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For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<<https://www.tga.gov.au/treatment-information-provided-tga>>.

Authorised Prescriber Scheme – Application form

Email completed form to:

Authorised.Prescribers@health.gov.au (preferred)

or fax to +61 2 6203 1105

HREC approval or specialist college endorsement is not required if the medicine, concentration (if any), dosage form, route of administration and indication match those listed on the **back of this form**. You will need to provide the relevant **item code** for the medicine you wish to apply for.

Privacy information

For general privacy information, go to <<https://www.tga.gov.au/privacy>>.

The TGA is collecting personal information in this form in order to:

- Assess the application; and
- Contact you, as the medical practitioner applying to supply the 'unapproved' therapeutic goods, to discuss the application where necessary.

The personal information of the medical practitioner may be disclosed to State and Territory authorities with responsibility for therapeutic goods or health practitioner registration.

PLEASE PRINT IN BLOCK LETTERS. Please complete the form clearly and in full. Forms cannot be processed if incomplete or illegible.

Product details

Item code (see back of form)

Only the item code, prescriber details and signature are required to be completed for medicines that match an entry on the back of this form (HREC approval or specialist college endorsement not required).

Code Number:

Trade name	Sponsor / supplier's name and address
Active ingredient / device product description (including variant)	
Dosage form	Route of administration
Indication / reason for prescribing	

Prescribing medical practitioner details

First name	Surname
AHPRA ID	Specialty
Email	
Phone	Fax
Principal practice address	

Approving/endorsing body

Name of approving ethics committee (if applicable)
Name of endorsing specialist college (if applicable)

Please tick:

I have attached the most recent letter from the approving ethics committee or endorsing specialist college

AND

I have attached a declaration from the ethics committee or specialist college that all necessary documentation has been reviewed and is appropriate

OR

Human Research Ethics Committee (HREC) approval or specialist college endorsement is not required as the medical practitioner is applying to become an Authorised Prescriber of medicines that match an entry on the back of this form.

I understand that:

- the product is not approved for marketing in Australia and that the Therapeutic Goods Administration (TGA) is unable to vouch for the quality, safety or efficacy of this unapproved product, and that its use is regarded as experimental;
- the giving of an authority under subsection 19(5) or sections 32CM or 41HC does not render the Commonwealth, the Secretary or a delegate of the Secretary liable to a person in respect of loss, damage, or injury of any kind suffered by the person as a result of, or arising out of the use of, therapeutic goods by that person or another person;
- that in order to be given such an authority, I must be either:
 - a medical practitioner engaged in clinical practice in a hospital and have approval from the ethics committee of the hospital to supply and or use the unapproved product, or
 - a medical practitioner treating patients outside a hospital setting and without access to an ethics committee that could approve the supply who has obtained endorsement from a specialist college that has an established expertise relevant to the use of the unapproved product, or
 - the product is included in the list of medicines specified in Regulation 12B(1B) of the *Therapeutic Goods Regulations 1990*.

I agree to:

- the collection of my personal information for the purposes set out above;
- obtain from each patient (or guardian) informed consent in relation to the proposed use of the unapproved product, and in this context, inform the patient that the product is not approved in Australia; OR inform the requesting doctor that the in vitro diagnostic medical device used to perform the test is not approved in Australia;
- the product only being prescribed for patients in my immediate care;
- the product only to being used in accordance with the treatment directions (being the protocol or product information or instructions for use);
- continuing to have an appropriate approval or endorsement in order to supply and or use the product (if applicable);
- report any suspected adverse events to the TGA, the sponsor and either the approving ethics committee or endorsing specialist college (as applicable); and
- comply with all relevant State/Territory legislation.

Please note that the giving of false or misleading information is an offence under the *Criminal Code Act 1995* and that penalties may be imposed.

Medical practitioner's signature

Date

List of medicines with an established history of use

HREC approval or specialist college endorsement is not required if the medicine, concentration (if any), dosage form, route of administration and indication match those listed below (as specified in regulation 12B(1B) of the *Therapeutic Goods Regulations 1990*).

