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

Cost Recovery Implementation Statement

2026-2027

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Contents

Introduction

Purpose of the Cost Recovery Implementation Statement

This Cost Recovery Implementation Statement (CRIS) provides information on how the Therapeutic Goods Administration (TGA), within the Department of Health, Disability and Ageing[1] (Department), implements cost recovery arrangements for its regulatory activities. The TGA's regulatory responsibilities include activities related to registering and listing medicines, as well as including medical devices (including in vitro diagnostic (IVD) devices) and biologicals in the Australian Register of Therapeutic Goods (ARTG). It also licences domestic manufacturers of therapeutic goods and oversees the ongoing monitoring and surveillance of these products to ensure their safety and efficacy.

Description of the activity

The TGA protects the health and safety of the community by regulating therapeutic goods for quality, safety, and efficacy. The TGA aims to deliver efficient, best practice regulatory outcomes through international collaboration and reform.

The TGA regulates therapeutic goods through:

- pre-market assessment
- post-market monitoring and enforcement of standards, and
- licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

Therapeutic goods are divided broadly into 3 classes- medicines, medical devices, and biologicals. Medicines must be entered as either 'registered' or 'listed' medicines in the ARTG. Medical devices and biologicals must be 'included' in the ARTG before they may be supplied in or exported from Australia, unless exempted.

If a problem is discovered with a medicine, device, biological or manufacturer, the TGA can act. Possible regulatory actions vary from continued or heightened monitoring, to withdrawing the product from the market and revoking or cancelling a manufacturing licence.

Additionally, the TGA undertakes a range of public health activities which serve broader public good interests. These activities are discussed in more detail below.

Risk management approach to regulation

All therapeutic goods carry potential risks, from minor to potentially serious. The TGA applies scientific and clinical expertise to its decision making to establish that the benefits of a product outweigh any known risk. The level of regulatory control increases with the level of risk a medicine or medical device presents. This risk-benefit approach assures consumers that the products they take are appropriate for their intended use, while still providing access to products that are essential to their health needs.

[1] The TGA contributes to Health, Disability and Ageing's Outcome 1: Health Policy, Access and Support - Program 1.8: Health Protection, Emergency Response and Regulation

Industry/regulatory groups

The TGA's cost recovery arrangements cover the following industry sectors:

- prescription medicines
- over the counter medicines
- complementary medicines
- medical devices, including IVD devices
- blood, blood components and biologicals, and
- good manufacturing practice (GMP)[2].

The TGA provides several fee-free services for the public good, some of which do not directly relate to any product or industry group. The costs of undertaking these types of activities cannot be appropriately recovered from a particular sponsor or industry group. The costs of these services are met through government funding. While the TGA receives on-going funding for meeting the costs of certain public good activities, such as registration of orphan drugs and patient access to unapproved goods, on occasions it also receives time-limited funding for emerging issues, health emergencies, pandemic measures or other regulatory activities where cost recovery is not appropriate. In 2026-27, around 74% of funding will be generated through fees and charges set under the cost recovery arrangements.

[2] While not a separate industry sector, reporting separately on GMP activities provides greater transparency to stakeholders.

Government policy approval and statutory authority to cost recover/ charge

In the 1997–98 Budget, Budget Paper No.2, and Part II: Revenue Measures it was determined that from 1998-99 the TGA would fully recover all costs of its activities covered under the *Therapeutic Goods Act 1989* (the Act) from industry.

The Act provides legal authority for the TGA to charge for its activities within the scope of the Act. The *Therapeutic Goods (Charges) Act 1989* (the Charges Act) provides a legal authority to levy annual charges (a type of tax) on sponsors and manufacturers of medicines, medical devices and biologicals. Applicable fees and charges are prescribed in the subordinate regulations made under these Acts.

In the 2019-20 Mid-year Economic & Fiscal Outlook (MYEFO) as part of an ongoing measure, Improving Access to Medicines, Item 7, the Government announced funding of $33 million over 4 years for the TGA, with $15 million per year ongoing from 2022-23. This funding goes towards meeting costs of the Orphan Drugs program, mandatory reporting of shortages of critical medicines, and the Special Access Scheme and Authorised Prescribers Scheme, without needing to cost recover these programs.

In the 2023-24 Budget the Government provided $61 million over 4 years (see table below) for meeting costs of the TGA's public good activities where cost recovery was not considered appropriate, such as:

- compliance and enforcement for products and companies outside the regulatory system
- managing medicine and medical device shortages
- providing information to consumers and healthcare professionals, and
- continued assistance to small and medium enterprises in the sector, particularly those developing emerging technologies.

	2023-24 $'m	2024-25 $'m	2025-26 $'m	2026-27 $'m	Total $'m
Department of Health, Disability and Ageing	14.979	15.214	15.332	15.467	60.992
Total	**14.979**	**15.214**	**15.332**	**15.467**	**60.992**

Since the 2023-24 MYEFO, the Government has progressively provided funding to the Department for vaping regulation reform work, a portion of which has been provided to the TGA.

Cost recovery model

A: Pre-market regulatory activities for therapeutic goods

1. Prescription medicines

Medicines are grouped into schedules according to the appropriate level of regulatory control over their availability to consumers. Higher risk medicines, such as prescription medicines, must be registered in the ARTG before they can be made available for supply in Australia. Certain prescription medicines can be provisionally registered for a period of time. The requirements for a provisional registration of prescription medicines are set out in the Act. Prescription medicines are available from a pharmacist, supplied with a prescription from an appropriate registered health practitioner. Otherwise, only authorised health care professionals can supply prescription medicines, such as in a hospital setting, aged care setting and some community health centres. Examples include vaccines, blood pressure tablets, diabetes medications, antibiotics and strong painkillers.

There are some legal exemptions to the requirement for a prescription medicine to be registered in the ARTG before they are supplied in Australia. These include the:

- Special Access Scheme (SAS)
- Authorised Prescriber Scheme (AP), and
- Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) Schemes

Prescription medicines supplied in Australia must be manufactured in accordance with Good Manufacturing Practice (GMP) to ensure the quality, safety and efficacy of the product.

Regulatory framework

TGA scientific and technical website content is maintained according to the Australian Government website standards, and in line with legislative requirements for regulatory decision making.

International regulators, or regulator groups such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, publish guidelines that may be adopted by the TGA.

Registration in the ARTG

Before being placed in the ARTG, prescription medicines are assessed for quality, safety and efficacy. Most prescription medicines are registered through the standard registration pathway. As part of the implementation of several regulatory reforms in 2017-18 the TGA implemented “provisional” and “priority” pathways for registration of certain prescription medicines, provided they meet the legislative criteria.

Applications

All applications for registration of prescription medicines must be preceded by a pre-submission planning form (PPF). The TGA assesses all PPFs to ensure that application dossiers for registration in the ARTG contain all the appropriate and required information. The information provided in the PPF allows resources to be effectively assigned to the evaluation process. If the PPF is insufficient for planning purposes or indicates that mandatory requirements have not been met, the TGA may deem the PPF to be ‘not effective’ and the application will not proceed to the dossier submission stage. The PPF submission process improves the quality of applications and helps in meeting legislative timeframes.

