TGA Fees and Charges Proposal 2027–28

MTAA Response – November 2026

The Medical Technology Association of Australia (MTAA) thanks the TGA for the opportunity to comment. The TGA's cost pressures are acknowledged, and the proposed 2.58% increase to fees and the 2.37% to 2.49% increase to annual charges are regarded as reasonable and largely unavoidable.

The comments below focus on the proposed temporary additional 5% increase to medical device annual charges (total increases of 7.37% for Class IIa and above, and 7.42% for other medical devices and IVDs) to recover the costs of non-mandatory application audits. MTAA does not support recovering these costs through a broad-based increase to annual charges, for the following reasons:

a) Cost allocation is inequitable

Annual charges apply to all sponsors with existing ARTG entries, but non-mandatory audits arise from new applications selected under the Application Audit Framework. Sponsors with large established portfolios and little or no new application activity would bear additional costs for audits they do not trigger. The increase also applies across all medical device classes, including other medical devices and IVDs, although members' experience is that non-mandatory audits are more commonly associated with higher-risk applications such as Class IIb and Class III. The reasoning for applying the increase across all classes would be appreciated. MTAA understands that the TGA is not currently able to charge a fee for non-mandatory audits, and that work is underway to assess resourcing for audits and the broader review of TGA charging arrangements. Regulatory change as part of that review, such as an audit-specific fee, would be welcome so that audit costs can be linked more closely to the applications concerned.

b) Funding through annual charges risks creating a poor incentive

Recovery through annual charges provides a stable revenue stream that is independent of audit volume. This may unintentionally encourage a higher rate of non-mandatory audits. Under the Application Audit Framework, these audits are intended to be targeted and exceptional, used where there are specific concerns. MTAA seeks assurance that the funding model will not change the frequency or selection criteria for non-mandatory audits. Regular public reporting on the number of audits conducted, the risk factors behind selection, the cost of the activity and the findings would give sponsors confidence that audits remain targeted. Where audits of a particular category consistently identify no issues, a review of the selection criteria would be welcome.

c) Cumulative impact on sponsors

A further above-CPI increase compounds the cost of maintaining ARTG entries, particularly for smaller sponsors, and comes alongside reduced benefits under the Prescribed List. With limited ability to pass these costs on, sponsors may rationalise their portfolios, including cancelling entries for low-volume products that are no longer commercially viable. Some of these products serve small patient populations, so cancellations could affect patient access.

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Considerations

MTAA offers the following considerations for the TGA:

Basis of the 5%

The consultation paper notes that the increase has been calculated from the costs of undertaking non-mandatory application audits. Further insight into the underlying assumptions, such as expected audit volumes and unit costs, would be appreciated to help better understand how the proposed figure has been calculated.

Interim nature of the increase

The paper describes the increase as temporary until the review of TGA charging arrangements is finalised. It would be helpful to have this confirmed in writing, including how the 5% will be treated once new arrangements are in place, so that sponsors are not faced with the same costs recovered twice. Any indication of whether further above-CPI increases are anticipated beyond 2027-28 would also help industry with planning.

Service performance

Sponsors have absorbed successive increases in recent years, including those for digital transformation and UDI, and are now being asked to accept a further above-CPI increase. In that context, an indication of the improvements in service that can be expected with the increased fees and charges would be welcome, including:

- how the additional revenue will be used to support timely application processing, including audits, conformity assessment and variations;
- whether any changes to timeframes or key performance indicators are expected as a result, with reporting against statutory timeframes and any targets set, including audit turnaround times, so that the link between funding and outcomes is visible; and
- confirmation that non-mandatory audits will not extend overall application timeframes, noting the paper's statement that the framework is intended to improve timeliness of access to medical devices.

MTAA appreciates the TGA's consideration of these comments. Members are supportive of a sustainable cost-recovery model for the TGA, and would welcome further discussion on any of the points raised.

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