



Annual Charge Exemption scheme: Frequently asked questions

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About the Annual Charge Exemption scheme

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What is the ACE Scheme?

The Annual Charge Exemption (ACE) scheme replaced the low value turnover (LVT) scheme on 1 July 2015. The LVT scheme provided an exemption from annual charges for goods in the Australian Register of Therapeutic Goods (ARTG) with low sales turnover, and had been in place in various forms since 1990.

The purpose of the ACE scheme is to recognise that TGA's post-market monitoring costs should be recovered through annual charges on goods that have been placed into the market. The ACE scheme allows sponsors to include their goods in the ARTG in advance of their marketing, without incurring annual charges ***until the good commences generating turnover***.

Sponsors are required to make a declaration annually between 1 July and 22 July to confirm that an ARTG entry (excluding export only) which meets the legislated criteria for exemption, did not commence generating turnover in the previous financial year.

What are the key features of the ACE Scheme?

- All new goods that are registered, listed or included in the ARTG (excluding export only) and did not commence generating turnover, meet the legislated criteria for

exemption.

- As the criteria for exemption from annual charges is legislated, sponsors cannot apply for, or request, an exemption.
- Making a 'declaration' confirms an ARTG entry that has met the legislated criteria for exemption, has not commenced generating turnover. Making a 'notification' confirms an exempt ARTG entry has commenced generating turnover, causing the exemption to cease and the annual charges become payable.
- Sponsors of a new or existing (active or cancelled) ARTG entry (excluding export only) that has met the legislated criteria for exemption during a financial year (being 1 July to 30 June) and has not commenced generating turnover, must make a declaration of \$0 turnover in respect of that entry during the next declaration period which occurs annually between 1 July and 22 July
- If a sponsor does not make a declaration of \$0 turnover for an exempt ARTG entry between 1 July and 22 July of a year, the exemption will cease and the relevant annual charge for that entry will become payable for the previous and current financial year. Annual charges will continue to be payable each financial year up to and including the financial year in which the entry is cancelled from the ARTG.
- Annual charge invoices will be issued to sponsors for only those ARTG entries (excluding export only) which do not meet the legislated criteria for exemption.
- Once an ARTG entry commences generating turnover, the exemption ceases as the entry no longer meets the legislated criteria for exemption, even if the entry does not generate any turnover in a future financial year.
- A notification of turnover can be made at any time during a financial year, **except** during the declaration period which occurs annually between 1 July and 22 July.
- Annual charges become payable from the financial year in which the ARTG entry commenced generating turnover and will continue to be payable each financial year up to and including the financial year in which the entry is cancelled from the ARTG.
- Annual charges are payable annually by 15 September.
- An application may be made for waiver of an annual charge on the grounds of public health risk / financial viability. Waivers are only granted under exceptional circumstances.

What is the legislated criteria for exemption?

In order to be exempt, an ARTG entry must first meet the following legislated criteria:

- a. the entry was **new** in the ARTG during a financial year; or
- b. for an **existing** entry, a declaration was made in relation to the previous financial year; **and**

c. the entry **has not commenced generating** turnover

In all other cases, an ARTG entry has **not** met the legislated criteria for exemption and the annual charge in respect of that entry (excluding export only) is payable each financial year 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.

As the criteria for exemption from annual charges is legislated, sponsors cannot apply for an exemption.

What is the definition of 'turnover' under the ACE Scheme?

'Turnover' for a therapeutic good means "gross amount (in dollars) received (excluding GST) from sales (whether direct or indirect) of the goods in Australia by the person for the financial year".

Under regulation 43AAA of the *Therapeutic Goods Regulations 1990*, "a person's turnover of therapeutic goods for a financial year is of low value if the turnover is \$0".

Therefore, if an exempt ARTG entry commences generating turnover which is greater than \$0, it no longer meets the legislated criteria for exemption.

How long is an exemption valid for?

An exemption from annual charges is valid for a single financial year (1 July to 30 June).

Sponsors of an ARTG entry that has met the legislated criteria for exemption, must make a declaration of \$0 turnover annually between 1 July and 22 July **until the entry commences generating turnover or until the next declaration period after the entry is cancelled from the ARTG.**

What happens when an ARTG entry is cancelled?

