Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Annual Charge Exemption Scheme

Proposed ACE Scheme Compliance Program Changes

Version 1.0, February 2026

Confidentiality

All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

Annual Charge Exemption (ACE) Scheme _____ 5

ACE scheme objectives _____ 5
ACE scheme compliance program _____ 5
Compliance program issues _____ 6
ACE scheme statistics _____ 6
Proposed actions to address compliance program issues _____ 7
Change options _____ 8
ACE scheme information disclosure requirements _____ 9
Stakeholder impacts arising from the proposed changes _____ 9
Consultation audience _____ 10
What we invite you to do _____ 10
How to submit your feedback _____ 10
Ancillary information: ACE scheme participation criteria _____ 11
Ancillary Information: ACE scheme and the Criminal Code _____ 12

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Assistance Section Regulatory Engagement Branch	February 2026

Annual Charge Exemption (ACE) Scheme

ACE scheme objectives

The Annual Charge Exemption (ACE) scheme commenced on 1 July 2015. It provides an exemption from paying Therapeutic Goods Administration (TGA) annual charges until a therapeutic good covered by an entry on the Australian Register of Therapeutic Goods (ARTG) begins generating turnover. The scheme allows sponsors to enter their goods in the ARTG in advance of marketing without incurring an annual charge, until the goods are taken to the market.

The scheme's objectives align with the Australian Government Cost Recovery Framework, which prescribes that individuals or organisations who create demand for a government activity should generally bear the associated costs, unless otherwise determined by the Government. TGA's post-market activities are funded through revenue derived from annual charges levied on sponsors within regulated industries.

There is no fixed period limiting eligibility for exemption under the scheme. Provided that sponsors make an annual declaration of $0 turnover, annual charges will only become payable once an entry starts generating turnover, whether this occurs in the initial active year or any subsequent year.

Further information about the ACE scheme is available on the TGA website.
https://www.tga.gov.au/products/regulations-all-products/fees-and-payments/annual-charge-exemption-scheme-therapeutic-goods

ACE scheme compliance program

Sponsors confirm and renew exemptions under the ACE scheme through annual self-declarations. The Compliance Program aims to uphold the integrity of the scheme by instituting regular reviews of sponsor records to verify the accuracy of self-declarations concerning exempt entries. The Compliance Program ensures that sponsors who are legitimately eligible for exemptions receive the full benefit, while ineligible entries are identified and addressed accordingly.

The TG Regulations specify conditions under which exemptions may cease, such as when a sponsor reports turnover on an entry or fails to declare $0 turnover during annual declaration or late lodgement periods. Exemptions may also be revoked if a compliance review discovers incorrect $0 turnover declarations. In these circumstances, the Secretary's delegate may cancel the exemption under TG Regulations 43AAG or 43AAGF, issue an exemption cessation notice, and invoice annual charges for each year that the entry was incorrectly recorded as exempt.

According to regulation 43AAA of the TG Regulations, turnover is considered low value if it amounts to $0 in a given financial year. Therefore, once an exempt ARTG entry starts generating turnover exceeding $0, it no longer satisfies the criteria for exemption.

Delegates of the Secretary may request sponsors to submit all documentation relied upon for annual self-declarations at any time. This information supports the ongoing integrity of the scheme and helps to mitigate revenue loss from incorrectly claimed exemptions. Compliance reviews verify the accuracy of declarations across relevant financial years.

Requests for information are issued via a Statutory Notice Requiring Information (the Notice), pursuant to applicable paragraphs of the TG Act: 31(1)(k), 31(2)(h), 32JA(1)(p), or 41JA(1)(j). Failure to respond to a Notice by its prescribed due date may result in penalties and related consequences.

The Secretary's delegate can request copies of all supporting documentation relating to annual $0 turnover declarations. In accordance with government requirements, sponsors must retain financial and related records for at least five years; therefore, delegates may request information regarding exempt entries' turnover status for up to five preceding financial years.

Compliance program issues

The Compliance Program is increasingly encountering ARTG entries for which the turnover status cannot be verified due to incomplete information.

