



Application for permission to import kava for medical and/or scientific purposes

Substances controlled under [Regulation 5](#) of the [Customs \(Prohibited Imports\) Regulations 1956](#).

To assist in the completion of this form, [guidance](#) is available on the ODC website.

1. Importer information		2. Exporter information	
Licence holder's name:		Overseas exporter's full name:	
Company name:			
Company address:		Overseas exporter's address:	
Postal address:		Export establishment ID No. (if known):	
		Mode of transport (sea/air):	
<input type="checkbox"/> Please tick if an Express envelope has been forwarded		Approx. date of arrival in Australia (import):	
Import establishment ID No. (if known):		Import licence number:	
Point of entry:			
3. Substance details			
Form of kava—for example, root, powder or approved therapeutic product:			
Pack type and size:		Concentration/strength:	
Total number of packs in shipment:		ARTG No. (Finished goods only):	
4. Purpose of import (Complete the following checklist)			
a. Is the kava an approved therapeutic product that is currently entered on the Australian Register of Therapeutic Goods (ARTG)?		<input type="checkbox"/> Yes (complete Schedule 1) <input type="checkbox"/> No	
b. Is the kava to be used in the manufacture of an approved therapeutic product that is currently entered on the Australian Register of Therapeutic Goods (ARTG)?		<input type="checkbox"/> Yes (complete Schedule 2) <input type="checkbox"/> No	
c. Is the kava a raw material and imported for medical purposes, other than those in a) or b)?		<input type="checkbox"/> Yes (complete Schedule 3) <input type="checkbox"/> No	
d. Is the kava for scientific use?		<input type="checkbox"/> Yes (complete Schedule 4) <input type="checkbox"/> No	
e. Will the kava be supplied to any other person for subsequent scientific and/or medical use?		<input type="checkbox"/> Yes (complete Schedule 5) <input type="checkbox"/> No	
5. Declaration and consent			
I hereby apply to the Secretary, Department of Health, for a permission to import a drug in accordance with Regulation 5 of the Customs (Prohibited Imports) Regulation 1956.			
I declare that to the best of my knowledge all the information in this application is true, correct and complete. I am aware that giving false or misleading information is a serious offence (see Division 136 and 137 of the <i>Criminal Code Act 1995</i>).			
I understand that it is standard practice for the Drug Control Section to provide any or all of the contents of this application, including personal information as defined in the <i>Privacy Act 1988</i> , to law enforcement agencies and regulatory agencies in the Commonwealth, States and Territories as necessary, in order to ensure laws and regulations are being complied with. I consent to all such disclosures and associated exchanges of information, including specifically personal information about me.			
Signature of licence holder or authorised contact:		Name:	
		Date:	
Position:		Email:	
Direct telephone:		Mobile:	

Schedules

- [Schedule 1: Approved therapeutic product](#)
- [Schedule 2: Kava to be used in the manufacture of an approved therapeutic product](#)
- [Schedule 3: Kava imported for medical purposes](#)
- [Schedule 4: Kava imported for scientific use](#)
- [Schedule 5: Supply of kava to other persons](#)

Schedule 1: Approved therapeutic product

Complete this schedule if you answered 'Yes' to question 4(a).

Provide details of products to be imported:

Label name:	
ARTG number:	
Sponsor name:	
Sponsors' TGA Client ID No.:	

If required, provide* additional information that supports your request: (attach additional pages if necessary*)**

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Schedule 2: Kava to be used in the manufacture of an approved therapeutic product

Complete this schedule if you answered 'Yes' to question 4(b).

Provide details of products to be imported in the following tables:

Label name:	
ARTG number:	
Sponsor name:	
Sponsors TGA Client ID number:	
Manufacturer's TGA Client ID number:	
Manufacturer's TGA licence number:	
Amount of imported kava to be used in manufacture of this product:	

Label name	
ARTG number	
Sponsor name	
Sponsors TGA Client ID number	
Manufacturer's TGA Client ID number	
Manufacturer's TGA licence number	
Amount of imported kava to be used in manufacture of this product	

Label name	
ARTG number	
Sponsor name	
Sponsors TGA Client ID number:	
Manufacturer's TGA Client ID number	
Manufacturer's TGA licence number	
Amount of imported kava to be used in manufacture of this product	

Schedule 3: Kava imported for medical purposes

Complete this schedule if you answered 'Yes' to question 4(c).

Provide a detailed description of the proposed use, including:

- How the kava will be used?
- Who the kava will be administered to?—for example, animals, humans.
- How much kava will be used for this purpose?
- Any regulatory approvals granted by the Therapeutic Goods Administration or Australian Pesticides and Veterinary Medicines Authority that authorise the use of kava in humans or animals?

TGA clinical trial notification (CTN) number: <i>(if applicable)</i>	
APVMA permit number: <i>(if applicable)</i>	
If required, provide* additional information that supports your request: <i>*attach additional pages if necessary</i>	

Schedule 4: Kava imported for scientific use

Complete this schedule if you answered 'Yes' to question 4(d).

1. Provide* a detailed description of the proposed use, including:

- The nature of any proposed scientific use.
- The names of research organisations or institutes in which kava will be used.
- Letters of support from any universities, colleges research institutes or organisations supporting or funding the proposed scientific use.
- Where the kava will be used.
- How the kava will be stored and used.
- How much kava will be used, for the purpose, and over what duration?

**attach additional pages if necessary*

2. Provide any relevant documents as attachments, including:

- Peer review scientific literature and studies confirming recent scientific use of kava that is related to the nature of the proposed scientific use.
- Official documentation showing approval of scientific use of kava issued by universities, colleges, research institutes or organisations or recognised ethics committees.
- Official documentation showing approval of funding to support scientific use of kava in a university, college, research institute or organisation.
- Legally binding agreements to sell kava to recognised scientific or research bodies.

Schedule 5: Supply of kava to other persons

Complete this schedule if you answered 'Yes' to question 4(e).

Provide details of who the kava will be supplied to:

Name:	
Company name:	
ABN:	
TGA Client ID number: (if applicable)	
Address:	
Phone:	
Fax:	
Nature of subsequent medical and / or scientific use:	

Name:	
Company name:	
ABN:	
TGA Client ID number: (if applicable)	
Address:	
Phone:	
Fax:	
Nature of subsequent medical and / or scientific use:	