Data evaluation

The data submitted with an application is divided into 3 types:

- quality data evaluated by chemists, biochemists, microbiologists and other TGA officers, which includes:
  - composition of the drug substance and the drug product
  - batch consistency
  - stability data
  - sterility data (if applicable)
  - impurity content
  - non-clinical data evaluated by toxicologists
  - pharmacology data
- toxicology data
- clinical data evaluated by a medical doctor (mostly results of clinical trials)

Decision making

Before making a decision around the suitability of a prescription medicine for registration in the ARTG, the delegate may consider independent expert advice provided by the Advisory Committee on Medicines.

Regulatory decisions in relation to new chemical entities or fixed dose combination products are published through the Australian Public Assessment Report.

Any person whose interests are affected by the decision may seek a reconsideration of the decision under section 60 of the Act.

Applications to change details of registration

Once a product has been registered, the sponsor can make further applications to change the details of registration. Examples of the types of changes that might be applied for include:

- a change in manufacturer
- an increase in shelf-life
- a change in patient population (e.g. allowing children to use the medicine)
- a change to the intended use (usually adding an extra medical condition that can be treated).

Changes may or may not require evaluation of data by the TGA, and the prescribed fees apply accordingly. Certain low risk changes to the details of registration can be made through the notification system implemented in 2017-18.

Export

While medicines for export from Australia must be of a similar quality and safety standard as those supplied domestically, they are not required to comply with the labelling standards or advertising requirements of Australia. Export-only medicines are required to be listed (not registered) in the ARTG before export.

2. Over the counter medicines

Over the counter (OTC) medicines are defined in the Therapeutic Goods Regulations 1990 (the Regulations). OTC medicines can be supplied as pharmacy medicines, pharmacist-only medicines and general sales medicines. Registered OTC medicines are lower risk than prescription medicines, but still require an appropriate level of scrutiny.

OTC medicines can be purchased for self-treatment from pharmacies, with selected products also available in supermarkets, health food stores and other retailers. Examples include cough and cold remedies, anti-fungal treatments, sunscreens, and non-prescription analgesics such as aspirin and paracetamol.

OTC medicines can be registered or listed in the ARTG depending on the level of risk associated with making the product available and accessible to consumers.

Registering an OTC medicine in the ARTG

Registered OTC medicines are considered higher risk than listed OTC medicines, based on their substances or the indications made for the medicine.

The pre-market regulatory processes for OTC medicines include:

- lodging an application for inclusion of a product in the ARTG via registration or listing
- administrative and technical screening
- scientific evaluation
- label assessment

- ensuring appropriate GMP is in place
- requesting advice from the Advisory Committee on Medicines
- advising the sponsor of the outcome of the application process, and
- updating the ARTG.

Listing an OTC medicine in the ARTG

The listing process for an OTC medicine is the same as listing a complementary medicine, which is described below.

3. Complementary medicines

Medicinal products containing ingredients such as herbs, vitamins, minerals, nutritional supplements, homoeopathic and certain aromatherapy preparations are referred to as 'complementary medicines' and are regulated as medicines under the Act. Complementary medicines may be either listed or registered, depending on their ingredients and the claims made for the medicine. Most complementary medicines are listed in the ARTG.

Listing a complementary medicine in the ARTG

Listed medicines are low risk medicines that are listed in the ARTG. There are 2 pathways to list a medicine in the ARTG.

Firstly, medicines can be listed via a streamlined electronic listing facility following self-certification by the sponsor of the safety, quality, and efficacy of the product. Under this process, the sponsor is required to select the indications for their medicine from the list of permitted indications that is maintained by the TGA. This process allows for early market access for the lowest risk complementary medicines.

Unlike other medicines, there is no evaluation of these products prior to the medicine being listed in the ARTG. To be eligible for this pathway a medicine must only:

- contain certain low risk ingredients in acceptable amounts that are permitted for use in listed medicine
- make therapeutic claims for health maintenance and health enhancement or certain indications for non-serious, self-limiting conditions, and
- be manufactured in accordance with the principles of GMP.

Secondly, medicines can be listed in the ARTG following sponsor certification of the safety and quality of the product, coupled with TGA assessment of the evidence of efficacy supporting the proposed indication(s). This pathway, commonly known as ‘Assessed Listing Pathway’, allows sponsors to apply for indications that fall outside the permitted indications list. In all other respects, the medicine meets the current eligibility criteria for listed medicines in that it contains only permitted ingredients and meets required quality and manufacturing standards. A proportion of listed complementary medicines are reviewed following their listing for compliance with the regulatory requirements. Applications can be made for evaluation of new substances proposed for suitability for use as an ingredient in listed medicines. New approved ingredients are added to the permitted ingredients list.

Registering a complementary medicine in the ARTG

Registered complementary medicines are higher risk than listed complementary medicines, based on their substances or the therapeutic claims made for the medicine. Registered complementary medicines, like all registered medicines, are fully evaluated for quality, safety and efficacy prior to being included in the ARTG and supplied.

4. Medical devices

The Australian medical devices regulatory framework sets requirements for the safety and performance of medical devices, in a series of Essential Principles. Manufacturers and sponsors must demonstrate their medical devices comply with the Essential Principles. The extent of assessment required to demonstrate compliance with these principles is based on the risk classification of the device, with higher risk devices undergoing greater assessment prior to being approved for supply to the Australian market.

To recover costs of pre-market and post-market regulatory activities, there are several fees and charges for medical devices. These include annual charges, application fees, conformity assessment fees and application audit fees.

Applications to include medical devices in the ARTG

Under the Act, medical devices must be included in the ARTG prior to supply in Australia, unless an exemption applies, including under sections 41HA, 41HB or 41HC of the Act. The level of assessment at the point of application for ARTG inclusion depends on the device's risk classification, the conformity assessment evidence provided, and whether any concerns with the application require the TGA to request further information before inclusion.

High-risk medical devices must have an ARTG entry for each device model, also known as unique product identifier. Lower risk devices can have multiple similar devices included under one ARTG entry, as a 'kind of medical device'. As the application fee is payable per ARTG entry, and the value of the fee is higher for higher risk medical devices, the overall costs associated with higher risk medical devices are greater.

Approval for each medical device is exclusive to the sponsor applying for inclusion. While approval for one sponsor cannot be used by other sponsors, even where the medical device is identical, devices can be distributed by multiple distributors on behalf of the same sponsor.

All medical devices must comply with regulatory requirements for safety, performance, design, construction and labelling. Medical devices are regulated using a risk-based classification framework. Manufacturers must demonstrate compliance through appropriate regulatory evidence, with requirements increasing according to the device risk classification. Manufacturers must demonstrate compliance through conformity assessment, including assessment of their quality management system for higher risk devices. Conformity assessment evidence for higher risk devices may be issued by the TGA or by recognised comparable overseas regulators or assessment bodies.