A primary reason for the inability to verify exemptions is the lack of sufficient information or data from sponsors. Common explanations provided include:

(i) absence of accurate historical records prior to integration into sponsor sales systems, and

(ii) corporate memory loss, particularly inconsistent record-keeping following transfers of sponsorship between entities.

For transfers approved under sections 10AB, 10F, or 10H of the TG Regulations - applicable to listed or registered medicines, included medical devices, or biologicals, respectively - in the past five years, the current sponsors are often unable to confirm or demonstrate whether the entries had $0 turnover before assuming responsibility for them.

Another frequent challenge arises from sponsors who do not respond to official Notices. While most sponsors engage with compliance reviews, there is a growing trend of non-response, impeding the TGA's ability to determine whether the sponsor is eligible for the exemption.

In the absence of information confirming sales activity during a financial year, the Compliance Program's enforcement options are limited. A delegate may cancel entries from the ARTG for failing to respond to a Notice issued under section 31 (and similar provisions) of the TG Act. However, cancelling entries does not affect any exemptions claimed against them; frequently, such unverifiable entries have already been cancelled by the sponsor, reducing the leverage to ensure cooperation and transparency. Accordingly, a Notice of Intent to Cancel an ARTG Entry becomes ineffective if the entry is already inactive.

The TGA does not possess additional mechanisms to compel sponsors to respond to requests for information, resulting in exemptions that are unverifiable.

Exemptions that are incorrectly or falsely claimed for entries that have commenced turnover are effectively cross subsidised by other non-exempt entries incurring annual product charges, disadvantaging compliant sponsors. Establishing powers to cancel exemptions when turnover status cannot be verified will help ensure a more equitable environment among sponsoring organisations. Additionally, these measures will reduce foregone revenue stemming from inadvertently incorrect or deliberately false declarations.

ACE scheme statistics

To provide context regarding the scale of potential non-compliance, the top ten financial beneficiaries of the scheme alone, during the five-year period from 2019-20 to 2023-24 reported $0 turnover, resulting in approximately $77.3 million in annual charges that would have otherwise been due. Should 20% to 25% of these exemptions remain unverified and were not eligible to be exempt, the TGA cannot properly account for up to $20 million in exemptions for these sponsors alone.

Sponsor	$ Value of Exemptions 2019-20 to 2023-24
Sponsor #1	$22,072,051
Sponsor #2	$18,110,464
Sponsor #3	$9,589,320
Sponsor #4	$5,439,070
Sponsor #5	$4,233,414
Sponsor #6	$4,106,862
Sponsor #7	$3,977,310
Sponsor #8	$3,480,720
Sponsor #9	$3,222,118
Sponsor #10	$3,025,962
Total	**$77,257,291**

As of 31 December 2025, a review of the ARTG confirmed that over 4,800 sponsors hold 96,120 active registered, listed, or included entries for the 2025-26 period. Of these sponsors:

- 1,950 have 22,250 ARTG entries, representing 23% of all active entries, which are classified as exempt under the scheme for 2025-26.
- 83% of the exempt entries are existing listings, with commencement dates prior to 1 July 2025, while the remaining 17% are new entries for 2025-26.

The total value of annual charges revenue foregone due to exempt entries in 2025-26 is estimated at $56.5 million, comprising $49.7 million from registered and listed medicine entries and $6.8 million from included medical devices, in vitro diagnostic (IVD) devices, and biologicals.

Proposed actions to address compliance program issues

Proposed amendments to the regulations governing the ACE scheme aim to address increasing instances of non-participation and undetected non-compliance. If implemented, these changes would empower the Secretary or their delegate to revoke Annual Charge exemptions on ARTG entries and impose applicable annual charges under the following circumstances:

- A sponsor fails to comply with a Notice issued under paragraphs 31(1)(k), 31(2)(h), 32JA(1)(p), or 41JA(1)(j) of the TG Act; or
- The sponsor does not, or cannot, demonstrate that an entry reported as $0 turnover for a financial year was legitimately exempt under the scheme and subsequently declared as such.

