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SUBMISSION

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AMA submission – changes to the Annual Charge Exemption Scheme

Consultation closes 20 March 2026

By email: ace.compliance@health.gov.au

The Australian Medical Association (AMA) welcomes the opportunity to comment on the proposed changes to the Annual Charge Exemption (ACE) Scheme Compliance Program. The AMA supports a robust, fair and transparent regulatory system for therapeutic goods, including appropriately funded post-market monitoring and compliance functions that protect patient safety and sustain confidence in the Australian Register of Therapeutic Goods (ARTG).

The AMA is not an ACE scheme participant. Our comments relate to scheme integrity, procedural fairness and the sustainability of post-market compliance funding.

Although the ACE scheme applies to sponsors, the consultation states its purpose includes recognising post-market monitoring costs are recovered through annual charges on goods placed into the market. Misuse of the scheme therefore undermines the cost-recovery basis that funds TGA post-market monitoring and compliance activity, effectively shifting costs onto compliant sponsors. Consistent with the consultation's reference to the Australian Government Cost Recovery Framework, the AMA considers it appropriate sponsors who create demand for the TGA's regulatory activities bear associated costs, and that compliance settings protect equitable cost recovery across the regulated sector.

The AMA has previously supported the role of a strong, independent regulator in ensuring therapeutic goods meet appropriate standards and maintaining confidence in regulatory processes that protect patients. Consistent with this position, the AMA has also supported comprehensive post-market vigilance and proactive monitoring activities to strengthen therapeutic goods safety and system confidence. The AMA therefore supports targeted reforms to reduce avoidable revenue leakage and strengthen post-market compliance capacity, while ensuring reforms remain proportionate and procedurally fair.

The AMA supports reform to strengthen the integrity and enforceability of the ACE scheme compliance program and considers Option 3 — linking eligibility to responding satisfactorily to statutory notices — the most proportionate approach presented. The AMA encourages the regulator to implement the proposed powers alongside clear guidance, procedural fairness safeguards, and specific attention to evidence gaps arising from sponsorship transfers, while maintaining ongoing public disclosure of exemptions to support transparency and integrity.

1. Preferred option and overall position

1.1 Preferred option: support for targeted enforceability measures (Option 3)

The AMA notes the ACE scheme has operated since 1 July 2015 and now represents material foregone revenue linked to post-market activities funded through annual charges. The consultation reports $77.3 million in annual charges foregone for the top ten beneficiaries (2019–20 to 2023–24) and estimates $56.5 million in foregone revenue in 2025–26, with 23 per cent of active ARTG entries classified as exempt. These figures underscore the need for proportionate tools to address unverifiable declarations and non-response.

The AMA supports the intent of the proposed reforms to address increasing instances of non-participation and unverifiable exemptions within the ACE scheme, particularly where sponsors fail to respond to statutory notices or cannot substantiate $0 turnover declarations. We agree the consultation's preferred approach (Option 3) is the most proportionate mechanism. It targets compliance action to circumstances where the regulator has sought information to verify eligibility, rather than creating a universal requirement for all sponsors to submit evidence annually.

This position is consistent with the AMA's broader position in support of enforceable, evidence-based regulatory frameworks designed to prevent exploitation of gaps in compliance and oversight.

1.2 Rationale: protecting post-market oversight and scheme integrity

The consultation identifies a growing inability to verify exemptions due to incomplete information, non-response to statutory notices, and record gaps following transfers of sponsorship. Incorrectly claimed or unverifiable exemptions can be effectively cross-subsidised by other non-exempt entries incurring annual charges, undermining cost-recovery principles and the sustainability of the compliance program. The AMA supports clear and workable mechanisms to recover annual charges where an exemption was incorrectly claimed or maintained — including where turnover is later identified or where a sponsor cannot substantiate eligibility when requested — so entries do not continue to benefit from an exemption once the legislated criteria are not met.

The AMA supports reforms that reduce incentives for non-cooperation and improve the regulator's capacity to verify eligibility, noting a credible post-market compliance system underpins confidence in therapeutic goods regulation and supports patient safety. This position aligns with the AMA's previous support for comprehensive product vigilance and proactive post-market monitoring measures to strengthen the robustness of surveillance processes.

2. Response to proposed options

Preferred: Option 3 (new eligibility requirement to respond to statutory notices)

The AMA does not support maintaining the status quo (option 1), given the reported increase of unverifiable exemptions and limited regulatory leverage where sponsors do not engage with statutory notices. We agree inaction risks diminishing the effectiveness of the compliance program and increasing foregone revenue, with flow-on implications for fairness among regulated entities.

We note the TGA's concern an annual evidence requirement may increase regulatory burden and may be inconsistent with the scheme's original administrative intent, particularly where the regulator is not resourced to verify every exemption each year. On balance, the AMA considers Option 2 less

proportionate than Option 3 because it would impose universal uplift in administrative requirements irrespective of risk.

