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|  | TGA use only*When completed this form will be classified as 'For official use only’* |  |
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# TGA Consultation Submission cover sheet

This form accompanies a submission for a consultation published by the Therapeutic Goods Administration (TGA)

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| Name and work title |       |
| Company/Organisation |       |
| Company/Organisation address |       |
| Contact phone |       | Contact email: |       |

## Publishing your submission

[ ]  **Publish my entire submission in full**, including my name and work title as it appears on the submission, on the TGA website. **Note:** [Australian Privacy Principle 8.1](http://www.oaic.gov.au/agencies-and-organisations/app-guidelines/chapter-8-app-8-cross-border-disclosure-of-personal-information#overseas-recipient) will not apply if you consent to this.

[ ]  Only **publish my submission** on the TGA website, **do not publish** my name or work title.

[ ]  **Only publish** my name and work title on the TGA website, **do not publish** my submission.

[ ]  **Do not publish** my name or work title **or** my submission on the TGA website.

[ ]  **Only publish some** of my submission on the TGA website. I have:

 Provided two copies - a complete submission that will not be published and a redacted submission which will be published. The redacted copy can be submitted with the parts of your submission that you **DO NOT** want published marked as ‘IN CONFIDENCE’

* + **OR** you may wish to apply track changes or blacked out text
	+ **AND/OR provide details** of content not to be published in the box below.(e.g. “Do not publish pages 3-5”)

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## Additional general information

Please provide the following general information to help with the analysis of stakeholder comments

Select as many boxes as apply:

|  |
| --- |
| I am, or I represent: |
| [ ]  Biomedical engineer | [ ]  Issuing Agency | [ ]  Registry |
| [ ]  Consumer | [ ]  Laboratory professional | [ ]  Regulator |
| [ ]  Consumer organisation | [ ]  Manufacturer (small) | [ ]  Regulatory affairs consultant |
| [ ]  Dental | [ ]  Manufacturer (medium) | [ ]  Researcher or research organisation |
| [ ]  General practitioner | [ ]  Manufacturer (large) | [ ]  Software provider/developer |
| [ ]  Government (state or territory) | [ ]  Manufacturer (Australian) | [ ]  Sole trader |
| [ ]  Government (federal) | [ ]  Manufacturer (Australian, export only) | [ ]  Specialist |
| [ ]  Health professional (please specify) | [ ]  Manufacturer (overseas) | [ ]  Sponsor |
| [ ]  Hospital | [ ]  Procurement | [ ]  Third party logistics/distributors  |
| [ ]  Industry organisation or peak body | [ ]  Professional body |  |
| [ ]  Other (please specify):       |

We may contact you to ask you for more information or to seek feedback about how the consultation was undertaken. Please tick this box to consent. [ ]

\* The *Privacy Act 1988* contains 13 Australian Privacy Principles. Australian Privacy Principle 8.1 provides that:

Before an APP entity discloses personal information about an individual to a person (the overseas recipient):

1. who is not in Australia or an external Territory; and
2. who is not the entity or the individual;

the entity must take such steps as are reasonable in the circumstances to ensure that the overseas recipient does not breach Australian Privacy Principles 2 - 13 in relation to the information. However, where a person consents to the publication of their personal information on the TGA Internet site or the Department of Health Internet site, APP 8.1 will no longer apply in relation to that publication.

For more information about the Australian Privacy Principles, visit the [Office of the Australian Information Commissioner’s website](http://www.oaic.gov.au).

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>.