In addition to the requirement to provide a conformity assessment document with an application for ARTG inclusion, the application process may also involve an assessment of other information as required by the TGA.

Application audits

Some applications for inclusion of medical devices in the ARTG will undergo an audit assessment:

- applications to include certain medical devices in the ARTG must be selected for an application audit. For these mandatory audits an application audit assessment fee is charged. There are 2 levels of application audit for non-IVD medical devices and one level of application audit for IVD medical devices
- TGA may also select any other application for inclusion for an audit. An audit assessment fee is not charged for these audits.

If an application audit is to be conducted, the TGA determines what level of assessment is appropriate for each application audit.

Conformity assessment

A conformity assessment is a systematic and ongoing examination of evidence and procedures to ensure that manufacturers of medical devices have systems and processes that provide assurance of conformity to the Essential Principles for quality, safety and performance.

A manufacturer must implement and maintain a post-market monitoring system for devices after supply, with reportable events reported as specified in the Regulations. A manufacturer's quality system certification may be subject to periodic surveillance audits.

For the majority of medical devices and IVDs, the TGA accepts documents issued by the assessment bodies or overseas regulators. These documents provide evidence that that body has assessed the manufacturer's compliance with the conformity assessment procedures or procedures comparable to conformity assessment and found it to be acceptable. As the Australian and the European Union (EU) regulatory requirements are similar, many manufacturers of medical devices authorised for supply in Australia have EC Certificates issued by EU Notified Bodies. Many manufacturers rely on certification under the Medical Devices Single Audit Program (MDSAP).

Manufacturers may choose to seek a conformity assessment certificate from the TGA, rather than relying on overseas certification. There are different fees for various types of TGA conformity assessment certificate applications and for surveillance audits.

Export

Sponsors wanting to export medical devices from Australia must meet regulatory requirements set out in the legislation. Before a sponsor can export a medical device from Australia, the device must:

- be included in the ARTG, or
- be exempt from registration.

A medical device that is intended by the manufacturer to be for export only is classified as a Class I medical device, for which there is no requirement for the manufacturer of such device to have a certification or approval issued by an assessment body or regulator. The labelling or packaging of such devices should contain the words 'for export only'. Export only medical devices are still required to comply with the Essential Principles.

If a medical device is imported or manufactured and supplied in Australia, and exported from Australia, the device is classified in accordance with the classification rules provided in Schedule 2 or 2A of the Therapeutic Goods (Medical Devices) Regulations 2002.

5. Other therapeutic goods listed in the ARTG

A small number of other therapeutic goods that do not meet the definition of a medical device, medicine or biological are regulated under Chapter 3 of the Act. These devices do not need to be listed in the ARTG and include tampons, menstrual cups, and hard surface disinfectants without specific claims. Hard surface disinfectants with specific claims do need to be listed in the ARTG and sponsors need to pay fees and charges for those products.

6. Biologicals

Biologicals include human tissue and cell therapy products. Tissue therapy products involve the use of tissues as therapeutic goods, while cell therapy products involve the use of isolated living cells either as therapeutic goods or as replacements for cells that are defective or deficient in particular disorders.

Some examples of tissue therapies currently being used are:

- skin replacement after severe burns
- transplantation of heart, kidney, liver, lung or pancreas
- bone, tendons and ligaments to repair injuries
- heart valves to replace defective heart valves, and
- corneas to restore eyesight.

Some examples of cell therapies currently being used, or currently under development, are:

- chondrocytes used for cartilage regeneration

- isolated pancreatic islet cells for the treatment of diabetes, and
- mesenchymal progenitor cells for the treatment of musculoskeletal defects and in a range of other clinical applications such as cardiovascular repair.
- Inclusion in the ARTG
- The regulation of biologicals involves the following registration and approval activities:
- sponsors of Class 1 biologicals are required to attest compliance with relevant mandatory standards
- Class 2, 3 and 4 biologicals undergo pre-market evaluation prior to ARTG inclusion
- highly manipulated Class 3 and 4 biologicals are subject to the highest levels of pre-market evaluation, and
- manufacturers of Class 2, 3 and 4 biologicals are required to demonstrate compliance with manufacturing principles equivalent to the Australian Code of Good Manufacturing for human blood and blood components, human tissues and human cellular therapy products (2013).

7. Blood and blood components

Blood, blood components and plasma derivatives are regulated under the Act:

- 'blood' means whole blood extracted from human donors, and
- 'blood components' means therapeutic components that have been manufactured from blood and includes red cells, white cells, progenitor cells, platelets and plasma.

'Blood components' does not include products derived through the fractionation of plasma. Plasma derivatives are prescription medicines subject to full regulation, including compliance with set standards, licensing of manufacturers and inclusion in the ARTG after review of manufacturing, pre-clinical and clinical data.

Some blood and blood components are exempt from regulation, including those:

- collected by a medical practitioner in the course of medical treatment and for the purposes of diagnosis or testing for a medical condition
- manufactured by a medical practitioner for therapeutic application to a particular patient under the practitioner's care, or
- manufactured by a blood collection centre for a medical practitioner for therapeutic application to a particular patient under the practitioner's care.

8. Patient access to unapproved therapeutic goods

There are circumstances where patients may require access to certain medicines or medical devices that have not been approved for supply in Australia. Under the Act, access to unapproved goods is available to patients under 2 main schemes:

a) Special Access Scheme

The Special Access Scheme (SAS) provides for the import and/or supply of an unapproved therapeutic good for a single patient, on a case-by-case basis. There are 3 categories under the scheme:

- **Category A** is a notification pathway which can be accessed by a prescribing medical practitioner or a health practitioner on behalf of a prescribing medical practitioner for patients who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.
- **Category B** is an application pathway which can be accessed by health practitioners for patients who do not fit the Category A definition and where the unapproved good is not deemed to have an established history of use and cannot therefore be accessed through

Category C. An approval letter from TGA is required before the good may be accessed. Approvals for medicines accessed through this pathway are typically only issued to medical and dental practitioners.

- **Category C** is a notification pathway which allows health practitioners to supply goods that are deemed to have an established history of use without first seeking prior approval. The goods deemed to have an established history of use are specified in a list along with their indications and the type of health practitioner authorised to supply these products for the respective indications.

b) Authorised prescribers

A medical practitioner may be granted authority to become an Authorised Prescriber (AP) of a specified unapproved therapeutic good, or class of unapproved therapeutic goods, to specific patients, or classes of recipients, with a particular medical condition. Following TGA assessment of an application, the medical practitioner becomes an AP and can prescribe that product for that condition to multiple patients in their immediate care without further TGA approval.

The TGA does not charge a fee to the users of these services. They are provided free of charge to enable timely access to unapproved medicines or medical devices essential for treating a terminally ill patient in highly time sensitive situations, or where the health practitioner feels there are no approved and available options to treat their patient's condition for their specific circumstances. It is in the public's interest to save a life or alleviate suffering through timely access to critical therapeutic goods, where possible.

