

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

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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Note: This table relates only to the provisions of this instrument as originally made.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) |
| 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 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 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 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 |
| 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 |
| 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 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 |
| 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 |
| 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