



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

# Request for early scientific advice

## Requests for scientific advice under s.22G *Therapeutic Goods Act 1989*

Use this form to seek the TGA's advice on a biowaiver justification proposed for inclusion with an application to register a new medicine for oral ingestion.

Requests are limited to the following types of justifications:

- Biopharmaceutical Classification System (BCS)-based biowaiver justification
- Additional strength biowaiver justification
- Justification for use of an overseas reference product in a bioequivalence study.

This is an optional process, operating independently from the process of applying for registration of a medicine.

Based on the data submitted with this request, we will advise whether the proposed justification is acceptable and a biowaiver is appropriate for the medicine.

More information about this process is on the TGA website at [Early scientific advice](#).

### How to pay fees and submit your request

Current fees are at <https://www.tga.gov.au/schedule-fees-and-charges>. Payment confirmation is required before the request can be processed.

- **Credit card (preferred):** Pay online with a credit card at <https://www.bpoint.com.au/payments/TGA>, (select Early Scientific Advice). Once paid, add the receipt number to section 3 of this form.
- Other payment options are available at <https://www.tga.gov.au/payment-options>.

Submit the completed form and supporting data via email as an eCTD sequence to [esubmissions@health.gov.au](mailto:esubmissions@health.gov.au), cc: [accountsrec@health.gov.au](mailto:accountsrec@health.gov.au).

If submitting supporting data on physical media, email a copy of this request form to [accountsrec@health.gov.au](mailto:accountsrec@health.gov.au).

## Section 1. Organisation details

Organisation name

TBS client ID

Contact person

Position (e.g. regulatory affairs officer)

Telephone number

Email address


## Section 2. Request details

I am seeking TGA's advice on whether:

- a Biopharmaceutical Classification System (BCS)-based biowaiver justification is acceptable
- an additional strength biowaiver justification is acceptable
- a justification for use of an overseas reference product in a bioequivalence study is acceptable

for the following proposed registered medicine based on the data submitted with this request.

Drug substance (active ingredient)

Dosage form


## Section 3. Payment details

Payment receipt number

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## Section 4. Declaration

I declare that the information provided for the purposes of this request is current and correct to the best of my knowledge.

Name

Date