Active ingredient	Dosage form	Route of administration	Indication	Code
Allergens—multiple, various (including control solutions)	Drops	Intradermal	Confirmation of suspected allergic reactions	AP2
Allergens – multiple, various (including control solutions)	Drops	Skin prick	Confirmation of suspected allergic reactions	AP3
Amifampridine (3,4-diaminopyridine)	Tablet	Oral	Treatment of Lambert-Eaton Myasthenic Syndrome	AP4
Argipressin	Injection	Intravenous	To increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines	AP147
Betaxolol 0.25% (preservative free)	Eye drops	Ophthalmic	Treatment of elevated intraocular pressure where other treatments are inappropriate	AP5
Bismuth subcitrate	Tablet	Oral	Treatment of resistant <i>Helicobacter pylori</i> infection	AP6
Buspirone	Tablet	Oral	Treatment of generalised anxiety disorders	AP7
Calcitriol	Liquid	Oral	Prevention of hypophosphatemic rickets in children	AP8
Calcitriol	Liquid	Oral	Treatment of hypoparathyroidism (with severe hypocalcaemia)	AP9
Carbidopa	Tablet	Oral	Premedication for F-18 DOPA imaging	AP10
Ciclosporin, 0.05%	Eye drops, emulsion	Ophthalmic	Treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca (dry eye syndrome)	AP26
Cinnarizine	Tablet	Oral	Treatment of vestibular disorders such as vertigo, tinnitus, nausea and vomiting (including Meniere's disease)	AP13
Clobetasol propionate 0.05%	Cream	Topical	Treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed	AP14
Clobetasol propionate 0.05%	Lotion	Topical	Treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed	AP15
Clobetasol propionate 0.05%	Ointment	Topical	Treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed	AP16
Clofazimine	Capsule	Oral	Treatment of Leprosy	AP17
Clofazimine	Capsule	Oral	Treatment of granulomatous cheilitis	AP18
Clofazimine	Capsule	Oral	Treatment of Melkersson Rosenthal Syndrome	AP19
Clofazimine	Capsule	Oral	Treatment of confirmed mycobacterium avium paratuberculosis in immunocompromised patients recommended by an infectious disease specialist	AP20
Clofazimine	Capsule	Oral	Treatment of erythema nodosum leprosum	AP21
Clofazimine	Capsule	Oral	Treatment of drug resistant tuberculosis	AP22

Active ingredient	Dosage form	Route of administration	Indication	Code
Clofazimine	Capsule	Oral	Treatment of non-tuberculosis mycobacterial infections	AP23
Clofazimine	Capsule	Oral	Treatment of other infections as recommended by an infectious diseases specialist	AP24
Colecalciferol	Capsule	Oral	Treatment of severe vitamin D deficiency and prevention of osteoporosis	AP11
Colecalciferol	Injection	Intramuscular	Treatment of severe vitamin D deficiency and prevention of osteoporosis	AP12
Cyclopentolate, 0.2%, and phenylephrine, 1%	Eye drops	Ophthalmic	Production of mydriasis	AP25
Deflazacort	Tablet	Oral	Treatment of Duchenne muscular dystrophy	AP27
Dehydrated ethanol (alcohol) 96% - 100%	Ampoule	Topical	Treatment of progressive keratoconus and intra-operative use in superficial keratectomy (single use per procedure)	AP28
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	AP29
Diazoxide	Capsule	Oral	Treatment of hypoglycaemia	AP30
Diazoxide	Capsule	Oral	Treatment of hyperinsulinaemia	AP31
Diazoxide	Capsule	Oral	Treatment of Beckwith-Weiderman Syndrome	AP32
Diazoxide	Capsule	Oral	Treatment of insulinoma	AP33
Diazoxide	Suspension	Oral	Treatment of hypoglycaemia	AP34
Diazoxide	Suspension	Oral	Treatment of hyperinsulinaemia	AP35
Diazoxide	Suspension	Oral	Treatment of Beckwith-Weiderman Syndrome	AP36
Diazoxide	Suspension	Oral	Treatment of insulinoma	AP37
Diazoxide	Tablet	Oral	Treatment of hypoglycaemia	AP38
Diazoxide	Tablet	Oral	Treatment of hyperinsulinaemia	AP39
Diazoxide	Tablet	Oral	Treatment of Beckwith-Weiderman Syndrome	AP40
Diazoxide	Tablet	Oral	Treatment of insulinoma	AP41
Diflunisal	Tablet	Oral	Treatment of amyloidosis	AP42
Dimethyl sulfoxide (DMSO)	Solution	Intravesical	Symptomatic relief of interstitial cystitis	AP43
Disulfiram	Tablet	Oral	Deterrent to alcohol consumption	AP148
Doxycycline	Injection	Intralesional	Sclerotherapy of lymphatic malformations	AP44
F-18 DCFPyI (PSMA)	Injection	Intravenous	Prostate cancer imaging study	AP45
F-18 myocardial perfusion tracer (18F flurpiridaz)	Injection	Intravenous	Myocardial perfusion study	AP46
F-18 NaF (sodium fluoride)	Injection	Intravenous	Bone study	AP47

