



Australian Government
Department of Health and Aged Care
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 TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Notification of turnover

Annual Charge Exemption (ACE)



Please note:

Making a notification of turnover advises the TGA to issue the sponsor with an annual charge invoice in respect of a notified ARTG entry.

The *Therapeutic Goods Regulations 1990* provides an exemption from paying the annual charge for a good (excluding export only) that is registered, listed or included in the Australian Register of Therapeutic Goods (ARTG) until the ARTG entry commences generating turnover.

Once an ARTG entry commences generating turnover, **the exemption ceases**. The annual charge in respect of that ARTG entry will become payable for the financial year in which turnover is notified as having commenced and each financial year thereafter, up to and including the financial year in which the entry is cancelled from the ARTG, even if the entry has not generated turnover in a future financial year.

The annual charge invoice will be issued at the end of the month in which the notification is made. The date for payment of the annual charge invoice will be no later than the last day of the first month after the month in which notification of turnover was made.

The completed and signed declaration form must be submitted to the TGA by email to ace.scheme@health.gov.au. Please ensure the 'tracking' settings on your email account are set to request a "delivery receipt" and/or "read receipt".

Notification of turnover – Certification statement

I, [Name of authorised person], being a person authorised by
[Sponsor name], [Sponsor ID number],
hereby make this notification under regulations 43AAF and/or 43AAGE of the *Therapeutic Goods Regulations 1990*, to certify that the ARTG entries identified within this document **have commenced generating turnover** during financial year 1 July to 30 June [insert years].

I am aware that:

- it is an offence under section 137.1 and 137.2 of the Criminal Code to provide any false or misleading information or documents in relation to this notification.
- for ACE compliance monitoring purposes, the TGA may at any time, request information relied upon to determine turnover did commence in relation to the ARTG entries identified within this notification.
- by making this notification, the abovementioned sponsor will not be able to make any further declarations of \$0 turnover for the notified ARTG entries.
- the sponsor will be issued with an annual charge invoice for the financial year in which turnover is notified as having commenced and each financial year thereafter, up to and including the financial year in which the entry is cancelled from the ARTG, even if the entry has not generated turnover in a future financial year.

Signature of authorised person:

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Email address:

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Contact phone number:

	Date:	
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ACE ID #:

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TRIM #:

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Date actioned:

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Actioned by:

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