Where an entry that has met the legislated criteria for exemption is cancelled from the ARTG during a financial year and the entry did not commence generating turnover prior to being cancelled, the sponsor must make a final declaration of \$0 turnover during the next declaration period which occurs annually between 1 July and 22 July.

Making a final declaration will complete the annual charge exemption cycle. The entry will not incur annual charges and no further declarations are required.

NOTE: To ensure declarations made in relation to previous financial years are true and accurate, the TGA may at any time, request that sponsors provide information in relation to their declaration(s) in order to verify that an exempt ARTG entry (**active or cancelled**)

had not commenced generating turnover within the financial year for which the declaration was made.

NOTE: Sponsors should not wait until the declaration period commences before cancelling an ARTG entry. Cancellation (<https://www.tga.gov.au/form/request-cancel-artg-entry> (<https://www.tga.gov.au/node/288261>)) of an entry from the ARTG **must be effective in the ARTG on or before 30 June**. A declaration can still be made for a cancelled entry that has met the legislated criteria for exemption..

What happens when there is a transfer of sponsorship?

The policy which applies to transfers of sponsorship is that the exemption follows the ARTG entry.

This is to ensure that any sponsor who receives an ARTG entry by a transfer of sponsorship is not affected (positively or negatively) upon receiving the entry. If an entry is exempt when transferred, the exemption continues for that entry (under the new sponsor) until:

- a. the sponsor makes a notification of turnover during the financial year confirming the exempt entry has commenced generating turnover; or
- b. the sponsor does not make a declaration of \$0 turnover during the next declaration period which occurs annually between 1 July and 22 July

Importantly, if an exempt ARTG entry is transferred to another sponsor during a financial year, the sponsor who 'acquired' the exempt entry is responsible for making a declaration of \$0 turnover during the next declaration period which occurs annually between 1 July and 22 July.

Before the declaration of \$0 turnover can be made, the sponsor who acquired the exempt ARTG entry must obtain evidence from the sponsor who relinquished or 'disposed' of the entry, to confirm whether (or not) the entry had commenced generating turnover during the financial year, prior to the date upon which the entry was transferred.

Example

Sponsor A transfers an exempt ARTG entry to Sponsor B on 1 January. As the exemption follows the entry, Sponsor B becomes responsible for making a declaration of \$0 turnover for the entry (ONLY if the entry did not commence generating turnover in the financial year in which the transfer occurred) during the next declaration period which occurs annually between 1 July and 22 July.

As Sponsor B is responsible for making the next declaration of \$0 turnover, Sponsor B must obtain evidence from Sponsor A to confirm the ARTG entry had not commenced generating turnover between 1 July and 31 December of that financial year (prior to the entry being transferred).

Importantly, both sponsors should always be mindful that it is an offence under the Criminal Code to make a false or misleading declaration. Both sponsors should therefore ensure evidence in support of \$0 turnover is retained for compliance purposes.

Are exemptions published on the TGA website?

Certain details about ARTG entries which meet the legislated criteria for exemption (<https://www.tga.gov.au/node/111>), are published on the TGA website under subsection 61(5C) of the *Therapeutic Goods Act 1989* which authorises the publication of kinds of therapeutic goods information relating to exemptions under the Annual Charge Exemption Scheme.

Declaration of \$0 turnover

What is a declaration of \$0 turnover?

A 'declaration of \$0 turnover' confirms an (active or cancelled) ARTG entry (excluding export only) that has met the legislated criteria for exemption, **has** not commenced **generating turnover** in the previous financial year and is therefore exempt from paying annual charges for that financial year.

Making a declaration of \$0 turnover between 1 July and 22 July does not incur a fee.

When is a declaration of \$0 turnover made?

Access to make a declaration of \$0 turnover is only available during the declaration period which occurs annually **between 1 July and 22 July**.

Making a declaration of \$0 turnover during this period does not incur a fee.

NOTE: A declaration **cannot be made prior to 1 July**

How is a declaration of \$0 turnover made?

