



This form, when completed, will be classified as 'For official use only'.
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>.

Special Access Scheme – Category C

Important information

Email completed form to SAS@health.gov.au (preferred) or fax to 02 6232 8112.

The therapeutic goods, indications and health practitioners that are authorised to supply these goods for the particular indication through the SAS Category C pathway are on the **back of this form**.

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:

- verify the supply of the therapeutic goods occurred in accordance with the applicable Instrument
- The personal information of the health practitioner may be disclosed to State and Territory authorities with responsibility for therapeutic goods or medical practitioner registration.

Do not provide the name of the patient. Only provide the patient's initials and other information as requested on this form.

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

Patient details (minimum of 3 (three) identifiers required)

Patient initials	Gender Male <input type="checkbox"/> Female <input type="checkbox"/> Intersex/Indeterminate/Unspecified <input type="checkbox"/>	DOB	MRN (if applicable)
Diagnosis(es) or Medical Condition(s)			Previous SAS No. (if applicable)

Product details

Medicine/biological/medical device

SAS Category C code (see back of form)	Trade name (for medicines only)
Expected quantity ⁱ required for treatment and/or duration	

Treating health practitioner details

First name	Surname
AHPRA ID	Health practitioner ⁱⁱ type
Email	Speciality
Fax	Phone
Principle practice address	

Submitter details (if different)

Business or practice name (e.g. Pharmacy name)	
First name	Surname
Health practitioner type	Fax
Email	Phone
Preferred Contact: <input type="checkbox"/> Treating health practitioner <input type="checkbox"/> Submitter	Preferred contact method: Email <input type="checkbox"/> Fax <input type="checkbox"/> Phone <input type="checkbox"/>

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.

Submitter's signature	Date
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Please only send the first page of this form to the TGA.

SAS Category C codes

Medicines <<https://www.legislation.gov.au/Details/F2017L00859>>

Code	Active ingredient(s), Dosage Form, Release mechanism*, Route of administration*	Indication(s)	Authorised Health Practitioner(s)
M1	Triamcinolone acetonide, Suspension for Injection, ophthalmic	Treatment of inflammatory ocular conditions	Medical Practitioner
M2	Triamcinolone acetonide, Suspension for Injection, ophthalmic	Visualization during vitrectomy.	Medical Practitioner
M3	Melatonin, Syrup, Oral	Treatment of sleep disorders	Medical Practitioner
M4	Melatonin, Modified release tablet, oral	Treatment of sleep disorders	Medical Practitioner
M5	Melatonin, Tablet, Oral	Treatment of sleep disorders	Medical Practitioner
M6	Melatonin, Capsule, Oral	Treatment of sleep disorders	Medical Practitioner
M7	Bismuth subcitrate, Tablet, Oral	Treatment of resistant <i>Helicobacter Pylori</i> infection	Medical Practitioner
M8	Tetracycline, Capsule, Oral	Treatment of resistant <i>Helicobacter Pylori</i> infection	Medical Practitioner
M9	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
M10	Riboflavin, 0.1% (in other diluents), Eye Drops, Ophthalmic	Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment for progressive keratoconus.	Medical Practitioner
M11	Flunarizine, Tablet, Oral	Prophylactic treatment of migraine	Medical Practitioner
M12	Cyclosporin, 0.05%, Eye drops, Emulsion, Ophthalmic	Treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca.	Medical Practitioner
M13	Cinnarizine, Tablet, Oral	Treatment of vestibular disorders such as vertigo, tinnitus, nausea and vomiting (including Meniere's disease).	Medical Practitioner
M14	Hypertonic sodium chloride, 5%, Eye drops, Ophthalmic	Temporary relief of corneal oedema (hypertonicity)	Medical Practitioner
M15	Hypertonic sodium chloride, Eye drops, Ophthalmic	Temporary relief of corneal oedema (hypertonicity)	Medical Practitioner
M16	Dexamethasone, 0.1%, Eye drops, Ophthalmic	Treatment of non-infected, steroid responsive, inflammatory conditions of the eye	Medical Practitioner
M17	Buspirone hydrochloride, Tablet, Oral	Treatment of generalised anxiety disorders	Medical Practitioner
M18	Paromomycin, Capsule, Oral	Antiprotozoal treatment of the following amoebic infections:- <i>blastocystis hominis</i> , <i>diplomoeba fragilis</i> , <i>entamoeba histolytica</i> and parasite infection	Medical Practitioner
M19	Allergens – multiple, various	Confirmation of suspected allergic reactions	Medical Practitioner
M20	Cyclopentolate, 0.2%, & phenylephrine, 1%, Eye drops, Ophthalmic	Production of mydriasis.	Medical Practitioner
M21	Verteporfin Powder for injection, intravenous infusion	Photosensitisation for photodynamic therapy	Medical Practitioner
M22	Pyrazinamide, Tablet, Oral	Treatment of resistant tuberculosis	Medical Practitioner
M23	Furazolidone, Tablet, Oral	Treatment of resistant <i>Helicobacter Pylori</i> infection	Medical Practitioner
M24	Pristinamycin, Tablet, Oral	Treatment of confirmed Methicillin-resistant <i>Staphylococcus aureus</i> and Vancomycin-resistant enterococcus infection where there is history of failed therapy with the other available antibiotics, at sites in relation to bone/joint/prosthesis. Treatment of other infections as prescribed by an infectious disease specialist	Medical Practitioner
M25	Glycopyrronium bromide, Tablet, Oral	Treatment of excessive salivation in patients with neurological conditions	Medical Practitioner