The AMA supports Option 3 in principle because it strengthens enforceability where a sponsor fails to respond to, or cannot satisfy, a lawful request for information, enabling the regulator to revoke exemptions and apply annual charges where eligibility cannot be established. The AMA supports this reform because it corrects a perverse incentive in a self-declaration scheme. Where a sponsor fails to respond to a valid statutory notice, the scheme should not default to continued exemption by inertia. Rather, non-response (or an inability to substantiate eligibility when requested) should result in revocation of the exemption and liability for the relevant annual charges, subject to appropriate procedural fairness and review mechanisms.

The consultation anticipates these consequences will incentivise better record-keeping and improve accuracy of self-declarations, and the AMA considers this a sound approach to retain a targeted compliance model.

3. Key safeguards and implementation considerations (to strengthen the proposal)

3.1 Procedural fairness and consistency in decision-making

The consultation proposes that where exemptions are revoked, sponsors would be notified and provided a statement of reasons. The AMA supports these safeguards and recommends the final model (including guidance materials) clearly articulate:

- clear expectations for what constitutes a "satisfactory" response to a statutory notice;
- reasonable timeframes and practical pathways for sponsors to seek clarification where requests are complex; and
- transparent review/appeal processes consistent with good administrative practice.

Guidance should also outline the decision pathway, including any available internal review and external review mechanisms, so sponsors understand their rights and obligations. These measures would help ensure the compliance tool is applied predictably and fairly, supporting confidence in the integrity of the scheme. Given the scheme already relies on transparency measures, including publication of exempt entries, the AMA considers any expansion of compliance powers should be accompanied by published operational guidance and periodic public reporting on exemption cancellations and related compliance outcomes, so scheme integrity is strengthened through both enforcement and transparent administration.

3.2 Sponsorship transfers and "corporate memory loss"

The TGA has identified sponsorship transfers as a recurring driver of unverifiable turnover status, with current sponsors often unable to demonstrate whether entries had $0 turnover before the transfer. The AMA notes sponsor accountability persists where declarations are lodged through third-party agents and supports clear communications reinforcing this responsibility. Guidance should restate the turnover definition (gross receipts excluding GST for Australian sales, excluding exports) to reduce inadvertent error and disputes.

The final framework should explicitly address this risk and include clear expectations about record transfer and retention when sponsorship changes hands. It should also contain guidance about what evidence is acceptable in cases where corporate restructures or acquisitions have occurred. For

example, this could include requiring, as part of transfer documentation and due diligence, that objective turnover/sales evidence (or an agreed evidentiary equivalent) for relevant prior years is transferred between sponsors and is readily available for a compliance review. Where this cannot be provided, the regulator should consider whether the exemption can appropriately continue, or whether additional conditions should apply.

3.3 Record retention expectations and proportionality

The consultation notes sponsors must retain financial and related records for at least five years, and delegates may request information for up to five preceding financial years. The AMA supports record retention as a necessary foundation for a self-declaration model, and recommends the regulator continue to apply a proportionate approach to evidentiary expectations, particularly for older entries and complex corporate histories, while maintaining firm consequences for non-response and deliberate misrepresentation.

3.4 Deterrence settings and clarity on false or misleading declarations

Under the current arrangements, sponsors are reminded false or misleading statements may be referred for prosecution under the Criminal Code, and penalties may range from cancellation of exemptions to prosecution depending on severity. The AMA supports clear deterrence settings and recommends communications about compliance action distinguish clearly between (i) non-response or inability to verify eligibility, and (ii) suspected deliberate false declarations, to ensure proportionality and transparency.

3.5 Compliance monitoring and public reporting

The AMA notes the ACE scheme already includes compliance monitoring arrangements, including the TGA's ability to request evidence supporting $0 turnover declarations and to cancel exemptions where turnover is identified, with deliberate false declarations subject to enforcement action. The proposed amendments are therefore best understood as strengthening the practical consequences where eligibility cannot be verified due to non-response or inadequate substantiation, and the AMA supports periodic public reporting on exemption cancellations and compliance outcomes to reinforce deterrence and confidence in administration.

4. Publication and transparency of exemptions

4.1 Support for continuing publication of exemptions

The AMA supports continued public disclosure of exemptions as an integrity mechanism, consistent with our public support for transparency measures in therapeutic goods regulation. As the TGA has explained, publishing information regarding exempt entries enables third parties to notify the regulator where an exempt entry appears to be supplied in the market. We support the TGA's intention to remake the current instrument scheduled to sunset in October 2026, without changing its scope. Maintaining this disclosure supports confidence in the scheme's administration by improving visibility of exemptions and enabling credible third-party information to be considered where appropriate.

The consultation notes third-party reports are uncommon, but credible reports have resulted in regulatory action and further investigation where warranted (including possible prosecution under the Criminal Code). The AMA acknowledges this can assist compliance where credible information

suggests supply contrary to a $0 turnover declaration; ongoing publication therefore supports integrity while remaining a light-touch transparency measure.

4.2 Accuracy, correction pathways and stakeholder confidence

Consistent with our advice above, the AMA recommends the ongoing publication framework include clear mechanisms for correcting errors and a transparent approach to how the published information is maintained and updated, to preserve confidence for stakeholders who rely on disclosure as a signal of scheme status.

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