

Therapeutic Goods (Authorised Supply of Medicines) Rules 2019

I, Adrian Bootes, as delegate of the Minister for Health, make the following rules.

Dated 13 September 2019

Adrian Bootes

Acting 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 (Authorised Supply of Medicines) Rules 2019*.

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Note: This table relates only to the provisions of this instrument as originally made.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

(c) Register; and

(d) supply.

In this instrument:

***Act*** means the *Therapeutic Goods Act 1989*.

***listed*** means included in the part of the Register for goods known as listed goods.

***medical practitioner*** has the same meaning as in section 19 of the Act.

***registered*** means included in the part of the Register for goods known as registered goods or provisionally registered goods.

***Regulations*** means the *Therapeutic Goods Regulations 1990*.

***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 immediately before 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 Regulations.

5 Authorisation

*Supply by, or to a patient of, a medical practitioner*

(1) A medical practitioner is authorised to supply a medicine that contains an active ingredient specified in column 2 of an item in the table in Schedule 1, to a patient of that practitioner, in circumstances where:

(a) the medicine only contains the active ingredient in the strength and concentration specified (if any) in column 2 of that item; and

(b) the medicine is in the dosage form specified in column 3 of that item; and

(c) the medicine is 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 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 registered or listed; 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.

(3) A health practitioner is authorised to supply a medicine that contains an active ingredient specified in column 2 of an item in the table in Schedule 1, to a patient of a medical practitioner (***the*** ***treating practitioner***), in circumstances where:

(a) the medicine only contains the active ingredient in the strength and concentration specified (if any) in column 2 of that item; and

