) Rules 2020* that shows the text of the law as amended and in force on 11 February 2022 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

1 Name

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

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.

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.

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**
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 *Helicobacter Pylori* 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
11A	ciclosporin, 0.05%	eye drops, emulsion	ophthalmic	treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca (dry eye syndrome)
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 dermatitis/eczema where other treatments have failed
14	clobetasol propionate	lotion	topical	treatment, or prolongation

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
	0.05%			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 *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
16A	colecalciferol	capsule	oral	treatment of severe vitamin D deficiency and prevention of osteoporosis
16B	colecalciferol	injection	intramuscular	treatment of severe vitamin D deficiency and prevention of osteoporosis
17	cyclopentolate, 0.2%, and phenylephrine, 1%	eye drops	ophthalmic	production of mydriasis
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 sensitive to preservative-containing

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				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
26A	disulfiram	tablet	oral	deterrent to alcohol consumption
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 *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

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
36	Gallium-68 prostate specific membrane antigen (PSMA)	injection	intravenous	prostate cancer imaging 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)
40A	iloprost	injection	intravenous infusion	treatment of patients with severe disabling Raynaud's phenomenon; or treatment of peripheral ischaemia
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
42A	interferon alpha-2b	eye drops	ophthalmic	treatment of ocular surface squamous neoplasia
43	ketotifen	tablet	oral	treatment of allergic conditions
44	levofloxacin	tablet	oral	treatment of resistant *Helicobacter Pylori* 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
46A	lifitegrast	eye drops	ophthalmic	treatment of dry eye disease
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

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
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
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) *blastocystis hominis*; (b) *dientomoeba fragilis*; (c) *entamoeba histolytica*; (d) parasite infection
61	pimozide	tablet	oral	treatment of schizophrenia, chronic psychosis or Tourette syndrome
62	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; or treatment of refractory or

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				resistant *mycoplasma genitalium* infections; or treatment of other infections as prescribed by an infectious disease specialist
62A	progesterone	injection	subcutaneous	treatment of progesterone deficiency
62B	progesterone in oil	injection	intramuscular	treatment of progesterone deficiency
63	pyrazinamide	tablet	oral	treatment of tuberculosis
64	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
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

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
71	tacrolimus 0.1%	ointment	topical	treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in adults
71A	Technetium-99m (99m Tc) prostate specific membrane antigen (PSMA)-I&S	injection	intravenous	prostate cancer imaging study
72	tetracycline	capsule	oral	treatment of resistant *Helicobacter Pylori* infection
73	tetracycline	tablet	oral	treatment of resistant *Helicobacter Pylori* infection
74	tick-borne encephalitis vaccine	injection	intramuscular	prevention of tick-borne encephalitis
75	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 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	intravenous	photosensitisation for

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
		injection	infusion	photodynamic therapy
80	yttrium-90 (Y-90) Citrate	injection	intraarticular	radiosynovectomy treatment

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation "(md not incorp)" is added to the details of the amendment included in the amendment history.

Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods (Medicines—Authorised Supply) Rules 2020	16 Sep 2020 (F2020L01170)	17 Sep 2020	—
Therapeutic Goods (Authorised Supply) Amendment (Medicines and Medical Devices) Rules 2022	10 Feb 2022 (F2022L00123)	11 Feb 2022	—

Endnote 4—Amendment history

Provision affected	How affected
s 2	rep LA s 48D
s 6	rep LA s 48C
Sch 1	am F2022L00123
Sch 2	rep LA s 48C