Australian Government

Department of Health and Aged Care

Office of Drug Control

Guidance for completing:

Applications for a licence/permit to import - Special Access Scheme (SAS) and Authorised Prescriber (AP) 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
8 August 2022	1.2	Updated Department name	ODC
October 2022	1.3	Updated information	ODC

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, 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:

Therapeutic Goods Administration
Experimental Products Section
PO Box 100
Woden ACT 2606

Phone: 1800 020 653

Email: SAS@health.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 Narcotics Control Section (NCS).

Anabolic/androgenic and hormone substances, subject to Regulations 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. NCS 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 a licence and permit to import an unapproved medicine containing a narcotic, psychotropic and/or precursor substance the application form titled '**Application for a licence/permit to import Special Access Scheme (SAS) and Authorised Prescriber (AP) only**' must be submitted to NCS. 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
- **Category C** - a completed notification on the form prescribed by the TGA
- **Authorised Prescriber (AP)** - an approval from the TGA confirming status as an Authorised Prescriber.

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 anabolic/androgenic agent or hormone, then you do not need to complete a licence application (i.e. complete page 2 of the application only)

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 Medical Practitioner or Registered Pharmacist, not the patient.	

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	
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 NCS. State the licence holder's name. Please note - anabolic/androgenic and hormone substances, subject to Regulations 5G 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 licence number (if applicable)	State your import licence number, which can be found on your licence issued by NCS, if applicable.
2. Exporter Information	
Overseas exporter's full name	State the full name of the overseas exporter
Overseas exporter's address	State the physical address of the overseas exporter to be displayed on the import permit
3. Patient Details	
Patient's initials	Initials of the patient. Do not include the patient's name.
Patient's date of birth	Date of birth of patient
Type of application	Indicate whether you are utilising Special Access Scheme Category A, Category B, Category C or Authorised prescriber and **attach the notification or approval from the TGA.**

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 mg/mL for liquids or mg per 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 and Category C notifications) OR approved by the TGA (Category B approvals).
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 Medical Practitioner or Registered Pharmacist, not the patient.	

Submitting an application

You can submit your application in the following ways:

Mail	Narcotics Control Section Office of Drug Control GPO Box 9848 Canberra ACT 2601
Email	NCS@health.gov.au

NCS 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 and Category C**) 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.

It is the responsibility of the importer to ensure that the triplicate copy of the permit is completed at the time of importation and the hardcopy returned to NCS.

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

Unused or **expired** permits must be returned within **14 Days.**