The fee waiver is consistent with the Regulations as they do not provide for charging of applications under these two schemes.

In 2024-25, there were 38,167 SAS Category A notifications, 235,276 SAS Category B applications, 95,801 SAS Category C applications, and 22,437 AP applications. The annual cost of these fee-free services is estimated to be $8.8 million, or around $23 per application/notification. Cost recovery of this through an application fee levied on patients and/or medical practitioners is unlikely to be cost-efficient. Moreover, such a process would impact time critical access to these products for seriously ill patients. Cost recovery for these activities is therefore not considered appropriate, and the costs are met through government funding.

9. Orphan drug program

The TGA's orphan drug program is an activity undertaken for the public good, with the objective of assisting sponsors to bring medicines for rare diseases or new dose forms for special patient populations to market that may otherwise not be available. A medicine may be eligible for orphan drug designation if all orphan criteria prescribed in regulations 16J (3) or 16J (4) of the Regulations are satisfied.

The orphan drug program is part of a global movement to promote treatment of approximately 7,000 rare diseases. This incentive is provided by the TGA in the form of a fee waiver. Under regulation 45 (12) of the Regulations, application and evaluation fees for the assessment of orphan drugs are not charged by the TGA, but the quality, efficacy and safety of orphan drugs are assessed to the same standard as for other registered medicines. Once an orphan drug is entered on the ARTG, the annual charge is payable subject to the annual charge exemption (ACE) scheme.

In 2024-25, the TGA assessed 28 orphan drug applications. The total cost attributed to the orphan drug program was $7 million in foregone revenue. The costs of the orphan drug program are met through government funding.

B: Compliance, monitoring and enforcement

The TGA's compliance and enforcement activities are governed by the TGA Compliance Principles and the Regulatory Compliance Framework, which together set out a risk-based, intelligence-led approach to monitoring, compliance and enforcement across all regulated therapeutic goods activities.

These frameworks guide the TGA to apply regulatory powers in a manner that is evidence-based, proportionate and directed to areas of greatest risk to public health and regulatory integrity, while promoting a fair and compliant therapeutic goods market.

The TGA monitors compliance with, and enforces where necessary, the legislation, regulations and rules relating to the import, export, manufacture, advertising and supply of therapeutic goods to protect consumers and maintain confidence in the regulatory system.

Risk-based compliance and monitoring

Australians have the right to expect that therapeutic goods meet acceptable standards of safety and quality.

One of the TGA's core roles is to regulate therapeutic goods based on a scientific and clinical assessment of the evidence of both the risks and the benefits of a product. While risks cannot be wholly eliminated, the TGA manages them to ensure their impact on public health is kept at an acceptable level.

This risk-based approach underpins both pre-market regulatory assessment and post-market monitoring and compliance activities, ensuring resources are directed to areas of greatest potential harm.

The TGA applies a risk-based approach to monitoring and compliance activities, prioritising risks based on the nature and severity of potential harm, including:

- direct harm from a product, including its use or promotion
- indirect harm arising from misleading or inaccurate information delaying or replacing appropriate medical care, and
- systemic risks to confidence in the regulatory framework and therapeutic goods market.

These activities ensure that regulatory effort is targeted to areas of highest risk and supports timely and proportionate intervention to reduce harm.

Approach to surveillance

The TGA employs a combination of proactive and reactive surveillance strategies, including acting on signals and reports of non-compliance from a number of external sources.

All identified signals of non-compliance are recorded, assessed and prioritised using intelligence-led triage processes to determine risk, priority and appropriate response pathways.

Monitoring activities are supported by data analytics, digital surveillance, including online environments, and intelligence from stakeholders and partner agencies to identify emerging risks and inform regulatory responses.

Approach to compliance and enforcement

A range of compliance and enforcement tools are employed to address alleged non-compliance and to encourage compliance with the Act. The TGA publishes information on its website about its compliance and enforcement tools, as well as regulatory compliance activities and the outcomes of compliance actions.

Regulatory education for industry

The TGA provides regulatory education to market-entry applicants and information to Small and Medium Enterprises (SMEs) prior to market entry, to minimise the risk and likelihood of non-compliance. The majority of stakeholders comply with regulatory requirements. Through engagement with the TGA, stakeholders develop a clearer understanding of their regulatory obligations, supporting voluntary compliance and reducing the likelihood of non-compliance.

Prioritisation of compliance and enforcement matters

The TGA takes all referrals and complaints seriously and, consistent with the Regulatory Compliance Framework, assesses and prioritises compliance activities based on the level of risk and potential harm to public health. While not all matters can be pursued, a structured, intelligence-led and risk-based framework is applied to ensure resources are directed to areas of greatest impact. These prioritisation processes support consistent decision making across compliance activities.

In deciding on a course of action the following will generally be considered:

- seriousness of the alleged non-compliance and failure to follow the regulatory requirements
- risk of harm or injury related to a product itself, including the way in which a product is used or being promoted for use
- indirect risk of harm from reliance on misleading or inaccurate information in lieu of seeking professional health care advice and treatment
- compliance history and behaviour of the responsible person or business, and
- level of compliance of the industry sector.

Compliance actions aim to address unsafe or non-compliant goods and maintain confidence in the regulatory system.

Compliance efforts are directed toward high-risk products, behaviours and sectors, including emerging risks and areas of low voluntary compliance, ensuring an agile and timely response to high-impact issues.

Other agencies

The TGA works with domestic and international partners where appropriate to support its monitoring and compliance functions. This includes regulatory, border and law enforcement agencies and supports coordinated responses, information sharing and joint investigations to address complex or jurisdictional risks.

Therapeutic Goods Advertising

From 1 July 2018, the TGA became the single body responsible for handling complaints about therapeutic goods advertising to the public. It considers complaints about advertisements for medicines, medical devices and other therapeutic goods across a range of media, including broadcast and mainstream print media, billboards, cinema films, and the internet.

Where a complaint about a product advertisement is received, the TGA will assess the validity of the complaint and, if necessary, ensure that appropriate corrective and compliance action is taken.

Advertising Education

The TGA provides education to advertisers, consumers, health professionals and industry to promote voluntary compliance with advertising requirements. These activities support understanding of obligations and contribute to improved compliance outcomes.

Education activities assist advertisers to apply the advertising requirements by providing information that:

- raises awareness of their legal obligations
- helps advertisers understand how to comply and meet their obligations, and
- keeps advertisers updated on changes to the requirements.

C: Regulation of manufacturers of therapeutic goods

Good manufacturing practice

Australian manufacturers of medicines, blood and biological therapeutic goods are required to hold a GMP licence. To obtain the licence, a manufacturer must demonstrate that they have the ability to comply with the relevant Codes of GMP, and appropriate facilities to manufacture safely. Overseas manufacturers of therapeutic goods supplied to Australia must provide evidence of compliance with equivalent GMP standards or otherwise undergo on-site inspections in the same manner as manufacturers based in Australia.