A declaration of \$0 turnover can be made online via the TGA Business Services (TBS) portal (<https://business.tga.gov.au/>) by navigating through 'Applications > Annual Charge Exemption > Manage My Entries > Submit Declaration of \$0 Turnover'.

Making an online declaration through the TBS (<https://www.tga.gov.au/node/287189>) portal allows sponsors to efficiently view and select eligible entries (*if any*) for exemption. TBS automatically provides electronic confirmation once a declaration has been submitted successfully.

Sponsors who require access to TBS are encouraged to contact the administrator of your organisation's account. If the administrator is no longer associated with the organisation or you wish to update the administrator, please complete and return an Updating Organisation Administrator form (<https://www.tga.gov.au/node/287111>).

How often is a declaration of \$0 turnover made?

Annually, between 1 July and 22 July. Sponsors are required to make a declaration of \$0 turnover on an annual basis to confirm that an ARTG entry (excluding export only) has **not commenced** generating turnover.

If an exempt entry was cancelled from the ARTG during a financial year and the entry has not commenced generating turnover during that financial year prior to be cancelled, the sponsor must make a final declaration of \$0 turnover during the next declaration period which occurs annually between 1 July to 22 July. Once a final declaration has been made, no further declarations are required in respect of that entry.

What happens after a declaration of \$0 turnover is made?

Once a declaration of \$0 turnover has been made in respect of the previous financial year, the exemption for that ARTG entry will be confirmed (i.e. the entry has not commenced generating turnover). Therefore, the entry will not incur annual charges for that financial year.

What happens if a declaration is not made?

If a declaration of \$0 turnover is not made in respect of an ARTG entry (excluding export only) that has met the legislated criteria for exemption, turnover is assumed to have commenced in the previous financial year. The exemption will therefore cease and the annual charge in respect of that entry will become payable. Annual charges will continue to be payable each financial year up to and including the financial year in which the entry is cancelled from the ARTG, even if the entry has not generated turnover during a future financial year.

The TGA will issue the sponsor with **two annual charge invoices** in August for the previous financial year in which turnover is assumed to have commenced and the current financial year. Payment of both annual charge invoices are due by 15 September.

What happens if a declaration is not made but should have been?

Sponsors who inadvertently fail to make a declaration of \$0 turnover during the annual declaration period (between 1 July and 22 July) may submit a late declaration in respect of an ARTG entry (excluding export only) that has met the legislated criteria for exemption, **between 23 July and 15 September**.

A late declaration **must be accompanied by payment of the prescribed fee and must be received by the TGA no later than 15 September**.

Late declarations (and/or payment of the prescribed fee) received by the TGA after 15 September, cannot be accepted as the date is legislated and cannot be extended.

The prescribed fee for making a late declaration under regulation 43AAE or 43AAGD of the *Therapeutic Goods Regulations 1990* is set out in the TGA Schedule of Fees and Charges, under 'General Fees (<https://www.tga.gov.au/fees-and-charges-summary-1-october-2022>)'.

Access to make a late [declaration \(https://www.tga.gov.au/annual-charge-exemption-scheme-forms\)](https://www.tga.gov.au/annual-charge-exemption-scheme-forms) is only available **between 23 July and 15 September**. Sponsors must remit payment of the prescribed fee (per instructions provided in the late declaration form) and submit evidence of payment (i.e. remittance advice) together with the completed and signed late declaration by email to ace.scheme@health.gov.au **no later than 15 September**.

Late declaration

What is a late declaration?

Sponsors who inadvertently fail to make a declaration of \$0 turnover during the annual declaration period which occurs between 1 July and 22 July, in respect of an entry on the Australian Register of Therapeutic Goods (ARTG) (excluding export only) that has met the legislated criteria for exemption, can make a late declaration.

A 'late declaration' confirms an (active or cancelled) ARTG entry (excluding export only) that has met the legislated criteria for exemption, has not commenced generating turnover in the previous financial year and is therefore exempt from paying annual charges for that financial year.

NOTE: Making a late declaration **between 23 July and 15 September must be accompanied by payment of the prescribed late declaration fee (https://www.tga.gov.au/annual-charge-exemption-scheme-forms)** and must be **received by the TGA no later than 15 September**.

