Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022

made under subsection 19(7A) of the

Therapeutic Goods Act 1989

Compilation No. 4

Compilation date: 17 October 2024

Includes amendments up to: F2024L01321

Prepared by the Department of Health and Aged Care, Canberra

About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022* that shows the text of the law as amended and in force on 17 October 2024 (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 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 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 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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.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 and OTG—Authorised Supply) Rules 2022.*

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;
(h) therapeutic goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

active ingredient has the same meaning as in the Regulations.

nurse practitioner means a person who is:

(a) registered under a law of a state or internal territory as a registered nurse; and
(b) endorsed as a nurse practitioner by the Nursing and Midwifery Board of Australia.

Note: The Nursing and Midwifery Board of Australia works in partnership with the Australian Health Practitioner Regulation Agency.

Regulations means the *Therapeutic Goods Regulations 1990.*

SAS Guidance means the document titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 3.0, October 2024) published by the Therapeutic Goods Administration, as in force or existing on 1 October 2024.

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*.

therapeutic vaping kit has the same meaning as in the Regulations.

therapeutic vaping pack has the same meaning as in Regulations.

therapeutic vaping substance has the same meaning as in the Regulations.

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.

5A Authorisation—therapeutic vaping goods

Supply by a medical practitioner or nurse practitioner

(1) A health practitioner who is a medical practitioner or a nurse practitioner is authorised to supply a therapeutic good to a patient of that practitioner where:
(a) the therapeutic good is within the class of therapeutic goods specified in column 2 of an item in the table in Schedule 1A; and
(b) the therapeutic good is in the dosage form specified in column 3 of that item; and
(c) the therapeutic good is to be 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 supply is to a patient who is 16 years of age or over; and
(f) the conditions specified in subsection (2) are satisfied.

(2) The medical practitioner or nurse practitioner must:
(a) inform the patient, or a parent or a guardian of the patient, that the therapeutic good is not a listed good or registered good; and
(b) obtain informed consent from the patient, or a parent or a guardian of the patient, in relation to, and before, the supply of the therapeutic good; and
(c) supply the therapeutic good in accordance with good medical practice or good nursing practice (as the case requires); and
(d) if the medical practitioner or nurse practitioner becomes aware that the patient has suffered an adverse event in relation to the therapeutic good—notify the Therapeutic Goods Administration and the sponsor of the therapeutic good about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance; and
(e) if the medical practitioner or nurse practitioner becomes aware of a defect in the therapeutic good—notify the Therapeutic Goods Administration and the sponsor of the therapeutic good in accordance with the reporting guidelines set out in the SAS Guidance.

Supply by a pharmacist—with prescription

(3) A pharmacist is authorised to supply a therapeutic good to a patient of a medical practitioner or a nurse practitioner (the ***treating practitioner***) where:
  (a) the therapeutic good is within the class of therapeutic goods specified in column 2 of an item in the table in Schedule 1A; and
  (b) the supply is requested by the treating practitioner; and
  (c) the therapeutic good is in the dosage form specified in column 3 of that item; and
  (d) the therapeutic good 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 supply is to a patient who is 16 years of age or over; and
  (g) the conditions specified in subsection (4) are satisfied.

(4) The pharmacist supplying the therapeutic good must:
  (a) if the pharmacist becomes aware that the patient has suffered an adverse event in relation to the therapeutic good—notify the Therapeutic Goods Administration and the sponsor of the therapeutic good about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance; and
  (b) if the pharmacist becomes aware of a defect in the therapeutic good—notify the Therapeutic Goods Administration and the sponsor of the therapeutic good in accordance with the reporting guidelines set out in the SAS Guidance.

Supply by a pharmacist—without prescription

(5) A pharmacist is authorised to supply a therapeutic good to a patient where:
  (a) the therapeutic good is within the class of therapeutic goods specified in column 2 of an item in the table in Schedule 1A; and
  (b) the therapeutic good is in the dosage form specified in column 3 of that item; and
  (c) the therapeutic good is to be 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 supply is to a patient who is 18 years of age or over; and
  (f) the pharmacist requests and sights evidence of the patient's identity and age; and
  (g) the quantity of the goods does not exceed the quantity that is reasonably required for a patient's therapeutic use for 1 month and that quantity is supplied to the patient only once in a month; and
  (h) the concentration of nicotine in the goods does not exceed 20 mg/mL; and
  (i) the conditions specified in subsections (6) and (7) are satisfied.