GMP is a generally accepted term internationally, describing a set of principles and procedures that, when followed by manufacturers of medicines and biologicals, helps to ensure that the products manufactured will possess the required quality.

GMP related regulatory activities

Licensing

The TGA usually undertakes inspections of Australian manufacturers prior to the issue of a licence to ensure that the manufacturer can comply with the manufacturing principles set under the Act and has suitable premises to undertake the proposed manufacturing steps. Inspections may be conducted on-site or remotely. The extent of the inspection depends on the size and complexity of the manufacturing processes.

The TGA participates in international harmonisation activities to ensure that GMP requirements applied in Australia are best practice.

Monitoring GMP compliance

The TGA has an ongoing program to verify the suitability of manufacturers to produce therapeutic goods for supply in Australia. The TGA undertakes periodic planned and unplanned inspections of manufacturers to assess the level of compliance with the applicable manufacturing standards, both domestically and overseas. The level and frequency of inspections for a particular manufacturer is influenced by its size and complexity but also by its compliance history. In particular, manufacturers with a history of lower levels of compliance are subject to a higher frequency of on-site inspections, compared with more compliant manufacturers. This helps to ensure that therapeutic goods supplied in Australia are of appropriate quality and allows TGA to take appropriate regulatory action where safety concerns are identified.

D: Clinical trials

The TGA is responsible for 2 schemes providing access to unapproved medicines, biologicals and medical devices for patients participating in a clinical trial:

a. **CTN Scheme** involves a notification only with a notification fee. No approval or decision is made by the TGA under this scheme

b. **CTA Scheme** involves a sponsor applying to seek approval to supply 'unapproved' therapeutic goods in a clinical trial. Where there are changes to approved clinical trials, the sponsor is required to seek approval for these variations. The applications must be accompanied by the prescribed fee.

The routine Good Clinical Practice (GCP) inspection program was implemented for medicines and biologicals in the 2021-22 financial year. The GCP program allows the TGA to verify compliance of clinical trial sites with Australian legislation and guidelines. The program aims to strengthen the TGA’s monitoring activities and protect the safety and wellbeing of clinical trial participants.

Design of cost recovery charges

Costs of TGA activities

In line with the Australian Government Charging Framework (AGCF), costs are categorised into the following groups for cost allocation:

a. **Direct costs** can be easily traced to a cost object[3] with a high degree of accuracy. The allocation of direct costs to a cost object is relatively straightforward. The most common direct costs are staff salaries which includes on-costs such as training, superannuation and leave, and supplier costs such as contractor costs.

b. **Indirect costs** are the costs that cannot be easily linked to a cost object or for which the costs of tracking outweigh the benefit. Indirect costs are apportioned to a cost object using the internal costing methodology. Common indirect costs include

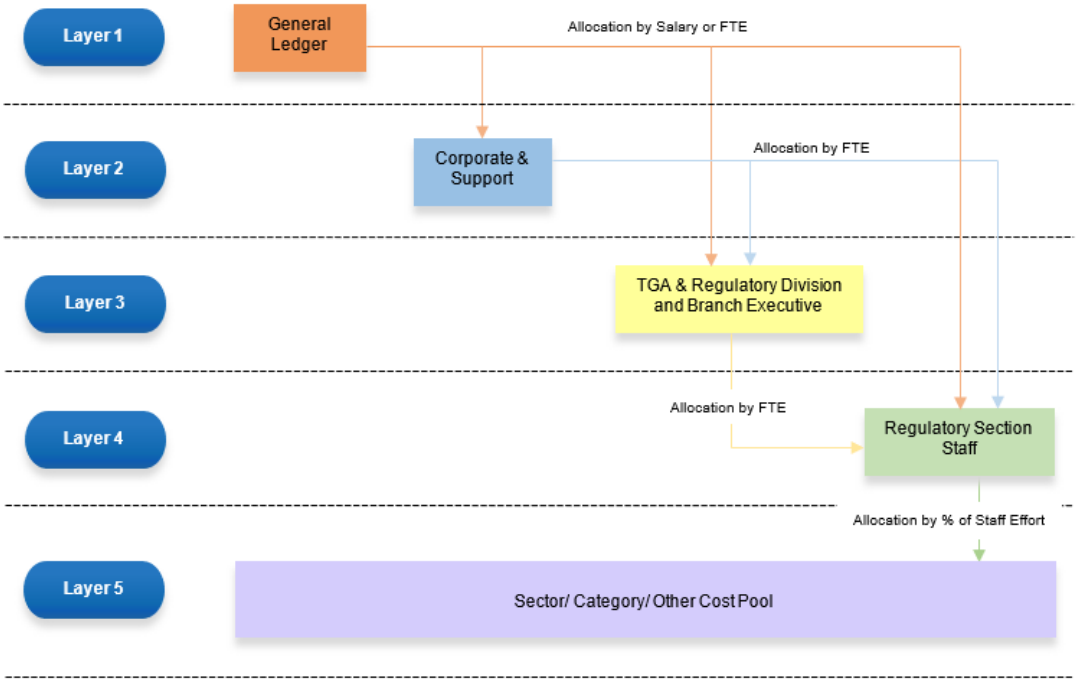
   i. overhead costs such as corporate costs including finance, human resources, IT, office accommodation, and

   ii. salaries of staff in support areas such as regulatory practice and support functions.

While most capital assets are funded through the TGA cash reserves, depreciation and amortisation costs are included in costings as indirect costs. This cost is also taken into consideration in the bottom-up costing for new items of fees and charges.

A software solution is used for activity-based costing (ABC). The staff work effort, captured through a work effort survey, attributes the time of regulatory effort to each regulatory activity and determines the direct cost. Indirect costs are allocated to regulatory activities based on full-time equivalent (FTE) allocated to each cost object.

The diagram below depicts the current cost model attributing direct and indirect costs to TGA activities.



[3] A specific process, output or activity to which costs are assigned.

Fees and charges

The characteristics of a government activity determine the type of cost recovery charge used. There are 2 types of cost recovery charges:

a. **Cost recovery fees:** Fees are charged when a good, service or regulation, in certain circumstances, is provided directly to a specific individual or organisation. Fees are used to recover the cost of the pre-market services performed. Fees are designed to reflect as closely as possible the underlying cost of service. TGA has limited authority under the Act to waive or reduce fees.

b. **Cost recovery levies:** Charges are imposed when a good, service or regulation is provided to a group of individuals or organisations, such as an industry sector, rather than to a specific individual or organisation. A cost recovery levy is a tax and is imposed via a separate taxation Act. It differs from general taxation as it is 'earmarked' to fund activities provided to the group which pays the levy.

Other than for export only products, all therapeutic goods registered, listed or included in the ARTG are subject to annual charges, a type of levy. Annual charges are used to recover the costs of pharmacovigilance and other post market monitoring and compliance activities, where:

- they cannot be reasonably assigned to individual sponsors, and
- revenue generated through levies is earmarked to the activity provided to the group of levy payers.