Code	Active ingredient(s), Dosage Form, Release mechanism*, Route of administration*	Indication(s)	Authorised Health Practitioner(s)
M26	Cholecalciferol, Capsule, Oral	Treatment of severe vitamin D deficiency and prevention of osteoporosis	Medical Practitioner
M27	Cholecalciferol, Intramuscular Injection	Treatment of severe vitamin D deficiency and prevention of osteoporosis	Medical Practitioner

Biologicals <<https://www.legislation.gov.au/Details/F2017L00868>>

Code	Product Name, Active ingredient(s), Route of administration	Indication	Authorised Health Practitioner(s)
B1	MinerOss Cortical & Cancellous Chips (anorganic bovine bone), Oral-maxillofacial	Calcium source for particulate bone grafts	Dental Practitioner
B2	MinerOss Block Allograft (anorganic bovine bone), Oral-maxillofacial	Calcium source for particulate bone grafts	Dental Practitioner
B3	MinerOss Cancellous (anorganic bovine bone), Oral-maxillofacial	Calcium source for particulate bone grafts	Dental Practitioner
B4	MinerOss Cortical (anorganic bovine bone), Oral-maxillofacial	Calcium source for particulate bone grafts	Dental Practitioner
B5	MinerOss X Cancellous (anorganic bovine bone), Oral-maxillofacial	Calcium source for particulate bone grafts	Dental Practitioner
B6	MinerOss X Cortical (anorganic bovine bone), Oral-maxillofacial	Calcium source for particulate bone grafts	Dental Practitioner
B7	MinerOss X Syringe (anorganic bovine bone), Oral-maxillofacial	Calcium source for particulate bone grafts	Dental Practitioner
B8	MinerOss X Collagen (anorganic bovine bone), Oral-maxillofacial	Calcium source for particulate bone grafts	Dental Practitioner
B9	MinerOss XP Cancellous (anorganic bovine bone), Oral-maxillofacial	Calcium source for particulate bone grafts	Dental Practitioner
B10	AlloDerm GBR RTM (human skin tissue matrix), Oral-maxillofacial	Graft protection and containment	Medical Practitioner Dental Practitioner
B11	AlloDerm GBR RTM (human skin tissue matrix), Oral-maxillofacial	Flap extender to achieve primary closure	Medical Practitioner Dental Practitioner
B12	AlloDerm RTM (human skin tissue matrix), Oral-maxillofacial	Root coverage	Dental Practitioner
B13	AlloDerm RTM (human skin tissue matrix), Oral-maxillofacial	Gingival augmentation	Dental Practitioner
B14	AlloDerm RTM (human skin tissue matrix), Oral-maxillofacial	Soft tissue ridge augmentation	Dental Practitioner
B15	AlloDerm RTM (human skin tissue matrix), Oral-maxillofacial	Soft tissue augmentation around implants	Dental Practitioner
B16	Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial	Extraction socket grafting	Dental Practitioner
B17	Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial	Ridge and sinus augmentation	Dental Practitioner
B18	Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial	Bone augmentation around implants	Dental Practitioner
B19	Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial	Bony defects	Dental Practitioner
B20	Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial	Composite grafting with appropriate MinerOss® products only	Dental Practitioner
B21	Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial	Filling of periodontal defects	Dental Practitioner
B22	Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial	Extraction socket grafting	Dental Practitioner
B23	Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial	Ridge and sinus augmentation	Dental Practitioner
B24	Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial	Bone augmentation around implants	Dental Practitioner
B25	Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial	Bony defects	Dental Practitioner
B26	Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial	Composite grafting with MinerOss®	Dental Practitioner

Code	Product Name, Active ingredient(s), Route of administration	Indication	Authorised Health Practitioner(s)
B27	Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial	Filling of periodontal defects	Dental Practitioner
B28	Tutoplast (sterilized human tissue allograft), Ocular	Ocular conditions	Medical Practitioner
B29	Tutoplast (sterilized human tissue allograft), Topical	Soft tissue graft	Medical Practitioner
B30	Amniotic Membrane, Ophthalmic	Ophthalmic use	Medical practitioner
B31	Puros Cortico-Cancellous Particulate Allograft (human bone tissue), Oral-maxillofacial	For hard and soft tissue augmentation procedures	Medical Practitioner Dental Practitioner
B32	Puros Cancellous Particulate Allograft (human bone tissue), Oral-maxillofacial	For hard and soft tissue augmentation procedures	Medical Practitioner Dental Practitioner
B33	Puros Cortical Particulate Allograft (human bone tissue), Oral-maxillofacial	For hard and soft tissue augmentation procedures	Medical Practitioner Dental Practitioner

Medical Devices <<https://www.legislation.gov.au/Details/F2017L00867>>

Code	Product name, Manufacturer Name, Description (including manufacturer's intended purpose and any variant details)	Indication	Authorised Health Practitioner(s)
D1	Synovasure lateral flow test IFU	An adjunct for the detection of periprosthetic joint infection (PJI) in the synovial fluid of patients experiencing pain, inflammation, or both, in a replacement joint	Medical practitioner

* These will only be included if clinically relevant, for example where multiple dosage forms and/or routes of administration are known to exist and are used for substantially different indications these will be specified.

ⁱ For substances captured by the Customs (Prohibited Imports) Regulations 1956 the quantity must be provided.

ⁱⁱ The health practitioner type is any of the following: Medical practitioner; ATSI health practitioner; dentist; radiographer; nurse; midwife; occupational therapist; optometrist; pharmacist ; podiatrist; psychologist.