Active ingredient	Dosage form	Route of administration	Indication	Code
Famotidine	Injection	Intravenous	Prevention and management of hypersensitivity reactions to chemotherapy	AP149
Flunarizine	Tablet	Oral	Treatment of vestibular disorders	AP48
Flunarizine	Tablet	Oral	Prophylactic treatment of migraine	AP49
Flunarizine	Capsule	Oral	Treatment of vestibular disorders	AP50
Flunarizine	Capsule	Oral	Prophylactic treatment of migraine	AP51
Furazolidone	Tablet	Oral	Treatment of resistant <i>Helicobacter pylori</i> infection	AP52
Gallium-68 (Ga-68) Galligas	Aerosol	Inhalation	Lung ventilation study	AP53
Gallium-68 (Ga-68) - MAA	Injection	Intravenous	Lung perfusion study	AP54
Gallium-68 prostate specific membrane antigen (PSMA)	Injection	Intravenous	Prostate cancer imaging study	AP55
Glycopyrronium bromide	Tablet	Oral	Treatment of excessive salivation in patients with neurological conditions	AP56
Hyoscine hydrobromide	Patch	Transdermal	Treatment of excessive salivation	AP57
Hypertonic sodium chloride, 5 %	Eye ointment	Ophthalmic	Temporary relief of corneal oedema (hypertonicity)	AP58
Hypertonic sodium chloride, 5%	Eye drops	Ophthalmic	Temporary relief of corneal oedema (hypertonicity)	AP59
Iloprost	Injection	Intravenous infusion	Treatment of patients with severe disabling Raynaud's phenomenon	AP150
Iloprost	Injection	Intravenous infusion	Treatment of peripheral ischaemia	AP151
Indigo carmine	Injection	Intravenous	Intraoperative detection of suspected urethral injuries during abdominal and pelvic surgical procedures	AP60
Indocyanine green dye	Injection	Intravenous	Intra-operative diagnostic use	AP61
Interferon alpha-2b	Eye drops	Ophthalmic	Treatment of ocular surface squamous neoplasia	AP152
Ketotifen	Tablet	Oral	Treatment of allergic conditions	AP62
Levofloxacin	Tablet	Oral	Treatment of resistant <i>Helicobacter pylori</i> infection	AP63
Levofloxacin	Tablet	Oral	Treatment of drug resistant tuberculosis	AP64
Levomepromazine	Tablet	Oral	Treatment of nausea and vomiting	AP65
Levomepromazine	Tablet	Oral	Treatment of agitation	AP66
Levomepromazine	Injection	Subcutaneous	Treatment of nausea and vomiting	AP67
Levomepromazine	Injection	Subcutaneous	Treatment of agitation	AP68
Lifitegrast	Eye drops	Ophthalmic	Treatment of dry eye disease	AP153
Lorazepam	Injection	Parenteral	Treatment of acute severe behavioural episodes in the hospital setting	AP69

Active ingredient	Dosage form	Route of administration	Indication	Code
Lutetium-177 (Lu 177) dotatate	Injection	Intravenous	Treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs)	AP154
Lutetium-177(Lu 177) prostate specific membrane antigen (PSMA)	Injection	Intravenous	Treatment of metastatic castration-resistant prostate cancer	AP155
Melatonin	Syrup	Oral	Treatment of sleep disorders	AP70
Melatonin	Capsule	Oral	Treatment of sleep disorders	AP71
Melatonin	Immediate release tablet	Oral	Treatment of sleep disorders	AP72
Melatonin	Lozenge	Oral	Treatment of sleep disorders	AP73
Mexiletine	Tablet	Oral	Treatment of ventricular arrhythmia	AP74
Mexiletine	Tablet	Oral	Treatment of myotonic disorders	AP75
Mexiletine	Capsule	Oral	Treatment of ventricular arrhythmia	AP76
Mexiletine	Capsule	Oral	Treatment of myotonic disorders	AP77
Moxifloxacin 0.5%	Eye drops	Ophthalmic	Treatment of refractory bacterial conjunctivitis	AP78
Nadolol	Tablet	Oral	Treatment of ventricular tachycardia	AP79
Nadolol	Tablet	Oral	Treatment of long QT Syndrome	AP80
Natamycin 5%	Eye drops	Ophthalmic	Treatment of refractory fungal blepharitis, conjunctivitis or keratitis	AP81
Neomycin	Tablet	Oral	Sepsis prevention for colorectal operation	AP82
Nicotine in solution, salt or base form	Liquid or solid	Inhalation	Smoking cessation	AP83
Nifedipine	Immediate release tablet	Oral	Treatment of preterm labour	AP156
Nifedipine	Immediate release tablet	Oral	Treatment of pre-eclampsia	AP141
Nifedipine	Capsule	Oral	Treatment of preterm labour	AP142
Nifedipine	Capsule	Oral	Treatment of pre-eclampsia	AP143
Nitazoxanide	Tablet	Oral	Treatment of giardiasis	AP84
Nitazoxanide	Tablet	Oral	Treatment of cryptosporidiosis	AP85
Nitazoxanide	Tablet	Oral	Treatment of blastocystis	AP86
Nitazoxanide	Suspension	Oral	Treatment of giardiasis	AP87
Nitazoxanide	Suspension	Oral	Treatment of cryptosporidiosis	AP88
Nitazoxanide	Suspension	Oral	Treatment of blastocystis	AP89
Paromomycin	Capsule	Oral	Antiprotozoal treatment of <i>Blastocystis hominis</i>	AP90

