



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

TGA use only

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

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

Organisation details

Sponsor, Manufacturer and Agent

This form should be completed by or for each organisation that:

- is involved with the supply or manufacture of therapeutic goods in Australia
- is conducting a clinical trial in Australia
- is involved with the supply of Proprietary Ingredients
- provides regulatory services on behalf of another organisation mentioned above (Agents).

This form collects information about the legal entity making applications under the *Therapeutic Goods Act 1989* and the authority granted by that entity to others to make applications on its behalf. Please refer to the following link for [TGA Business Services \(TBS\) Terms and Conditions](#).

Section 1. Organisation details

Note: Sponsors must be located in Australia

*Organisation details:

☐ **Sponsor** - a sponsor must be a resident of Australia or be an incorporated body in Australia and conducting business in Australia where the representative of the company is residing in Australia. Additional information is available on the TGA website at: [Role of the sponsor](#)

☐ **Manufacturer** - a manufacturer is a business or individual that produces goods. Additional information is available on the TGA website at: [Manufacture of therapeutic goods](#)

☐ **Agent** - an agent is a regulatory affairs consultant offering services, including advice and assistance, in relation to regulatory requirements. Additional information is available on the TGA website: [Regulatory affairs consultants](#)

***Indicate the business activity of the client for whom you are supplying information (tick all that apply).**

- | | | | |
|--|--|---|---|
| <input type="checkbox"/> Prescription Medicines | <input type="checkbox"/> Listed Medicines | <input type="checkbox"/> Blood Bank | <input type="checkbox"/> Medical Devices |
| <input type="checkbox"/> OTC Medicines | <input type="checkbox"/> Export Only | <input type="checkbox"/> Tissue Bank | <input type="checkbox"/> Custom Made Devices |

***Are you registering for (tick all that apply).**

☐ **Clinical Trials** - are research investigations usually conducted by hospitals or universities. Additional information is available on the TGA website [Clinical trials](#).

☐ **PI Supplying** - Proprietary Ingredient (PI) is a confidential formulation usually containing two or more accepted ingredients. Additional information is available on the TGA website [Notification of a new Proprietary Ingredient](#).

☐ **Neither** - If you do not intend to run a clinical trial or supply a PI.

***Organisation name:**

ABN / ACN

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***Address details:**

*Street address

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*Suburb

	*State:		*Postcode:	
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*Postal address

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*Suburb

	*State:		*Postcode:	
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***Corporate contact and billing details:**

*Contact email

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*Contact telephone

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*Billing email

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*Billing Cc email

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Section 2. Organisation administrator

***Administrator account details**

Please nominate one representative from your company to be the Administrator. The Administrator is responsible for creating and maintaining contacts for the organisation. There can only be one Administrator appointed to an account at one time. For more information about the Administrator role see [TGA Business Services - Administrator role presentation](#).

For information and guidance on the TGA Business Services (TBS) site see [TGA Business services - how to use the site](#).

Note: A sponsor and Australian manufacturer organisation must maintain at least one Australian representative at all times. If you have nominated an Administrator who is located overseas you **must** complete Section 3 of this form.

*Administrator full name

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*Email

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*Telephone

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Section 3. Australian representative



Note: Sponsors and Australian manufacturers must maintain at least one Australian representative at all times. If you have nominated an Administrator who is located overseas, please complete Section 3 of this form.

Overseas manufacturers and agent organisation do not need to complete this section.

This section is only required to be completed by a sponsor or Australian manufacturer which has nominated an overseas Administrator.

Note: Overseas manufacturers and agent organisations do not need to complete this section.

Please nominate an Australian representative from your organisation to be listed as an authorised contact. This person will be the first point of contact for the TGA.

*Australian representative full name:

*Email

*Telephone

Section 4. Declaration



The following declaration must be signed.

- For a corporation, by the company director or company secretary
- For other clients, by the owner, partner, individual or regulatory affairs agent

The signatory will also be added to the TGA Business Services (TBS) Portal as an authorised representative with submitter access.

Note: providing information that is false or misleading to a Commonwealth entity or in connection with a Commonwealth law is a serious offence subject to criminal penalties under the *Criminal Code Act 1995*.

By signing this form, I declare that the information provided is true and correct.

*Full name

*Email

*Telephone

*Signature

	*Date:	