Australian Government
Department of Health
Office of Drug Control

Guidance for completing:

Applications for a licence to import - Special Access Scheme (SAS) only

Application for a permit to import drug substances - Special Access Scheme (SAS) only

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Office of Drug Control

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Version control

Updates to this document will occur automatically on the Office of Drug Control website and the revision table below will list the amendments as they are approved.

Date	Version	Amendments	Approved by
8 December 2016	1.0	Original publication	ODC
26 July 2017	1.1	Updated contact details	ODC

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Introduction

This guidance will assist a medical practitioner or registered pharmacist to complete an application for a licence (if required) and permit to import an unapproved medicine containing a drug substance controlled under Regulation 5, 5A and 5G & 5H of the Customs (Prohibited Imports) Regulations 1956 in accordance with the provisions of the Special Access Scheme (SAS).

Under Australian therapeutic goods legislation, medical practitioners can request access to unapproved medicines in certain circumstances. Such use may require approval by the Experimental Products Section (EPS) of the Therapeutic Goods Administration (TGA) under what is referred to as the SAS. To obtain more information on the SAS please see Special Access Scheme on the TGA website or contact the TGA at:

Experimental Products Section
Therapeutic Goods Administration
Australian Government Department of Health
PO Box 100
Woden ACT 2606

Phone: 1800 020 653

Email: eps@tga.gov.au

The importation of narcotic, psychotropic and precursor substances subject to Regulation 5 of the Customs (Prohibited Imports) Regulations 1956 is prohibited unless the importer holds a licence and permit issued by the Drug Control Section (DCS).

Antibiotic and anabolic/androgenic substances, subject to Regulations 5A and 5G/5H respectively, require a permit only.

The substances subject to these import controls are listed in Schedule 4, Schedule 7A and Schedule 8 of the Customs (Prohibited Imports) Regulations 1956. DCS has also prepared a list of controlled substances to assist in identifying drug substances that are prohibited imports and subject to licensing/permitting requirements.

To apply for an annual licence to import an unapproved medicine containing a narcotic, psychotropic and/or precursor substance the application form titled '**Application for a licence to import Special Access Scheme (SAS) only'** must be submitted to DCS. To apply for a permit to import an unapproved medicine containing a controlled drug substance the application form titled **'Application for a permit to import drug substances (Special Access Scheme only)'** must be submitted to DCS. Importers must apply for a permit to import for each consignment of goods.

All applications for a licence/permit to import an unapproved medicine containing a controlled drug substance under the SAS must include either:

- **Category A** - a completed notification on the form prescribed by the TGA; or
- **Category B** - an approval from the TGA confirming that a particular course of drug treatment has been approved

Licenses and permits are not granted to individuals for the purpose of obtaining unapproved medications for personal use. If you are an individual wanting to access unapproved medications containing a controlled drug substance you should consult your doctor.

The guidance provided here will assist you in completing and submitting the application forms.

Completing the licence application form

If you already have a valid licence to import then you do not need to complete this form. If the drug substance is an antibiotic or an anabolic/androgenic agent then you do not need to complete a licence application.

Part of application form	Explanation of required information
1. Applicant Details	
Name of Medical Practitioner or Registered Pharmacist	Under the Special Access Scheme the application for a licence may only be made by a Medical Practitioner or Registered Pharmacist.
Profession	Select your profession
Medicare Provider No. or Pharmacy Registration No.	Provide your Medicare provider number or pharmacist registration number.
2. Business Information	
Company name (if applicable)	State the name of your company/practice, if applicable
Street address	Provide the street address at which activities associated with your profession are carried out.
Postal address	Provide the address where you would like your licence to be posted. Permits will be sent by standard mail unless an express post envelope accompanies the application.
3. Declaration and Consent	
Make sure you read and understand the declaration and consent. Sign the application form. Complete the contact details of the person signing the form. The form must be signed by the licence holder or a person that the licence holder has authorised in writing to make applications under the licence.	

Completing the permit application form

A permit is required for each proposed importation of the controlled drug.