Accordingly, the proposed regulatory changes would introduce more comprehensive compliance requirements for scheme participants. These powers are to be administered by a delegate of the Secretary through the ACE Scheme Compliance Program.

Sponsors found to have provided incorrect or unverifiable declarations would face cancellation of exemptions and be liable for the relevant charges for each affected year. Additional authority to compel information to support exemption declarations is expected to significantly enhance compliance within the scheme, ensuring that sponsors are held accountable for inaccurate reporting.

Penalties for detected non-compliance may range from cancellation of exemptions to referral of knowingly false or misleading statements for prosecution under the Criminal Code, subject to the severity of the infraction.

It is anticipated that increased awareness of these consequences will encourage sponsors to improve their internal record-keeping and ensure greater accuracy in self-declarations following each financial year. Further details regarding the options being considered to strengthen the Compliance Program are set out later in this paper.

Change options

The following options are being considered to address instances of undisclosed non-compliance by proposing amendments to the TG Regulations. These amendments would enable the imposition of financial penalties by authorising a delegate of the Secretary to revoke exemptions (for any relevant years) if a sponsor fails to respond satisfactorily to a valid request for information under section 31 or cannot provide sufficient information regarding an exempt entry, such as failing to maintain appropriate records for exempt goods.

Option 1. Maintain the status quo and continue to rely on the existing self-declaration system.

Continuing without action would not address the issues identified in the Compliance Program, so those issues will likely continue to diminish the effectiveness of the Compliance Program. Additionally, taking no action to address the issues increases the risk that the number of sponsors cooperating transparently may decline further as more sponsors become aware of the limited consequences for misusing the scheme. Failure to amend compliance powers could result in increasing unverifiable exemptions, increasing foregone revenue without capacity to address this.

Incorrectly claimed exemptions are currently offset through annual charges levied on non-exempt ARTG entries. This form of cross-subsidisation contradicts Australian Government Cost Recovery Policies and is unsustainable.

Option 2. Amend TG Regulations 43AAGC and 43AAD so that a sponsor is only exempt from liability for charges if their declaration under TG Regulations 43AAGC(c) and 43AAD(c) includes supporting evidence confirming $0 turnover.

While maintaining accurate records for exempt goods is essential, requiring sponsors to provide evidence annually would increase regulatory burden, contrary to the scheme's original intent to reduce administrative demands. Although this solution could enhance compliance, it would impose undue complexity on some stakeholders with limited access to historical information. Furthermore, the TGA currently lacks the capacity to verify every exemption each financial year; thus, the existing five-year sample testing and compliance review method remains the most practical for both sponsors and the TGA.

Option 3. Introduce a new eligibility requirement under TG Regulations 43AAGC and 43AAD (as a new paragraph (d)), stipulating that sponsors must respond to statutory notices related to the scheme to remain eligible.

Beyond self-disclosure of incorrect declarations, enhancing disclosure can be achieved by amending TG Regulations 43AAGC, 43AAD, 43AAG, and 43AAGF to reinforce scheme integrity. These amendments would ensure that therapeutic goods only qualify for the scheme when evidence supports the sponsor's declaration of $0 turnover, or when the sponsor has responded to a statutory notice under section 31 relating to scheme compliance.

If these amendments are enacted, failure to respond adequately to a statutory notice would allow the Secretary or delegate to revoke the ARTG entry's exemption. This is the TGA's preferred solution. The ability to cancel exemptions and apply annual charges in response to non-compliance should incentivise greater cooperation and transparency among sponsors.

Additionally, the amendments would require the Secretary or delegate to notify sponsors of revoked exemptions and provide a statement of reasons, commonly due to non-response to statutory notices or failure to provide objective evidence of low-value turnover. Such mutual obligations aim to guarantee fair process and comprehensive communication regarding the cancellation of exemptions and subsequent charges.

If approved, these changes are expected to result in improved compliance, thereby increasing the number of goods subject to annual charges.