Active ingredient	Dosage form	Route of administration	Indication	Code
Paromomycin	Capsule	Oral	Antiprotozoal treatment of <i>Dientamoeba fragilis</i>	AP91
Paromomycin	Capsule	Oral	Antiprotozoal treatment of <i>Entamoeba histolytica</i>	AP92
Paromomycin	Capsule	Oral	Antiprotozoal treatment of any of parasite infection	AP93
Pimozide	Tablet	Oral	Treatment of schizophrenia	AP94
Pimozide	Tablet	Oral	Treatment of chronic psychosis	AP95
Pimozide	Tablet	Oral	Treatment of Tourette syndrome	AP96
Pristinamycin	Tablet	Oral	Treatment of confirmed methicillin-resistant <i>Staphylococcus aureus</i> or vancomycin-resistant <i>enterococci</i> infection where there is history of failed therapy with the other available antibiotics, at sites in relation to bone/joint/prosthesis	AP97
Pristinamycin	Tablet	Oral	Treatment of refractory or resistant <i>Mycoplasma genitalium</i> infections	AP98
Pristinamycin	Tablet	Oral	Treatment of other infections as prescribed by an infectious disease specialist	AP99
Progesterone	Injection	Subcutaneous	Treatment of progesterone deficiency	AP144
Progesterone in oil	Injection	Intramuscular	Treatment of progesterone deficiency	AP145
Pyrazinamide	Tablet	Oral	Treatment of tuberculosis	AP100
Riboflavin, 0.1% in 20% dextran	Eye drops	Ophthalmic	Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus	AP101
Riboflavin, 0.1% in 1.1% hydroxypropyl methylcellulose (HPMC)	Eye drops	Ophthalmic	Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus	AP102
Riboflavin, 0.1% in sodium chloride	Eye drops	Ophthalmic	Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus	AP103
Riboflavin, 0.22% in sodium chloride	Eye drops	Ophthalmic	Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus	AP104
Ripasudil 0.4%	Eye drops	Ophthalmic	Treatment of refractory corneal oedema	AP105
Ripasudil 0.4%	Eye drops	Ophthalmic	Treatment of refractory glaucoma	AP106
Sodium benzoate	Tablet	Oral	Treatment of urea cycle disorders	AP107
Tacrolimus 0.03%	Ointment	Topical	Treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in children	AP108
Tacrolimus 0.1%	Ointment	Topical	Treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in adults	AP109
Technetium-99m (99m Tc) prostate specific membrane antigen (PSMA)-I&S	Injection	Intravenous	Prostate cancer imaging study	AP146
Tetracycline	Capsule	Oral	Treatment of resistant <i>Helicobacter pylori</i> infection	AP110
Tetracycline	Tablet	Oral	Treatment of resistant <i>Helicobacter pylori</i> infection	AP111