When is a late declaration made?

Access to make a late declaration is only available **between 23 July and 15 September**. A late declaration **must be accompanied by payment of the prescribed late declaration fee (<https://www.tga.gov.au/annual-charge-exemption-scheme-forms>)** and must be **received by the TGA no later than 15 September**.

NOTE: A late declaration cannot be made after 15 September as this date is legislated and cannot be extended.

How is a late declaration made?

Sponsors must complete a paper-based late declaration form, remit payment of the prescribed fee (per instructions provided in the late declaration form) and submit evidence of payment (i.e. remittance advice) together with the completed and signed late declaration form to the TGA by email to ace.scheme@health.gov.au **no later than 15 September**.

What happens after a notification of turnover is made?

Once a late declaration and payment of the prescribed late declaration fee (<https://www.tga.gov.au/annual-charge-exemption-scheme-forms>), has been received by the TGA, the Annual Charge Exemption (ACE) scheme delegate will assess the validity of the late declaration and confirm that payment of the prescribed late declaration fee has been receipted. If the ACE delegate is satisfied that the requirements for making a late declaration have been met, the exemption for that ARTG entry will be confirmed in relation to the financial year in which the late declaration is made.

NOTE: Failure to make a declaration of \$0 turnover between 1 July and 22 July may result in two annual charge invoices being issued in August. The ACE delegate must be satisfied that the requirements for making a late declaration between 23 July and 15 September have been met before cancellation of annual charge invoices (if applicable) can occur.

The sponsor will be notified in writing to confirm if an ARTG entry has, or has not, met the legislated criteria for exemption.

What happens if a late declaration is not made?

If a late declaration is not made **between 23 July and 15 September** in respect of an ARTG entry (excluding export only) that has met the legislated criteria for exemption, turnover is assumed to have commenced in the previous financial year. **The exemption will therefore cease permanently.**

Annual charge invoices issued in August in respect of that entry are **payable by 15 September**.

Annual charges will continue to be payable each financial year up to and including the financial year in which the entry is cancelled from the ARTG, even if the entry has not generated turnover during a future financial year.

Notification of turnover

What is a notification of turnover?

A notification of turnover' confirms an (active or cancelled) ARTG entry (excluding export only) that is currently exempt from annual charges, **has commenced generating turnover**. Once an entry commences generating turnover in Australia, the exemption ceases and the annual charge in respect of that entry will become payable each financial year including the financial year in which the turnover commenced, up to and including the financial year in which the entry is cancelled from the ARTG.

Sponsors who make a notification of turnover during a financial year are **not required** to make a declaration in respect of a notified ARTG entry during the next declaration period which occurs annually between 1 July and 22 July.

When is a notification of turnover made?

A notification of turnover should be made as soon as the entry commences generating turnover. In the month after the notification is made, the sponsor will be issued with an annual charge invoice in respect of the notified entry for the financial year in which the turnover commenced.

Annual charges will be issued in August of each new financial year thereafter.

Failure to submit a notification of turnover as soon as an entry has commenced generating turnover, will result in the sponsor being issued with two annual charge invoices in August for the financial year in which the entry commenced generating turnover and the current financial year.

Annual charges in respect of the ARTG entry will then be payable each financial year 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.

Access to make a notification of turnover is only available between **16 September and 30 June**.

How is a notification of turnover made?

Sponsors must complete a paper-based notification of turnover and submit the signed document to the TGA by email to toace.scheme@health.gov.au

What happens after a notification of turnover is made?

Once a notification of turnover has been made for an ARTG entry (excluding export only), the exemption will cease. Annual charges in respect of that entry will become payable from the financial year in which the turnover commenced. The notified ARTG entry will incur an annual charge each financial year thereafter, up to and including the financial year in which the entry is cancelled from the ARTG.

The annual charge invoice will be issued in the month the notification is made.

Sponsors who make a notification of turnover during a financial year are **not required** to make a declaration in respect of a notified ARTG entry during the next declaration period which occurs annually between 1 July and 22 July.

What happens if a notification of turnover is not made?