Part of application form	Explanation of required information
1. Importer information	

Part of application form	Explanation of required information
Licence holder's name (if applicable)	The importation of narcotic, psychotropic and precursor substances subject to Regulation 5 of the Customs (Prohibited Imports) Regulations 1956 is prohibited unless the importer holds a licence issued by DCS. State the licence holder's name. Please note - antibiotic and anabolic/androgenic substances, subject to Regulations 5A and 5H respectively, require a permit only.
Company name	State your company's name.
Company address	State the physical address to be displayed on the import permit.
Postal address	State the postal address to which you would like the import permit sent. Permits will be sent by standard service mail unless an express post envelope accompanies the application.
Import establishment ID No:	Each establishment is given a unique identifier by DCS, for example RN123 or CV987. State your import establishment ID number if known.
Point of entry	The planned entry point for the import into Australia. Specify port city and state.
Import licence number (if applicable)	State your import licence number, which can be found on your licence issued by DCS, if applicable.
Approximate date of import	Indicate the expected import date for the consignment if the import permit is issued. If the exact date is not known, provide the approximate time period.
2. Exporter Information	
Overseas exporter's full name	State the full name of the overseas exporter.
Export establishment ID No:	Each overseas exporter is given a unique identifier by DCS, for example O12345. State the export establishment ID number if known. There is an expectation that companies that conduct their business with the same overseas entity on a regular basis should be able to include this code on their application.
Overseas exporter's address	State the physical address of the overseas exporter to be displayed on the import permit.

Part of application form	Explanation of required information
Mode of transport	Specify whether the shipment will be transported to Australia by sea or air.
3. Patient Details	
Patient's initials	Provide the initials of the patient only.
Patient's date of birth	Provide the date of birth of the patient.
Type of application	The Special Access Scheme (SAS) is administered by the Therapeutic Goods Administration and allows access to unapproved therapeutic goods. There are two categories under the scheme: **Category A:** For patients who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in absence of early treatment. Where you are proposing that the use of the drug you intend to import would be in accordance with Category A of the SAS you must attach a completed Category A notification on the form prescribed by the Therapeutic Goods Administration (TGA). If you are proposing to use a therapeutic good in accordance with Category A of the SAS then you are required to notify the TGA. Matters relating to: · getting approvals under the SAS · notification of category A use · interpretation of the *Therapeutic Goods Act 1989*, or Therapeutic Goods Regulations 1990 should be referred to the TGA. **Category B:** For patients who do not fit the definition of Category A. Where you are proposing that the use of the drug you intend to import would be in accordance with Category B of the SAS you must attach an approval from the TGA that confirms a particular course of drug treatment has been approved. DCS can only advise on aspects that relate to licensing and permitting functions under the Customs (Prohibited Imports) Regulations 1956.

Part of application form	Explanation of required information
4. Substance Details	
Substance name:	Provide the name of the drug (e.g. morphine sulphate).
Trade name:	Provide the trade name of the goods.
Concentration/strength	Indicate the concentration/strength of the controlled substance. Show the amount of controlled substance in the preparation, for example X mg/mL for liquids or Y mg/tablet for tablet products. The concentration should be expressed in metric units.
Form of substance	Indicate the form of the finished goods, for example tablets, capsules, vials, ampoules etc.
Pack type and size	Provide details on the pack type and the size. For example; 24 tablet blister pack; 100 mL bottle; box of 100 tablets; box of 6 x 2mL ampoules.
Total number of packs in shipment	Specify the total number of packs (as defined above) that make up the proposed shipment. For example 25 packs of 24 tablets; 100 bottles of 100 mL; 1000 boxes of 100 tablets, 250 boxes of ampoules. The total amount of drug proposed for import should be consistent with the treatment regime that has been: determined by the prescriber (Category A notifications) OR approved by the TGA (Category B approvals).
Drug code	This is an identifier assigned to specific substances and preparations by DCS. State the drug code if you know it. There is an expectation that companies that import the same products on a regular basis should be able to include this code on their application.
5. Declaration and Consent	
Make sure you read and understand the declaration and consent. Sign the application form. Complete the contact details of the person signing the form. The form must be signed by the licence holder or a person that the licence holder has authorised in writing to make applications under the licence.	

Submitting an application

You can submit your application in the following ways:

Mail	Drug Control Section Office of Drug Control Australian Government Department of Health PO Box 9848 (MDP 95) Canberra ACT 2601
Fax	02 6203 1740
Email	dcs@health.gov.au

DCS endeavours to process import applications that are linked to the proposed use of medicines under the Special Access Scheme within 1 working day (**Category A**) or 5 working days (**Category B**) from the date of receipt. While a very high proportion of applications are processed within this target timeframe, there will be times where high demand for permits may result in slightly longer processing times.

Application forms that contain incomplete or incorrect information will be returned to you for amendment, resulting in delays in processing.

It is the responsibility of the importer to ensure that the triplicate copy of the permit is endorsed by the Australian Border Force and the importer at the time of importation.

It is the responsibility of the importer to return the endorsed triplicate copy to DCS no later than 14 working days after the importation has occurred. Failure to comply with this condition may result in cancellation of import licenses.