Different levels of post-market monitoring are required for different classes of therapeutic goods depending on the level of risk the good could pose. Annual charges have been set to reflect the level of post-market and associated costs required for the regulated good, rather than the size of the individual business. For example, the 2026-27 annual charge for a Class I medical device is $121, whereas a high-risk biological has an annual charge of $10,022.

2026-27 Fees and Charges

Every year, the TGA reviews its budget outlook and considers possible changes to fees and charges for the following financial year. Over the past decade, increases have generally been limited to a composite indexation factor based on the Wage Price Index (WPI) and Consumer Price Index (CPI). While this has provided consistency and predictability for industry, it has not kept pace with the TGA's underlying and increasing cost pressures.

As a result, revenue has not kept pace with known and growing cost pressures. Over time, this has led to ongoing deficits and a steady reduction in cash reserves. While the TGA has mitigated this through efficiencies and cost savings, these measures alone are no longer sustainable as a long-term solution. This reflects a broader issue where cost-recovered revenue is not keeping pace with the true cost of delivering regulatory services.

2026-27 cost pressures

At the time of development of the 2026-27 fees and charges proposal, overall costs were estimated to increase by $13.6 million, of which $11.3 million relates to cost recovered activities and $2.3 million to government funded activities. This includes increase in salary and staff-related costs, and corporate costs. The single largest component of the TGA costs is salary, contractor and other staff-related costs. Employee costs were estimated to increase by $6.9 million for the 2026-27 financial year, mainly related to the 3.4% pay increase from March 2026 through the Department's Enterprise Agreement. This also includes leave provision increases, and staff pay increments which are due in July 2026.

Corporate costs were estimated to increase by $6.6 million, due to an indexation-based increase to the chargeback payment and an increase in the proportion of departmental staff who work at the TGA.

Laboratory maintenance costs are projected to rise by $0.1 million. Ongoing investment in laboratory infrastructure is critical, including equipment servicing, calibration and upgrades. This is essential to ensuring compliance with advancing scientific and regulatory requirements and maintaining our capability to uphold regulatory integrity and public safety.

Indexation factor

The indexation factor for 2026-27, based on the previously used formula of the average (composite indexation) of the CPI and the WPI, was 3.3%:

- 50% of CPI Sep 2024 to Sep 2025: 3.2%: 1.6%
- 50% of WPI Sep 2024 to Sep 2025: 3.4%: 1.7%

Options for changes to fees and charges

The approach to indexation-only increases is now considered financially unsustainable for the TGA. In this context, 2 options were developed and presented during stakeholder consultation for changes to TGA fees and charges for 2026-27. The options were designed to balance financial sustainability with the need to manage impacts on industry, and to provide transparency on the trade-offs between full cost recovery and more moderate increases.

Option 1 proposed full recovery of known cost increases for 2026-27, requiring increases of 4.8% in fees and approximately 6.1-6.3% in annual charges. This comprised the standard indexation of 3.3%, alongside an additional increase, to fully recover identified cost pressures. Under this option, the TGA's fees and charges were more closely aligned with the efficient cost of delivering regulatory activities. While this option results in higher increases for sponsors and manufacturers, it will prevent further deterioration of the structural deficit, maintain cash reserves, and support the TGA's ability to deliver timely and effective regulatory services.

Option 2 proposed partial recovery of known cost increases for 2026-27, requiring a 4.3% increase to fees and charges in 2026-27. This comprised the standard indexation of 3.3%, alongside an additional increase of 1% applied across both fees and annual charges. Under, this option, the TGA would have only partially recovered known cost increases, leaving a projected shortfall of $2.3 million in 2026-27. While it is recognised that this reduces the immediate financial impact on industry, it would have resulted in an ongoing funding gap, requiring further savings and efficiencies. Over time, this would worsen the structural deficit, and constrain the TGA's ability to sustain regulatory capability and deliver services in line with legislated and expected standards.

Stakeholder feedback acknowledged the financial pressures facing the TGA and the need to maintain a well-functioning regulatory system, while also highlighting concerns about affordability and cumulative increases in fees and charges over time.

Both options were provided to Government to allow a clear choice between fully addressing the funding gap now or continuing with a more gradual approach. Option 1 showed what was required to bring revenue back in line with costs and stabilise the TGA's financial position in 2026-27. Option 2 showed the impact of keeping increases lower, including the remaining shortfall and pressure on cash reserves.

Government decision

A Government decision was made to implement Option 1 for 2026-27. This approach fully recovers identified cost pressures in accordance with the AGCF and prevents further deterioration of the structural deficit. The decision also supports the maintenance of cash reserves and ongoing delivery of regulatory activities. In summary, to fully cost recover the $11.3 million of projected additional costs for cost recovered activities in 2026-27, the increases to fees and charges are:

a) All fees - 4.8%, comprising 3.3% relating to indexation, and an additional 1.5% increase
b) All annual charges - 6.4%, comprising 3.3% relating to indexation, and an additional 3.1% increase.

In applying the indexation factor to annual charges, additional increases included in 2023-24 and 2024-25 for cost recovery of the TGA's digital transformation program and the Unique Device Identification (UDI) system were excluded from the base. As a result of this, effective indexation increases to annual charges are slightly lower than the indexation factor.

The table below summarises the increase to TGA fees and charges for 2026-27:

Changes to fees and charges in 2026-27		Increase
All TGA fees		4.80%
Charges	Medicines and Biologicals Annual Charges	6.30%
	Medical Devices Class II and above	6.10%
	Other Medical Devices and IVD annual charges	6.20%
	Manufacturing licences and Other therapeutic goods (OTG)	6.30%

Reduced fees for UDI-specific Consents to Supply applications

In addition, the Government approved a reduction in the fee for Unique Device Identification (UDI)-specific Consent to Supply applications. This better aligns the fee with the efficient cost of assessment, and supports implementation of the UDI framework.

Compliance with the *Therapeutic Goods (Medical Devices) Regulations 2002* Unique Device Identification (UDI) requirements commences on 1 July 2026 for Class III and IIb medical devices, with compliance for lower device classes required in the following years. Compliance with UDI requirements will impact manufacturing processes, quality management systems, information technology infrastructure, and overall business operations of medical device manufacturers and sponsors. The risks associated with non-compliance for medical devices already on the market has been assessed by the TGA as minimal, as it is unlikely to affect medical device safety or performance. Manufacturers or sponsors unable to meet the UDI obligations may apply to the TGA for *Consent to import, supply, or export medical devices that do not meet the Essential Principles*. The TGA's process for UDI-specific Consent to Supply applications is expected to require less effort and therefore a reduced fee will be payable to assess and approve each application. Use of the Consent to Supply process supports continued supply of medical devices as manufacturers and sponsors work towards full UDI compliance.