Active ingredient	Dosage form	Route of administration	Indication	Code
Tick-borne encephalitis vaccine	Injection	Intramuscular	Prevention of tick-borne encephalitis	AP112
Tinidazole	Tablet	Oral	Treatment of <i>Trichomonas vaginalis</i> infections of the genito-urinary tract in female and male patients	AP113
Tinidazole	Tablet	Oral	Treatment of giardiasis	AP114
Tinidazole	Tablet	Oral	Treatment of amoebic dysentery	AP115
Tinidazole	Tablet	Oral	Treatment of amoebic liver abscess	AP116
Tinidazole	Tablet	Oral	Treatment of acute giardiasis in children	AP117
Tinidazole	Tablet	Oral	Treatment of acute amoebic dysentery in children	AP118
Tinidazole	Tablet	Oral	Treatment of amoebic liver disease in children	AP119
Tinidazole	Tablet	Oral	Prevention of infection of the surgical site	AP120
Tizanidine	Capsule	Oral	Treatment of spasticity where other treatments have failed	AP121
Tizanidine	Tablet	Oral	Treatment of spasticity where other treatments have failed	AP122
Triamcinolone acetonide	Suspension for injection	Ophthalmic	Treatment of non-infectious uveitis	AP123
Triamcinolone acetonide	Suspension for injection	Ophthalmic	Visualisation during vitrectomy	AP124
Triamcinolone acetonide	Suspension for injection	Ophthalmic	Treatment of diabetic macular oedema	AP125
Triamcinolone acetonide	Suspension for injection	Ophthalmic	Treatment of cystoid macular oedema secondary to retinal vein occlusion	AP126
Triamcinolone acetonide	Suspension for injection	Ophthalmic	Treatment of uveitic macular oedema	AP127
Triamcinolone acetonide	Suspension for injection	Ophthalmic	Treatment of post-operative macular oedema (cataract surgery)	AP128
Verteporfin	Powder for injection	Intravenous infusion	Photosensitisation for photodynamic therapy	AP129
Yttrium-90 (Y-90) Citrate	Injection	Intraarticular	Radiosynovectomy treatment	AP130

List of medicinal cannabis medicines with Established History of Use

HREC approval or specialist college endorsement is not required to be submitted to the TGA if the medicine, concentration (if any), dosage form, route of administration and indication match those listed below (as specified in regulation 12B(1C) of the *Therapeutic Goods Regulations 1990*).

Active ingredient category and circumstances	Dosage form	Route of administration	Indication	Code
<p>Category 1: CBD medicinal cannabis product (CBD ≥98%) Circumstances:</p> <p>a) cannabidiol comprises 98% or more of the total cannabinoid content of the medicine; and</p> <p>b) any cannabinoids, other than cannabidiol, in the medicine are only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the medicine; and</p> <p>c) the medicine contains no other active ingredients</p>	liquid	oral	Treatment of refractory chronic pain in adult patients	AP131
			Treatment of refractory anxiety in adult patients	AP132
<p>Category 1: CBD medicinal cannabis product (CBD ≥98%) Circumstances:</p> <p>a) cannabidiol comprises 98% or more of the total cannabinoid content of the medicine; and</p> <p>b) any cannabinoids, other than cannabidiol, in the medicine are only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the medicine; and</p> <p>c) the medicine contains no other active ingredients</p>	capsule	oral	Treatment of refractory chronic pain in adult patients	AP133
			Treatment of refractory anxiety in adult patients	AP134
<p>Category 2: CBD dominant medicinal cannabis product (CBD ≥60% and <98%) Circumstances:</p> <p>a) cannabidiol derived from cannabis comprises 60% or more and less than 98% of the total cannabinoid content of the medicine; and</p> <p>b) other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine; and</p> <p>c) the medicine contains no other active ingredients</p>	liquid	oral	Treatment of refractory chronic pain in adult patients	AP135
			Treatment of refractory anxiety in adult patients	AP136
<p>Category 2: CBD dominant medicinal cannabis product (CBD ≥60% and <98%) Circumstances:</p>	capsule	oral	Treatment of refractory chronic pain in adult patients	AP137

Active ingredient category and circumstances	Dosage form	Route of administration	Indication	Code
a) cannabidiol derived from cannabis comprises 60% or more and less than 98% of the total cannabinoid content of the medicine; and b) other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine; and c) the medicine contains no other active ingredients			Treatment of refractory anxiety in adult patients	AP138
Category 3: Balanced medicinal cannabis product (CBD <60% and ≥40%) Circumstances: a) cannabidiol derived from cannabis comprises 40% or more and less than 60% of the total cannabinoid content of the medicine; and b) other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine; and c) the medicine contains no other active ingredients	liquid	oral	Treatment of refractory chronic pain in adult patients	AP139
Category 3: Balanced medicinal cannabis product (CBD <60% and ≥40%) Circumstances: a) cannabidiol derived from cannabis comprises 40% or more and less than 60% of the total cannabinoid content of the medicine; and b) other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine; and c) the medicine contains no other active ingredients	capsule	oral	Treatment of refractory chronic pain in adult patients	AP140