

Therapeutic Goods (Authorised Supply of Specified Medicines) Rules 2017

*Therapeutic Goods Act 1989*

I, LARRY KELLY, a delegate of the Minister for Health for the purposes of subsection 19(7A) of the *Therapeutic Goods Act 1989*, make the following Rules.

Dated 28 June 2017

(signed by)

**LARRY KELLY**

Delegate of the Minister for Health

1 Name

 These Rules are the *Therapeutic Goods (Authorised Supply of Specified Medicines) Rules 2017*.

2 Commencement

 These Rules commence on 3 July 2017.

3 Authority

 These Rules are made under subsection 19(7A) of the *Therapeutic Goods Act 1989*.

4 Authorisation to supply medicines

 (1) A health practitioner of the class specified in column 5 in an item in table 1 is authorised to supply a medicine that:

(a) contains only the active ingredient or ingredients, in the strength or concentration (if any), specified in column 1 in the item; and

(b) is in the dosage form specified in column 2 in the item;

 to a person if:

(c) the person is a patient of the health practitioner; and

(d) the medicine is to be administered through the route of administration specified in column 3 in the item; and

(e) the supply is for an indication specified in column 4 in the item; and

(f) the following conditions are satisfied:

(i) the health practitioner must inform the patient, or a parent or guardian of the patient, that the medicine is not registered or listed;

(ii) the health practitioner must ensure that the medicine is supplied only after receiving informed consent from the patient, or a parent or guardian of the patient;

(iii) the health practitioner must ensure that the medicine is supplied in accordance with good medical practice;

(iv) if the health practitioner becomes aware that the patient has suffered an adverse event in relation to the medicine, the health practitioner must notify the Therapeutic Goods Administration, and the sponsor of the medicine, about the adverse event, in accordance with subsection (3);

(v) if the health practitioner becomes aware of any defect in the medicine, the health practitioner must notify the Therapeutic Goods Administration, and the sponsor of the medicine, about the defect, in accordance with subsection (3).

 (2) A health practitioner is authorised to supply a medicine that:

(a) contains only the active ingredient or ingredients, in the strength or concentration (if any), specified in column 1 in an item in table 1; and

(b) is in the dosage form specified in column 2 in the item;

 to a person if:

(c) the person is a patient of another health practitioner (the ***treating practitioner***); and

(d) the treating practitioner is a health practitioner of the class specified in column 5 in the item; and

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

(f) the medicine is to be administered through the route of administration specified in column 3 in the item; and

(g) the supply is for an indication specified in column 4 in the item; and

(h) the following conditions are satisfied:

(i) if the health practitioner supplying the medicine becomes aware that the patient has suffered an adverse event in relation to the medicine, the health practitioner must notify the Therapeutic Goods Administration, and the sponsor of the medicine, about the adverse event, in accordance with subsection (3);

(ii) if the health practitioner supplying the medicine becomes aware of any defect in the medicine, the health practitioner must notify the Therapeutic Goods Administration, and the sponsor of the medicine, about the defect, in accordance with subsection (3).

 (3) For the purposes of subparagraphs (1)(f)(iv) and (v) and (2)(h)(i) and (ii), notification must be in accordance with the reporting guidelines set out in the document titled *Special Access Scheme Guidance for health practitioners and sponsors*, version 1.0, published by the Therapeutic Goods Administration in June 2017.

**Table 1: Authorised supply of medicines**

| **Item** | **Column 1****Active ingredient(s) and strength or concentration** | **Column 2****Dosage form** | **Column 3****Route of administration** | **Column 4****Indication(s)** | **Column 5****Authorised health practitioner** |
| --- | --- | --- | --- | --- | --- |
| 1 | Triamcinolone acetonide | Suspension for injection | Ophthalmic | Treatment of inflammatory ocular conditions | Medical practitioner |
| 2 | Triamcinolone acetonide | Suspension for injection | Ophthalmic | Visualization during vitrectomy. | Medical practitioner |
| 3 | Melatonin | Syrup | Oral | Treatment of sleep disorders | Medical practitioner |
| 4 | Melatonin | Modified release tablet | Oral | Treatment of sleep disorders | Medical practitioner |
| 5 | Melatonin | Capsule | Oral | Treatment of sleep disorders | Medical practitioner |
| 6 | Melatonin | Tablet | Oral | Treatment of sleep disorders | Medical practitioner |
| 7 | Bismuth subcitrate | Tablet | Oral | Treatment of resistant *H.Pylori* infection | Medical practitioner |
| 8 | Tetracycline | Capsule | Oral | Treatment of resistant *H.Pylori* infection | Medical practitioner |
| 9 | Riboflavin, 0.1% in 20% dextran | Eye drops | Ophthalmic | Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment for progressive keratoconus.  | Medical practitioner |
| 10 | Riboflavin, 0.1% in sodium chloride (hypotonic) | Eye drops | Ophthalmic | Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment for progressive keratoconus.  | Medical practitioner |
| 11 | Flunarizine | Tablet | Oral | Prophylactic treatment of migraine  | Medical practitioner |
| 12 | Cyclosporin, 0.05% | Eye drops, emulsion | Ophthalmic | Treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca. | Medical practitioner |
| 13 | Cinnarizine | Tablet | Oral | Treatment of vestibular disorders such as vertigo, tinnitus, nausea and vomiting (including Meniere's disease).  | Medical practitioner |
| 14 | Hypertonic sodium chloride, 5% | Eye drops | Ophthalmic | Temporary relief of corneal oedema (hypertonicity) | Medical practitioner |
| 15 | Hypertonic sodium chloride | Eye ointment | Ophthalmic | Temporary relief of corneal oedema (hypertonicity) | Medical practitioner |
| 16 | Dexamethasone, 0.1% | Eye drops | Ophthalmic | Treatment of non-infected, steroid responsive, inflammatory conditions of the eye | Medical practitioner |
| 17 | Buspirone | Tablet | Oral | Treatment of generalised anxiety disorders | Medical practitioner |
| 18 | Paromomycin | Capsule | Oral | Antiprotozoal treatment of the following amoebic infections:(a) *blastocystis hominis*;(b) *dientomoeba fragilis*;(c) *entamoeba histolytica*;(d) parasite infection  | Medical practitioner |
| 19 | Allergens – multiple, various | Skin prick test | Intradermal | Confirmation of suspected allergic reactions | Medical practitioner |
| 20 | Cyclopentolate, 0.2%, & phenylephrine, 1% | Eye drops | Ophthalmic | Production of mydriasis. | Medical practitioner |
| 21 | Verteporfin | Powder for injection | Intravenous infusion | Photosensitisation for photodynamic therapy | Medical practitioner |
| 22 | Pyrazinamide | Tablet | Oral | Treatment of resistant tuberculosis | Medical practitioner |
| 23 | Furazolidone | Tablet | Oral | Treatment of resistant *H.Pylori* infection | Medical practitioner |
| 24 | 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/prosthesisTreatment of other infections as prescribed by an infectious disease specialist | Medical practitioner |
| 25 | Glycopyrronium bromide | Tablet | Oral | Treatment of excessive salivation in patients with neurological conditions | Medical practitioner |
| 26 | Cholecalciferol | Capsule | Oral | Treatment of severe vitamin D deficiency and prevention of osteoporosis | Medical practitioner |
| 27 | Cholecalciferol | Injection  | Intramuscular | Treatment of severe vitamin D deficiency and prevention of osteoporosis | Medical practitioner |