A UDI Consent to Supply is an application that only includes non-compliance with one or more of the following UDI-related Essential Principles:

- 13A.2 - Patient Implant Cards
- 13.5 - Device identifier and production identifier are provided with the device
- 13.6 - Packaging identifiers are provided with the device
- 13C.1 - Identifiers are issued by recognised Issuing Agencies
- 13C.2 - Identifiers are in the Australian Unique Device Identification Database
- 13C.3 - Other device-related data is in the Australian Unique Device Identification Database
- 13C.4 - Australian Unique Device Identification Database information is accurate and up to date
- 13C.5 - Device identifier and production identifier are direct marked on the device.

Non-compliance with the UDI related Essential Principles can be included on a Consent to Supply application for non-UDI Essential Principles, however this will follow one of the existing Consent to Supply pathways.

The table below shows the reduced fee of UDI Consent to Supply applications.

Type of application	Fee Schedule	Current fee ($)	Reduced fee ($)
Application for consent to export, supply, or import a medical device, including an IVD medical device, for a single entry in the ARTG or an application for inclusion in the ARTG, that does not comply with the Essential Principles	Part 1 of Schedule 5 Item 1.15(a)	$583 (for all the devices to which the application relates)	$80 (for all the devices to which the application relates)
Application for consent to export, supply, or import a medical device, including an IVD medical device, for 2 or more entries in the ARTG or applications for inclusion in the ARTG, that do not comply with the Essential Principles	Part 1 of Schedule 5 Item 1.15(a) Additional entry Item 1.15(b)	$583 for the first entry, plus $117 for each additional entry	$80 for the first entry, plus $10 for each additional entry

The summary of TGA fees and charges for 2026-27 can be found on the TGA website.

Risk Assessment

A cost recovery risk assessment for the annual increases to fees and charges was undertaken in April 2026, resulting in an overall medium risk rating for TGA's cost recovery arrangements. The cost recovery risk rating is based on assessment of the criteria using the Charging Risk Assessment template for existing charging activity. The medium-risk components relate to the expected change in total annual revenue following the proposed increases, the highest percentage increase in individual fees, and the source of recovery being through fees and levies. All other risk factors render a low-risk rating.

The most likely risks identified for any ongoing changes to cost recovery arrangements were:

- cost recovery fees creating a disincentive to products entering the market
- inherent risks in implementing diverse cost recovery arrangements, and
- potential for misunderstanding of how fees and charges are calculated.

These risks are addressed by:

- continued improvements in regulatory and administrative functions
- implementing best practice in ABC methodology
- working closely with stakeholders and industry representatives to mitigate the cost impact to business
- providing clear education and communication on out costing and charging arrangements, and
- ensuring charging practices are aligned to our services and are transparent and defensible.

From a regulatory perspective, risk management is applied to regulating therapeutic goods by identifying, assessing, and evaluating the risks:

- posed by therapeutic goods before they can be approved for use in Australia (pre-market assessment or evaluation)
- posed by manufacturing processes before a manufacturer is issued with a licence to manufacture therapeutic goods (licensing of manufacturers), and
- that may arise following approval of the product and licensing of the manufacturer (post-market surveillance).

Stakeholder consultation on setting of fees and charges

Stakeholder engagement strategy

The TGA has a longstanding practice of undertaking targeted consultation with peak industry bodies regarding fees and charges. Bilateral meetings are conducted each year to discuss the detailed financial performance and changes to fees and charges with a focus on the forthcoming financial year. The TGA asks peak bodies to bring the proposed changes to fees and charges to the attention of their members. The TGA simultaneously publishes a public consultation paper on fees and charges to provide an opportunity for wider industry and other stakeholders to comment on the proposed fees and charges.

Industry associations are also regularly consulted in the process of regulation development and reform, and feedback is considered in developing impact analyses and any relevant cost recovery arrangements. The TGA uses several fora to consult and disseminate information regarding the TGA cost recovery, including:

- the TGA Consultative Committee which is a consultation forum with industry and non-industry bodies involved in the manufacture, use and consumption of therapeutic goods
- industry working groups for prescription and non-prescription medicines
- the TGA-Industry Working Group on Good Manufacturing Practice which facilitates consultation between TGA and the industry on matters relating to GMP, and
- the regulatory and technical consultative fora for medical devices and for complementary medicines.

The TGA uses additional means of consultation to ensure that stakeholders have been provided sufficient opportunity to comment on more significant changes in cost recovery policy or where more complex changes to fees are being considered or where there are multiple options for setting fees and charges.

Under the Government's guide to policy impact analysis, direct financial costs such as fees and charges attached to a regulation are excluded from the Regulatory Burden Measurement Framework. Accordingly, the TGA does not prepare an Impact Analysis for amendments to fees and charges for therapeutic goods and manufacturing licences. This is consistent with advice from the Office of Impact Analysis. Activity-based costing is the well-established mechanism for setting fees and charges, and a comprehensive targeted communication strategy is TGA's established consultation approach.

Based on stakeholder feedback, the TGA enhanced its consultation process for fees and charges from 2019-20 onwards. In addition to inviting the 3 additional medical device industry bodies, the TGA also brought forward the bilateral meetings to November/December each year to provide more notice of changes to sponsors.

The TGA's stakeholder engagement strategy was included in the consultation paper on the 2026-27 fees and charges proposal to seek comments from stakeholders with a view to further improve the strategy. One peak body raised concerns regarding the design of the consultation through the Consultation Hub. The TGA has noted this feedback and will consider refinements to its consultations in future.

Consultation on the 2026-27 fees and charges

Consistent with previous practice, the TGA consulted with the following 13 industry representative groups in November and December 2025 through a series of bilateral meetings:

- Accord Australasia
- Assistive Technology Suppliers Australasia
- AusBiotech
- AUScelerate (Formerly MTP Connect)
- Australian Dental Industry Association
- Australian Medical Manufacturers and Distribution Association[4]
- Complementary Medicines Australia
- Consumer Healthcare Products Australia
- Generic and Biosimilar Medicines Association
- Medical Technology Association of Australia
- Medicines Australia
- Optical Distributors & Manufacturers Association of Australia, and
- Pathology Technology Australia

To obtain broader feedback from industry and other stakeholders, the TGA also undertook a public consultation of its fees and charges. The 4-week consultation ended on 27 February 2026.

The TGA received 21 submissions, including 10 from peak industry bodies, 10 from sponsors and manufacturers of therapeutic goods, and one from a health care services institution. Of these submissions, 11 relate to medical devices and IVDs, 6 to medicines, and one each to personal hygiene, biotechnology, rehabilitation equipment, and clinical trials.

12 submissions, including 5 industry bodies, favoured partial cost recovery (Option 2), while 3 submissions from sponsors advocated for full cost recovery (Option 1).