ACE scheme information disclosure requirements

The TGA publishes information regarding exempt entries on its website following each annual declaration period. This publication aims to maintain transparency concerning which entries are exempt and identify the beneficiaries of the scheme.

Such disclosure, authorised by the **Therapeutic Goods Information (Exemptions from Annual Charges) Specification 2016** (**the Instrument**), enables third parties to notify the TGA if they become aware that an exempt entry is being supplied or sold in the market, warranting review of the exemption status. While reports of this nature are uncommon, each is evaluated on its merits. If deemed credible, the TGA conducts further enquiries with the relevant sponsor.

Note: Therapeutic Goods Information (Exemptions from Annual Charges) Specification 2016
The Instrument authorising the publication of information under subsection 61(5D) of the TG Act is scheduled to expire in October 2026.

In accordance with the Sunsetting process, the TGA intends to remake the Instrument to maintain transparency of the scheme following its expiry. Although no modifications to the scope are proposed, it has been determined essential to retain and remake the Instrument and its provisions, which facilitate the publication of information regarding exempt goods.

Stakeholder comments on the annual disclosure of exempt goods are welcomed. Such feedback may be provided as part of any submission prepared in response to issues arising from this consultation.

Third-party reports of scheme misuse have resulted in regulatory action when sponsors are notified that the TGA holds credible information indicating their declarations were inadvertently inaccurate or intentionally false and misleading. All such matters are referred for further investigation, including prosecution under the Criminal Code.

Stakeholder impacts arising from the proposed changes

The TGA has determined that organisations within the therapeutic goods industry will be primarily impacted by the proposed amendments, as they will need to maintain records demonstrating the turnover status of their entries for each financial year.

It is important to note that the record-keeping requirement is not considered an additional obligation or administrative burden for sponsor organisations, since such documentation is already required for forming the basis of the $0 declaration each year, taxation and financial reporting. Should the changes be implemented, sponsors will be responsible for ensuring they retain adequate records for products registered, listed, or included on the ARTG for supply in Australia. This includes maintaining evidence regarding when entries begin generating turnover.

The scheme applies universal eligibility criteria and conditions for all entities benefiting from the scheme. Sponsors using third-party regulatory affairs service providers (Agents) must ensure these providers are informed of, and comply with, the requirements when submitting annual declarations on the sponsor's behalf. Ultimately, responsibility for any declaration rests with the sponsor, who cannot transfer accountability for erroneous submissions to an Agent. This principle mirrors the responsibility borne by individual taxpayers for the accuracy of their personal income tax returns prepared by third-party agents.

Importers are subject to the same requirements and impacts as other Australian product sponsors. There are no regional disparities associated with the proposed changes. Turnover, in this context, is defined as the gross amount (excluding GST) received from sales (direct or indirect) of the goods in

Australia during the financial year. For goods intended for domestic supply, only sales within Australia are included in turnover calculations, and exports are excluded from this assessment.

Consultation audience

This consultation is directed primarily at sponsors of therapeutic goods, as the anticipated changes will be directly applicable to those product sponsors whose entries are, or will become, exempt under the scheme.

The proposed amendments are not expected to result in significant downstream effects on other parties, such as healthcare service providers, retailers (including pharmacies and related outlets), or consumers, since only sponsors involved in the supply and distribution of therapeutic goods are eligible to participate.

Note: Preliminary details regarding these proposed changes were presented during industry bilateral meetings convened in November 2025. These sessions included all major industry bodies and preceded the annual indexation adjustments to TGA fees and charges, which will take effect in the 2026–27 financial year.

What we invite you to do

Submissions are invited regarding the current status of the ACE Scheme Compliance Program, as well as on proposed amendments that would grant the Compliance Program greater discretion in determining the eligibility of ARTG entries for exemption from annual charges.

