

Friday, 30 January 2026

The Hon Dr Daniel Mulino MP
Assistant Treasurer, Minister for Financial Services
Parliament House
Canberra ACT 2600
E: prebudgetsubmissions@treasury.gov.au

Dear Assistant Treasurer,

AusBiotech, MTAA, Pathology Technology Australia, the Association of Therapeutic Goods Consultants (ATGC), and Assistive Technology Suppliers Australia Ltd (ATSA), welcome the opportunity to make a pre-Budget submission for the 2026-27 Federal Budget. This submission is focussed on the importance of maintaining public good funding to the Therapeutic Goods Administration (TGA) for activities that cannot be cost recovered under the Australian Government Charging Framework (AGCF).

Recommendation:

For the Federal Government to provide ongoing funding in the 2026-27 Federal Budget to ensure currently available TGA public good services are maintained at current levels.

Importance of public good funding:

The TGA plays a vital role in safeguarding the health of the Australian public. However, its remit has evolved significantly, and now includes a significant amount of ‘public health activities’ that go beyond evaluating, assessing and monitoring medicines and medical devices. Public good funding is used for support services that cannot be cost-recovered, including assistance to small and medium enterprises (SMEs), particularly those developing emerging technologies and devices. This is consistent with the Federal Government’s prioritisation of medical science and commercialisation, including biologics, advanced therapies, medical devices, digital and AI-enabled health, and diagnostics under the National Reconstruction Fund. Examples of other public good services provided by the TGA include adverse event report training for healthcare professionals, and support for non-industry users of the Australian Unique Device Identification (UDI) database.

Current appropriation funding ceases in 2026-27, and without ongoing funding arrangements, resourcing pressures could impact these activities. In a period of intense global competition for biotechnology and medical technology, ensuring our regulatory system is globally competitive and user-friendly for our SMEs is critical to ensuring Australia can continue to benefit from home grown health innovations. Some level of government funding for national health regulators is the norm globally. For example, the TGA’s counterpart in the United Kingdom, the Medicines and Healthcare products Regulatory

Agency (MHRA) receives a comparable level of government funding (MHRA 29% vs TGA 27%). In addition, the regulatory bodies in Canada (Health Canada) and the United States (FDA) receive more than half (52%) of their funding from government sources. Consequently, any reduction in the services offered by the TGA, would create questions regarding Australia's appropriate prioritisation of its health sector.

Public good-funded services are crucial to the life sciences and medical technology sectors, including increasingly complex medical software and innovative medical devices. Guidance and other services provided by the TGA help companies deliver innovations safely and efficiently to the Australian community. Regulatory engagement meetings for medical devices (inclusive of *in vitro* diagnostics), which have expanded beyond traditional pre-submission meetings to include scoping, application support, compliance, and strategic discussions, are particularly beneficial. These meetings help these businesses understand regulatory requirements, improve application quality, and coordinate timelines for inclusion on the Australia Register of Therapeutic Goods (ARTG) – thus ensuring compliance, supporting innovation, and helping Australian businesses bring new technologies to market sooner. Similarly, TGA services were crucial in supporting industry respond to the COVID-19 pandemic, including registration assistance, manufacturing and supply management.

Current appropriation funding ceases in 2026-27 and forward estimates show a reduction in 2027-28 of \$13.9 million in funding for fee-free and public good activities. Given the immense value derived from public good funding, we urge the Federal Government to continue funding at current levels.

Continuation of funding to the TGA is crucial to ensure Australian companies, particularly SMEs, continue to have timely access to regulatory support, guidance and information. We, therefore, urge the Federal Government to provide ongoing funding for the TGA's public good initiatives in the 2026-27 Federal Budget.

Yours sincerely,



Rebekah Cassidy
Chief Executive Officer
AusBiotech



Dean Whiting
Chief Executive Officer
Pathology Technology Australia



Ian Burgess
Chief Executive Officer
MTAA



Serena Ovens
Chief Executive Officer
Assistive Technology
Suppliers Australia



Wendy Free
President
Association of Therapeutic
Goods Consultants



About AusBiotech

AusBiotech is Australia's leading national and global advocate for life sciences, working to help its more than 3000 members thrive by shaping policy, creating connections, and fostering knowledge sharing. With an unrivalled national convening power, AusBiotech supports its members' growth by building an Australian life sciences ecosystem that leads in development and commercialisation, creating high-quality, innovative life sciences companies.

About Medical Technology Association of Australia (MTAA)

MTAA is the peak association representing companies in the medical technology industry. Our members range from Australian start-ups to global MedTech leaders, supplying the majority of non-pharmaceutical products used in the diagnosis, treatment, and management of disease and disability. MTAA works to ensure Australians benefit from innovative, safe, and effective medical technologies—ranging from syringes and implants to advanced imaging and digital health technologies—while supporting clinician education and training, to deliver better health outcomes to the Australian community.

About PTA

Pathology Technology Australia (PTA) is the member-based, peak industry body representing the manufacturers and suppliers of the technology responsible for more than 95% of pathology testing in Australian laboratories, hospitals and the community. Without this technology, efficient diagnosis, treatment, and monitoring of patients could not happen. Increasingly, our members' technology informs a more predictive, preventative, and personalised approach to healthcare, intended to improve patient outcome at a lower total cost to the healthcare system. Technology advancements in Genomics, Proteomics, Biomarkers, Point of Care Testing, and the digital enablers, underpin this transformative opportunity to drive a more sustainable and outcomes-based healthcare model.

About the Association of Therapeutic Goods Consultants

The Association of Therapeutic Goods Consultants Inc is the peak networking body for consultants in Australia and New Zealand, providing technical advice for sponsors and manufacturers of medicines and medical devices for human use.

About ATSA

ATSA is the leading industry body representing the views and aspirations of assistive technology suppliers across Australia to achieve excellence, quality, value and positive outcomes for suppliers, AT consumers, stakeholders and the broader community.