Several submissions raised concerns that current and proposed fees do not reflect regulatory risk or workload. This was particularly raised for low-risk therapeutic goods and sponsors holding multiple ARTG entries with limited ongoing regulatory engagement. Stakeholders contended that these groups receive comparatively less regulatory benefit yet bear an equal or increasing fee burden. Many submissions recommended a shift towards more risk-based and activity-based fee models that align fees with actual regulatory effort, required oversight, and benefits accrued to enhance proportionality, equity and regulatory efficiency.

Stakeholders sought clarity regarding efficiency gains resulting from prior industry-funded initiatives, especially those related to digital transformation and the UDI system implementation. Concerns were raised that these investments have not sufficiently delivered productivity or cost savings to counterbalance rising fees.

Certain industry bodies highlighted concerns about ongoing cross-subsidisation of public good activities using cost-recovered funds. They called for full government funding for such undertakings and urged increased allocation of this funding towards public-interest regulatory activities to ensure fees and charges remain equitable, proportionate and consistent with public interest outcomes.

Further, there were requests for greater transparency regarding the utilisation of additional fee and charge revenue, emphasising the need for clear communication about expected stakeholder outcomes. It is strongly anticipated that any increases in fees will be directly linked to measurable enhancements in regulatory performance, including assessment timeliness, service quality, and overall system efficiency.

[4] Australian Medical Manufacturers and Distribution Association did not attend this year's bilateral meeting. Therefore, the bilateral meeting presentations were provided to them for their feedback.

The feedback from the submissions was put forward to the Government for consideration along with the proposed changes to fees and charges for 2026-27. The Government approved the above changes to the TGA fees and charges for 2026-27, commencing from 1 July 2026.

Financial and non-financial performance

a) Financial performance

Financial Estimates - budget and 3 forward years as published in the PBS

The below table reflects the TGA's 2026-27 Budget as published in the Budget 2026-27: Health, Disability and Ageing Portfolio Budget Statements Table 3.1.1: Estimates of Special Accounts Cash Flows and Balances.

Financial Estimates	2026-27 Budget $'m	2027-28 Estimate $'m	2028-29 Estimate $'m	2029-30 Estimate $'m
Cost Recovery and Other Revenue	219.52	225.95	232.58	244.23
Government Appropriation	77.46	16.78	16.08	16.31
Expenses	297.61	242.73	248.66	260.54
Surplus (Deficit)	**(0.63)**	**0**	**0**	**0**
Cumulative Balance	**81.70**	**81.70**	**81.70**	**81.70**

Financial Outcomes - financial performance in previous financial years

Estimate

Details	2022-23 Estimate $'m	2023-24 Estimate $'m	2024-25 Estimate $'m	2025-26 Estimate $'m
Revenue from Government	22.53	34.78	74.33	70.30
Sale of goods and services	187.52	187.50	196.99	198.70
Other revenue and gains	8.01	8.04	5.41	7.52
Total A	**218.05**	**230.31**	**276.73**	**276.52**
Employee expenses	109.36	160.43	183.22	193.06
Suppliers	97.21	75.28	93.1	91.23
Depreciation and amortisation	5.4	5.69	4.44	2.71
Write-down and impairment of assets	4.52	0.43	2	0
Total B	**216.50**	**241.83**	**282.76**	**287.00**
Surplus (deficit)	**1.55**	**(11.52)**	**(6.03)**	**(10.48)**
Retained surplus	50.81	39.29	33.26	22.78
% of Retained surplus to TGA budget	23%	17%	12%	12%

Actual

Details	2022-23 Actual $'m	2023-24 Actual $'m	2024-25 Actual $'m	2025-26 Estimate $'m
Revenue from Government	21.44	34.78	74.33	70.30
Sale of goods and services	187.50	185.66	202.43	198.70
Other revenue and gains	9.81	4.89	5.36	7.52
Total A	**218.75**	**225.33**	**282.12**	**276.52**
Employee expenses	109.36	147.17	183.22	193.06
Suppliers	101.73	73.71	75.19	91.23
Depreciation and amortisation	5.40	5.69	4.93	2.71
Write-down and impairment of assets	4.52	1.99	22.91	0
Total B	**216.50**	**228.56**	**286.35**	**287.00**
Surplus (deficit)	**2.25**	**(3.23)**	**(4.23)**	**(10.48)**
Retained surplus	43.31	40.08	35.85	25.37
% of Retained surplus to TGA budget	20%	18%	13%	9%

Note: 2025-26 Actual will be published in the next update in November/ December 2026.

Until 2018-19, the TGA's activities were almost entirely cost recovered from industry, except for the cost of the medicines and chemicals scheduling function for which appropriated funding was provided. In addition, the TGA continued to receive appropriated funding in the form of an interest equivalency payment for funds held in the TGA Special Account (cash reserves). From 2019-20 onwards, additional funding was approved by government for activities for which it is not appropriate to recover costs from the industry.

In 2024-25 the TGA had a deficit of $4.23 million. Both revenue and expenditure were above budget, with revenue exceeding budget by $5.39 million and expenditure exceeding budget by $3.59 million. As a result, the deficit was $1.8 million lower than budgeted. Supplier expenditure, including contractors and contract for services, were below budget by $17.91 million, predominately due to delayed vaping work being delayed and reduced use of contract labour hire. Corporate expenses were over budget by $21.40 million, predominately due to impairment and write-off of intangible software of $22.65 million.

The appropriation funding for 2024-25 included $15 million (2019-20 MYEFO) for fee-free services, $13.40 million (2023-24 public good measure) for public good activities, $39.17 million for vaping measures (MYEFO 2023-24), and $6.76 million other government appropriations.

The TGA aims to maintain reserves to provide a buffer for volatility in revenue streams such as for applications, assessments, evaluations, inspections, and responses to major external or unplanned impacts including recalls and product tampering. The target for the reserve balance has been set at approximately 25% of the yearly operating budget in previous years, or around $50 million. There is no statutory requirement for the 25% figure.

Depreciation is accumulated in cash reserves for the replacement of assets. The Government expects the TGA to manage within its cost recovery resources and therefore investment in new, or replacement of existing, business systems must come from the responsible management of cash reserves.

The Government provided $23.28 million in funding for the Business Digital Transformation Project (DTP) and the enhanced implementation of Australia's UDI system for the safety and traceability of

medical devices. These funds are drawn from TGA cash reserves. The Government decision mandates cost recovery of $23.28 million from the industry over 6 years, commencing in 2024.

b) Non-financial performance

Each year we provide information about our regulatory performance through the TGA Performance Report and the TGA Business Plan. The statistics contained within the TGA Performance Report covers the period 1 July 2024 to 30 June 2025, contributing to public reporting that track our progress against priorities we have established for the financial year. The TGA's performance report containing the statistics for the period 1 July 2025 to 30 June 2026 will be released in 2027.

Key forward events

Key forward events schedule	Next scheduled update
Update actual financial information for 2025-26	November 2026

CRIS approval and change register

Date of CRIS change	Approver	CRIS change
XX/6/2026	Deputy Secretary, Health Products Regulation Group	CRIS approved for revised fees and charges from 1 July 2026

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Reference/Publication #