When preparing your submission, please:

- Review and respond to the options outlined above, indicate your preferred option, and provide any additional feedback or concerns regarding the proposed changes.
- Specify whether your organisation has previously undergone an ACE Compliance Review.
    - If so, you are encouraged to provide comments or observations about your current ability to meet their evidence requirements.
    - Describe any challenges encountered when required to demonstrate $0 turnover.
    - Assess whether you received adequate guidance concerning the information required to substantiate $0 turnover.
    - Summarise the key learnings following your compliance assessment and explain how these have influenced your organisation’s record-keeping practices, especially in relation to accurately mapping products between your internal systems and the corresponding ARTG records.

How to submit your feedback

You may review the consultation details on our consultation hub and submit your feedback by emailing your response to ace.compliance@health.gov.au.

We greatly appreciate your participation and the feedback provided throughout this consultation. After an internal review of all responses received, a summary of the consultation outcomes will be published on our website.

For any immediate questions or queries concerning these proposed changes, please contact us via email at ace.compliance@health.gov.au .

Ancillary information: ACE scheme participation criteria

To maintain an exemption on an entry, sponsors must submit an annual self-declaration confirming $0 turnover for the exempt entry following each financial year.

When providing this declaration, the sponsor must:

- Confirm that the entry did not generate turnover in the previous financial year; and
- Ensure an authorised individual signs the declaration, attesting that all information provided is accurate and true.

Eligibility criteria for exemptions from annual charges, as well as ongoing participation requirements, are detailed in the TG Regulations 43AAA to 43AAGF. The legislated criteria are illustrated in the following example:

Example:
To qualify for an exemption under the scheme for 2025–26, an entry must meet one of the following conditions:

- Be a new entry on the ARTG between 1 July 2025 and 30 June 2026; OR
- Be an existing entry on the ARTG as of 1 July 2025 that was:
  - Exempt under the scheme in 2024–25, and
  - Confirmed by a 2024–25 $0 turnover declaration submitted between 1 July and 22 July 2025, or
  - Confirmed by a late lodgement declaration of $0 turnover between 23 July and 15 September 2026,
  - Either the 1 July to 22 July, or 23 July to 15 September submission requalifies the entry to continue as exempt in 2025–26; AND
- The entry must not generate turnover between 1 July 2025 and 30 June 2026.

Failure to submit a declaration between 1 July and 22 July 2026 will result in the cessation of the exemption, and the sponsor will be invoiced for the 2025–26 annual charge. Similarly, if the entry remains active on the ARTG on 1 July 2026, the sponsor will also be billed the 2026–27 annual charge as a non-exempt entry.

Sponsors who inadvertently miss the annual declaration window may still submit a late declaration, provided the entry was exempt in the prior year and had $0 turnover. A valid late lodgement declaration made between 23 July, and 15 September 2026 will reinstate the exemption, and any previously invoiced charges will be credited.

Whether a timely or late $0 turnover declaration is submitted, the 2025–26 exemption will be confirmed, and the entry will remain exempt for 2026–27. No annual charges will apply until the entry generates turnover in a subsequent financial year.

In all cases, the exemption continues until 30 June 2027. On 1 July 2027, if the entry has not generated turnover, the sponsor must lodge a 2026–27 $0 turnover declaration to retain the exemption. This cycle continues each 1 July until turnover occurs, or the entry is cancelled from the ARTG.

If no declaration or late lodgement is submitted, the exemption will end permanently, and annual charges will apply each year until the entry is removed from the ARTG, irrespective of whether turnover is generated in future years.

Ancillary Information: ACE scheme and the Criminal Code

Sponsors are reminded that providing false or misleading information to obtain a benefit from the Commonwealth constitutes an offence under the Criminal Code. An annual charge exemption, confirmed by a sponsor's declaration of $0 turnover, qualifies as such a benefit.

If any deliberately false or misleading declarations are identified, the responsible sponsor will be referred for prosecution.

This reminder is included in all Notices to encourage affected sponsors, especially those selected for an ACE compliance review sample group, to self-disclose any inadvertent non-compliance they may discover.

The status of entries at the time a Notice is issued is not relevant. Whether the Notice pertains to active or cancelled ARTG entries, the Compliance Review assesses the turnover status of these entries over the previous five years. Accordingly, turnover status for each of those years must be verifiable.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au