(b) the supply is requested by the treating practitioner; and

(c) the medicine is in the dosage form specified in column 3 of that item; and

(d) the medicine is 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 (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 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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 | amifampridine (3,4-diaminopyridine) | tablet | oral | treatment of Lambert-Eaton Myasthenic Syndrome |
| 4 | bifidobacterium bifidum and Lactobacillus acidophilus | capsule | oral | prevention of necrotising enterocolitis |
| 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;  treatment of hypoparathyroidism (with severe hypocalcaemia) |
| 9 | cholecalciferol | capsule | oral | treatment of severe vitamin D deficiency and prevention of osteoporosis |
| 10 | cholecalciferol | injection | intramuscular | treatment of severe vitamin D deficiency and prevention of osteoporosis |
| 11 | cinnarizine | tablet | oral | treatment of vestibular disorders such as vertigo, tinnitus, nausea and vomiting (including Meniere's disease). |
| 12 | clobetasol propionate 0.05% | cream | topical | treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed |
| 13 | clobetasol propionate 0.05% | lotion | topical | treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed |
| 14 | clobetasol propionate 0.05% | ointment | topical | treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed |
| 15 | 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 |
| 16 | cyclopentolate, 0.2%, and phenylephrine, 1% | eye drops | ophthalmic | production of mydriasis |
| 17 | cyclosporin, 0.05% | eye drops, emulsion | ophthalmic | treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca |
| 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 | diazoxide | tablet | oral | treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome and insulinoma |
| 21 | diazoxide | capsule | oral | treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome and insulinoma |
| 22 | diazoxide | suspension | oral | treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome and insulinoma |
| 23 | diflunisal | tablet | oral | treatment of amyloidosis |
| 24 | dimethyl sulfoxide (DMSO) | solution | intravesical | symptomatic relief of interstitial cystitis |
| 25 | F-18 myocardial perfusion tracer (18F flurpiridaz) | injection | intravenous | myocardial perfusion study |
| 26 | F-18 NaF (sodium fluoride) | injection | intravenous | bone study |
| 27 | flunarizine | tablet | oral | treatment of vestibular disorders |
| 28 | flunarizine | capsule | oral | treatment of vestibular disorders |
| 29 | furazolidone | tablet | oral | treatment of resistant *Helicobacter Pylori* infection |
| 30 | Gallium-68 (Ga-68) Galligas | aerosol | inhalation | lung ventilation study |
| 31 | Gallium-68  (Ga-68) - MAA | injection | intravenous | lung perfusion study |
| 32 | glycopyrronium bromide | tablet | oral | treatment of excessive salivation in patients with neurological conditions |
| 33 | hyoscine hydrobromide | patch | transdermal | treatment of excessive salivation |
| 34 | hypertonic sodium chloride, 5 % | eye ointment | ophthalmic | temporary relief of corneal oedema (hypertonicity) |
| 35 | hypertonic sodium chloride, 5% | eye drops | ophthalmic | temporary relief of corneal oedema (hypertonicity) |
| 36 | indigo carmine | injection | intravenous | intraoperative detection of suspected urethral injuries during abdominal and pelvic surgical procedures |
| 37 | indocyanine green dye | injection | intravenous | intra-operative diagnostic use |
| 38 | insulin neutral-concentrated (Humulin R U-500) | solution for injection | subcutaneous | treatment of diabetes |
| 39 | levofloxacin | tablet | oral | treatment of resistant *Helicobacter Pylori* infection |
| 40 | levomepromazine | tablet | oral | treatment of nausea and vomiting or agitation |
| 41 | levomepromazine | injection | subcutaneous | treatment of nausea and vomiting or agitation |
| 42 | lorazepam | injection | parenteral | treatment of acute severe behavioural episodes in the hospital setting |
| 43 | ketotifen | tablet | oral | treatment of allergic conditions |
| 44 | melatonin | syrup | oral | treatment of sleep disorders |
| 45 | melatonin | modified release tablet | oral | treatment of sleep disorders |
| 46 | melatonin | capsule | oral | treatment of sleep disorders |
| 47 | melatonin | immediate release tablet | oral | treatment of sleep disorders |
| 48 | melatonin | lozenge | oral | treatment of sleep disorders |
| 49 | mexiletine | tablet | oral | treatment of ventricular arrhythmia or myotonic disorders |
| 50 | mexiletine | capsule | oral | treatment of ventricular arrhythmia or myotonic disorders |
| 51 | midodrine | tablet | oral | treatment of severe orthostatic hypotension |
| 52 | moxifloxacin 0.5% | eye drops | ophthalmic | treatment of refractory bacterial conjunctivitis |
| 53 | nadolol | tablet | oral | treatment of ventricular tachycardia or long QT Syndrome |
| 54 | natamycin 5% | eye drops | ophthalmic | treatment of refractory fungal blepharitis, conjunctivitis or keratitis |
| 55 | nitazoxanide | tablet | oral | treatment of giardiasis, cryptosporidiosis and blastocystis |
| 56 | nitazoxanide | suspension | oral | treatment of giardiasis, cryptosporidiosis and blastocystis |
| 57 | paromomycin | capsule | oral | antiprotozoal treatment of the following amoebic infections:  (a) *blastocystis hominis*;  (b) *dientomoeba fragilis*;  (c) *entamoeba histolytica*;  (d) parasite infection |
| 58 | pimozide | tablet | oral | treatment of schizophrenia, chronic psychosis and Tourette syndrome |
| 59 | pristinamycin | tablet | oral | treatment of confirmed methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant *enterococci* infection where there is history of failed therapy with the other available antibiotics, at sites in relation to bone/joint/prosthesis;  treatment of refractory or resistant *mycoplasma genitalium* infections;  treatment of other infections as prescribed by an infectious disease specialist |
| 60 | pyrazinamide | tablet | oral | treatment of tuberculosis |
| 61 | riboflavin, 0.1% in 20% dextran | eye drops | ophthalmic | intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus |
| 62 | riboflavin, 0.1% in sodium chloride | eye drops | ophthalmic | intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus |
| 63 | ripasudil 0.4% | eye drops | ophthalmic | treatment of refractory corneal oedema or refractory glaucoma |
| 64 | rufinamide | tablet | oral | adjunct treatment of seizures associated with Lennox-Gastaut syndrome in patients over 4 years of age |
| 65 | sodium benzoate | tablet | oral | treatment of urea cycle disorders |
| 66 | stiripentol | capsule | oral | treatment of intractable epilepsy and Dravet syndrome (severe myoclonic epilepsy of infancy (SMEI)) |
| 67 | stiripentol | tablet | oral | treatment of intractable epilepsy and Dravet syndrome (severe myoclonic epilepsy of infancy (SMEI)) |
| 68 | stiripentol | sachet | oral | treatment of intractable epilepsy and Dravet syndrome (severe myoclonic epilepsy of infancy (SMEI)) |
| 69 | tacrolimus 0.03% | ointment | topical | treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in children |
| 70 | tacrolimus 0.1% | ointment | topical | treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in adults |
| 71 | tizanidine | capsule | oral | treatment of spasticity where other treatments have failed |
| 72 | tizanidine | tablet | oral | treatment of spasticity where other treatments have failed |
| 73 | tetracycline | capsule | oral | treatment of resistant *Helicobacter Pylori* infection |
| 74 | tetracycline | tablet | oral | treatment of resistant *Helicobacter Pylori* infection |
| 75 | tick-borne encephalitis vaccine | injection | intramuscular | prevention of tick-borne encephalitis |
| 76 | triamcinolone acetonide | suspension for injection | ophthalmic | treatment of non-infectious uveitis or visualisation during vitrectomy |
| 77 | verteporfin | powder for injection | intravenous infusion | photosensitisation for photodynamic therapy |
| 78 | yttrium-90 (Y-90) Citrate | injection | intraarticular | radiosynovectomy treatment |

Schedule 2—Repeals

Therapeutic Goods (Authorised Supply of Specified Medicines) Rules March 2018

1 The whole of the instrument

Repeal the instrument