(6) The pharmacist must:

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

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

(c) supply the therapeutic good in accordance with good pharmacy practice; and

(d) provide professional advice to the patient on alternative cessation supports and therapies, appropriate dose and frequency depending on age, weight and severity of condition, length of treatment, suitable titration, and interactions with other medicines; and

(e) provide contact details about smoking cessation support services to the patient; and

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

(g) if the pharmacist becomes aware of a defect in the therapeutic good—notify the Therapeutic Goods Administration and the sponsor of the therapeutic good in accordance with the reporting guidelines set out in the SAS Guidance.

(7) The pharmacist must store the therapeutic good in a part of the pharmacy premises to which the public does not have access.

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,

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				nausea and vomiting (including Meniere's disease)
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

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				and prevention of osteoporosis
16	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
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

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
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 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
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)

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
41	hypertonic sodium chloride, 5%	eye ointment	ophthalmic	temporary relief of corneal oedema (hypertonicity)
42	iloprost	injection	intravenous infusion	treatment of patients 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

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
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 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

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
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; 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

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				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 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

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
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 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

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

Schedule 1A—Therapeutic vaping goods

Note: See section 5A.

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Class of therapeutic goods**	**Dosage form**	**Route of administration**	**Indication**
1	therapeutic vaping substances or therapeutic vaping substance accessories that: (a) contain nicotine as the only active ingredient; (b) are the subject of a notification under item 15 in Schedule 5A to the Regulations; and (c) are not the subject of a determination by the Secretary under item 15 in Schedule 5A to the Regulations	liquid or solid	inhalation	any one or more of the following: (a) use for smoking cessation; (b) management of nicotine dependence
2	therapeutic vaping substances or therapeutic vaping substance accessories that: (a) do not contain any active ingredients; (b) are the subject of a notification under item 15 in Schedule 5A to the Regulations; and (c) are not the subject of a determination by the Secretary under item 15 in Schedule 5A to the Regulations	liquid or solid	inhalation	any one or more of the following: (a) use for smoking cessation; (b) management of nicotine dependence
3	therapeutic vaping kits that: (a) contain one or more therapeutic vaping substances or therapeutic vaping	liquid or solid	inhalation	any one or more of the following: (a) use for smoking cessation;

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Class of therapeutic goods**	**Dosage form**	**Route of administration**	**Indication**
	substance accessories; and (b) are the subject of a notification under item 15 in Schedule 5A to the Regulations; and (d) are not the subject of a determination by the Secretary under item 15 in Schedule 5A to the Regulations			(b) management of nicotine dependence
4	goods in a therapeutic vaping pack that: (a) are or contain one or more therapeutic vaping substances or therapeutic vaping substance accessories; and (b) are the subject of a notification under item 15 in Schedule 5A to the Regulations; and (c) are not the subject of a determination by the Secretary under item 15 in Schedule 5A to the Regulations	liquid or solid	inhalation	any one or more of the following: (a) use for smoking cessation; (b) management of nicotine dependence

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 how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and "(md not incorp)" is added to 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 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 2022	23 Dec 2022 (F2022L01766)	24 Dec 2022	—
Therapeutic Goods (Medicines—Authorised Supply) Amendment (Vaping) Rules 2023	15 Dec 2023 (F2023L01683)	1 Jan 2024	—
Therapeutic Goods (Authorised Supply) Amendment (SAS Guidance) Rules 2024	6 Jun 2024 (F2024L00639)	5 Jun 2024	—
Therapeutic Goods (Authorised Supply) Amendment (SAS Guidance) Rules (No. 2) 2024	16 Oct 2024 (F2024L01321)	17 Oct 2024	—

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024	50, 2024	27 June 2024	Sch 4 (items 6-11, 18): 1 Oct 2024 (s 2(1) item 5)	Sch 4 (item 18)

Endnote 4—Amendment history

Provision affected	How affected
s 1…….	am F2023L01683
s 2…….	rep LA s 48D
s 4…….	am F2023L01683; F2024L00639; F2024L01321
s 5A……..	ad F2023L01683
	am Act No. 50, 2024
s 6…….	rep LA s 48C
Schedule 1……	am F2024L00639
Schedule 1A…….	ad F2023L01683
Schedule 2……	rep LA s 48C