If a sponsor chooses NOT to make a notification of turnover at the time an ARTG entry (excluding export only) commences generating turnover, the sponsor **must not** make a declaration in respect of that entry during the next declaration period which occurs annually between 1 July and 22 July. It will be assumed that turnover has commenced in the previous financial year and the TGA will issue the sponsor with **two annual charge invoices** in August of a year for both the previous and current financial years.

Annual charges will continue to be payable each financial year until the ARTG entry is cancelled from the ARTG, even if the entry has not generated turnover during a future financial year.

Payment of both annual charge invoices are due by 15 September of the year in which they are issued.

Waivers

What is a waiver?

A waiver will effectively cancel or reverse the annual charge that would otherwise be payable for a financial year. Sponsors of certain high risk therapeutic goods can seek a waiver from (payment of) an annual charge for the relevant financial year if:

- the good is **not already exempt** from paying an annual charge for the relevant financial year;

- it is **not financially viable** for the good to remain on the ARTG if the annual charge was payable; **AND**
- it is in the **interest of public health** for the good to remain on the ARTG.

The objective of the waiver provisions is to ensure the continued availability of essential therapeutic goods to the Australian public. The Secretary (decision maker) will only grant a waiver in exceptional circumstances.

Detailed information is available in the ACE scheme waiver guidance (<https://www.tga.gov.au/node/285134>).

When can an application for waiver be made?

Sponsors of **new goods** included on the ARTG:

- If an annual charge for a therapeutic good is payable for the financial year that it was first included on the ARTG, an application for a waiver must be made before 31 December in the next financial year.

NOTE: A waiver is only relevant if the sponsor is liable to pay the annual charge in relation to that financial year; that is, the sponsor of the therapeutic good has notified the TGA that turnover has commenced, therefore the good is no longer exempt from annual charges under the ACE scheme.

Sponsors of **existing goods** included on the ARTG:

- Where the therapeutic good was already included on the ARTG on the first day of the financial year to which the annual charge relates, and the sponsor would otherwise be liable to pay the annual charge for that good, an application for a waiver must be made during that financial year.

How long is a waiver valid for?

A waiver only applies for a single financial year and only applies to the annual charge issued for the financial year in which the waiver was granted.

Any waiver that was granted in a previous financial year will no longer apply in the next financial year. The sponsor will be required to make a new application each financial year.

How is an application for waiver made?

Sponsors must make an application for waiver in writing. The application **must address both the financial viability and public health criteria** referred to in the ACE scheme waiver guidance (<https://www.tga.gov.au/node/285134>) and also meet specific evidence requirements ([/node/285134#evidence-requirements](https://www.tga.gov.au/node/285134#evidence-requirements)).

Sponsors can include more than one ARTG entry and entries for different types of therapeutic goods in the one application. However, the information required (i.e. evidence requirements) must be provided in relation to each entry.

When making an application, the sponsor must ensure that:

- all the information you wish the Secretary (decision maker) to consider that is relevant to the criteria (i.e. evidence requirements), has been provided in support of the application;
- the Chief Financial Officer or equivalent within your company, has signed the application;
- all the relevant entries for which the application is being made, are listed in the application (per the evidence requirements, the list must include the ARTG number, the ARTG entry description, the annual charge invoice number and the type of therapeutic good); and
- an email address is provided to ensure you are notified of the Secretary's decision

NOTE: An application for waiver will only be assessed if it addresses the requirements set out in the Regulations. That is, sub regulations 43AAH(7) and 43AAH(8) as described in the [evidence requirements \(/node/285134#evidence-requirements\)](/node/285134#evidence-requirements). If the application does not properly address the requirements, the application **will not be considered**.

What happens if an application for waiver does not meet the criteria?

Where the information provided in an application is assessed as being incomplete, insufficient or incorrect and therefore does not address the criteria and [evidence requirements \(/node/285134#evidence-requirements\)](/node/285134#evidence-requirements), the application will not be considered on the basis it is not an 'application'.

An application that does not contain sufficient information or sufficiently persuasive information to satisfy the Secretary (decision maker) that it is in the interests of public health for the entry to remain on the ARTG and that it would not be financially viable if the sponsor were required to pay the annual charge, may result in refusal of the waiver.

