



Annual Charge Exemption scheme

Last updated:

30 June 2021

The Annual Charge Exemption (ACE) scheme provides an exemption from paying the annual charge for a good (excluding export only goods) that is registered, listed or included in the Australian Register of Therapeutic Goods (ARTG) until the entry or entries to which the good relates first commences generating turnover.

The purpose of the scheme is to recognise that TGA's post-market monitoring costs are recovered through annual charges on entries that have been placed into the market. The scheme allows sponsors to enter their goods in the ARTG in advance of their marketing without incurring an annual charge until the goods are taken to the market.

Once an entry commences generating turnover, the entry cannot be exempt from annual charges. The entry will incur an annual charge each financial year up to and including the financial year in which the entry is cancelled from the ARTG, even if the entry does not generate turnover in future financial years.

The Scheme

Sponsors of an ARTG entry (excluding export only entries) which meets the legislated criteria for exemption during a financial year (being 1 July to 30 June), must make a declaration of \$0 turnover for that ARTG entry during the next declaration period which occurs annually between **1 July and 22 July**.

To be exempt from annual charges under the ACE scheme, an entry must meet the following criteria:

- the entry was **new** in the ARTG during a financial year; or
- the entry was an **existing** ARTG entry on 1 July, the entry was qualified for ACE in the financial year, and a declaration of \$0 turnover was made in relation to the that financial year; and
- the entry (whether a new entry or existing entry) did not commence generating turnover.

In all other cases, an entry has not met the criteria for exemption and the annual charge in respect of the entry is payable for 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 later financial year.

Cancelled ARTG entries

Where an entry, which is currently exempt from annual charges under the ACE scheme, is cancelled from the ARTG 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.

Making a final declaration of \$0 turnover will conclude the annual charge liability arising in respect of the entry. The entry will not incur annual charges and no further declarations will be required to be made by the sponsor for that entry.

Annual declaration period between 1 July and 22 July

Sponsors can make a declaration of \$0 turnover online via the [TGA Business Services \(https://business.tga.gov.au/\)](https://business.tga.gov.au/) (TBS) portal **between 1 July and 22 July** each year.

A declaration of \$0 turnover can only be made between 1 July and 22 July. A declaration cannot be made prior to 1 July.

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

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

If a declaration of \$0 turnover is not made in respect of an entry which is subject to ACE in a financial year, turnover is assumed to have commenced on the entry in that financial year. The consequence is that the exemption will cease and the relevant annual charge for the entry will become due and payable for: (i) the previous financial year, as the entry was not invoiced in that year due to the ACE recorded on the entry; and, if the entry is still active on the ARTG on 1 July, (ii) the current financial year.

Example 1:

ARTG Entry No. 410267 was a new entry in the ARTG on 15 July 2020 so therefore was automatically qualified for ACE in financial year 2020-21. As the entry was qualified for ACE, no annual charge invoice was issued to the sponsor.

The sponsor of entry 410267 did not make a declaration of \$0 turnover for the entry between 1 July and 22 July 2021, so the ACE on the entry ceased. As the entry was not eligible to be exempt from annual charges in 2020-21, the sponsor is issued a 2020-21 annual charge for the entry. Likewise, because financial year 2021-22 has (already) commenced on 1 July 2021, the sponsor is also invoiced the relevant 2021-22 annual charge for the entry.

The 2020-21 and 2021-22 annual charge invoices are (both) due and payable by 15 September 2021.

Annual charges will continue to be incurred each financial year up to and including the financial year in which the entry is cancelled from the ARTG, even if the entry did not generate turnover during a later financial year.

Sponsors who inadvertently fail to make a declaration of \$0 turnover for an ACE entry during the declaration period 1 July to 22 July, may submit a late declaration between 23 July and 15 September of a financial year, but only if the entry was \$0 turnover.

A late declaration, **accompanied by the prescribed fee (<https://www.tga.gov.au/node/287173>)**, **must be received by the TGA no later than 15 September of the financial year**. Late declarations cannot be accepted after this date as the date is prescribed in legislation and cannot be extended in any circumstances.

A late declaration form (<https://www.tga.gov.au/annual-charge-exemption-scheme-forms>) is available for download from the TGA website between **23 July and 15 September** (only).

Example 2 – Late Declarations:

If the sponsor of entry 410267 identifies after 22 July 2021 that the entry did not in fact commence generating turnover in 2020-21, the sponsor may submit a late declaration (and fee) for the entry by 15 September 2021.

The consequence of the late declaration application is that the ACE on the entry will be restored, and credit memos will be issued for the (already) invoiced 2020-21 and 2021-22 annual charges.

The entry will continue to be exempt from annual charges under the ACE scheme until the next declaration period commences on 1 July 2022. The process then repeats per the examples above.

Compliance monitoring

To ensure declarations made in relation to previous financial years are accurate and true, the TGA may at any time, request that sponsors provide information in relation to their declaration(s) in order to verify that an entry did not commence generating turnover within the financial year for which a declaration of \$0 turnover was given.

Sponsors are required to retain evidence in support of a declaration of \$0 turnover 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 of \$0 turnover.

Should the TGA detect or become aware that an entry commenced generating turnover during a financial year for which a declaration of \$0 turnover was made, the exemption on the entry will be cancelled under regulation 43AAG or 43AAGF of the Therapeutic Goods Regulations 1990 and the relevant annual charge(s) for that year and all after will become due and payable.

Please note that making a false or misleading declaration to the Commonwealth is an offence under the *Criminal Code*. The TGA will seek to prosecute any sponsors who are found to have given false or misleading information for the purposes of obtaining a benefit from the Commonwealth (through annual charge exemptions under the ACE scheme).

Publishing of exemptions

In order to ensure transparency about the availability of therapeutic goods in Australia, all entries in the ARTG that had not commenced generating turnover and were exempt from annual charges (<https://www.tga.gov.au/node/111>) under the ACE scheme in previous financial years, are published on the TGA website annually under the authority of subsection 61 (5C) of the *Therapeutic Goods Act 1989*.

Exemptions published are accurate as at 19 November 2020.

View the Annual charge exemptions dataset (<https://www.tga.gov.au/resources/annual-charge-exemptions>)

Frequently asked questions (FAQ)



Frequently asked questions about the ACE scheme (<https://www.tga.gov.au/node/289322>)

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)