How much does an application for waiver cost?

There is no fee associated with applying for a waiver.

When will I be informed of the Secretary's decision?

The Secretary (decision maker) has 60 days from the date upon which the application for waiver is received, to consider the application and make a decision on whether or not to grant a waiver.

Written notice of the Secretary's decision, setting out the reasons for the decision, will be issued by email (to the email address provided in the application) as soon as practicable after the decision is made.

If the Secretary decides not to grant a waiver, the annual charge for the relevant financial year will become payable. The written notice of the Secretary's decision will specify the date upon which the annual charge becomes payable.

What if I disagree with the Secretary's decision not to grant a waiver?

The written notice of the Secretary's decision will state that you can, within 90 days after the decision comes to your notice, make a request for a review of the Secretary's decision not to grant a waiver, under regulation 48 of the *Therapeutic Goods Regulations 1990*. Further information and [guidance for requesting a reconsideration \(https://www.tga.gov.au/node/289300\)](https://www.tga.gov.au/node/289300), is available on the TGA website.

What happens if an entry is voluntarily cancelled from the ARTG?

If the Secretary (decision maker) granted a waiver for an entry and the sponsor subsequently requests that entry be cancelled (i.e. revoked) from the ARTG in the same financial year, the annual charge for that financial year would become payable.

Are waivers published on the TGA website?

Certain information about waivers that have been refused or granted will be published on the TGA website. Information will also be published about sponsors who, having been granted a waiver, are required to pay the annual charge because of a request they subsequently made to cancel the entry.

Compliance monitoring

How does the TGA ensure that a declaration of \$0 turnover is true and accurate?

To ensure declarations made in relation to previous financial years are true and accurate, the TGA may at any time, request that sponsors provide information in relation to their declaration(s) in order to verify that an exempt ARTG entry (active or cancelled) had not commenced generating turnover within the financial year for which the declaration was made.

Sponsors are required to retain evidence in support of a declaration, for up to five years. Evidence constitutes (but is not limited to) information the sponsor relied upon to determine that an entry did not commence generating turnover prior to making a declaration.

All ARTG entries for which a declaration of \$0 turnover has been made will be published on the TGA website.

What happens if a false or misleading declaration of \$0 turnover is made?

Sponsors are reminded that making a false or misleading declaration of \$0 turnover is an offence under the *Criminal Code*.

Should the TGA become aware of the sponsor having made a false or misleading declaration of \$0 turnover, the sponsor will be liable for the relevant financial years' annual charges, commencing from the year in which the false or misleading declaration of \$0 turnover was made.

Contact us

Who can I contact for assistance?

If you were unable to resolve your query by reviewing information about the ACE Scheme on the TGA website, you can contact the ACE Scheme by email to ace.scheme@health.gov.au or by phone on 02 6289 4639.

Version history

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA	May 2015
V1.1	Minor updates	TGA	June 2015
V2.0	Two Q&A added to General information	TGA	August 2015
V2.1	Minor updates	TGA	July 2016
V2.2	Minor updates	TGA	November 2016
V3.0	Updated	TGA	June 2017
V4.0	Updated	TGA	June 2018
V4.1	Minor updates	TGA	June 2019
V4.2	Minor updates	TGA	July 2019
V4.3	Minor updates	TGA	June 2020

Topics:

[Biological medicines \(https://www.tga.gov.au/products/medicines/biological-medicines\)](https://www.tga.gov.au/products/medicines/biological-medicines).

[Fees and payments \(https://www.tga.gov.au/how-we-regulate/fees-and-payments\)](https://www.tga.gov.au/how-we-regulate/fees-and-payments).

[Medical devices \(https://www.tga.gov.au/products/medical-devices\)](https://www.tga.gov.au/products/medical-devices).

[Medicines \(https://www.tga.gov.au/products/medicines\)](https://www.tga.gov.au/products/medicines).

[Other therapeutic goods \(https://www.tga.gov.au/products/other-therapeutic-goods\)](https://www.tga.gov.au/products/other-therapeutic-goods).