Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Cost Recovery Implementation Statement

2024-2025

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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 and Aged Care[1] (Department), implements and cost recovers its regulatory activities. The TGA's regulatory activities are associated with the registration and listing of medicines and inclusion of medical devices, including in vitro diagnostic (IVD) medical devices, and biologicals in the Australian Register of Therapeutic Goods (ARTG), and their ongoing monitoring and surveillance.

Description of the activity

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

To achieve this outcome, the TGA approves and regulates products based on an assessment of risks against benefits. The Australian community expects therapeutic goods in the marketplace to be safe, of high quality and of a standard at least equal to that of comparable countries. The TGA regulates therapeutic goods through:

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

Therapeutic goods are divided broadly into three 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 take action. Possible regulatory actions vary from continued monitoring to withdrawing the product from the market and revoking or cancelling a manufacturing licence.

In addition, the TGA undertakes a number of public health activities in the public good. These activities are discussed in more detail below.

Risk management approach to regulation

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

[1] The TGA contributes to Health and Aged Care's Outcome 1 - 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 medical devices
- blood, blood components and biologicals
- 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 from a government appropriation. 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, from time to time it also receives time limited funding for emerging issues, health emergency or pandemic measures. In 2024-25, around 78% of funding will be generated through fees and charges set under the cost recovery arrangements.

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 stated that from 1998-99 the TGA would fully recover all costs of its activities covered under the TGA Act from industry.

As the TGA operates on a cost recovery basis, to enable pre- and post-market regulatory activity, there are a number of fees and charges for therapeutic goods. These include annual charges, application and evaluation fees, conformity assessment fees and inspection fees which are imposed on sponsors and manufacturers of medicines, medical devices and biologicals.

The *Therapeutic Goods Act 1989* (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 four years for the TGA, with $15 million per year ongoing from 2022-23. This funding goes towards meeting costs of the Orphan Drugs, and Special Access Scheme and Authorised Prescribers programs, without needing to cost recover these programs.

In the 2023-24 Budget the Government provided $61 million over four years for meeting costs of the TGA's public good activities where cost recovery is not 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
- Continued assistance to small and medium enterprises in the sector, particularly those developing emerging technologies.

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

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

In the 2023-24 MYEFO Budget, the Government provided $55 million over two years to the Department for Measure - Enhanced Regulatory Model for Vaping Products, $23 million was provided to the TGA for activity relating to vaping.

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 are made available for supply in Australia. However, certain prescription medicines can be registered provisionally 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 doctor's prescription. Otherwise, only authorised health care professionals can supply prescription medicines, such as in a hospital setting. Examples include vaccines, blood pressure tablets, diabetes medications, contraceptive pills, 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 are implemented through:

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

The business area responsible for administering these exemptions ensures that they are administered in accordance with the legislative and regulatory frameworks.

To enable recovery of the costs of pre-market and post-market regulatory activities there are a number of fees and charges for medicines. These include annual charges, application fees and evaluation fees.

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, may publish guidelines that are reviewed, and 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 a number of regulatory reforms in 2017-18 the TGA implemented "provisional" and "priority" pathways for registration of certain prescription medicines, provided they meet the legislative criteria for such a pathway.

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 submission of the PPF improves the quality of applications and helps in meeting legislative timeframes.

Data evaluation

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

- quality data evaluated by chemists, biochemists, microbiologists and other TGA officers 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 take into consideration 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. Some examples of the types of change 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

Medicines for export from Australia must be of a similar quality and safety standard as those supplied domestically. However, they are not required to comply with the labelling standards or advertising requirements in force in 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 considered to be of lower risk than prescription medicines, but they 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, 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 to be of relatively higher risk than listed OTC medicines, based on their substances or the indications made for the medicine. Registered medicines are evaluated for quality, safety and efficacy prior to being accepted in the ARTG and able to be marketed.

The pre-market regulatory processes for OTC medicines include:

- lodgement of an application for product registration or listing on the ARTG
- 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
- updating the ARTG.

Once a product has been registered, the sponsor can make further applications to change the details of registration. Examples of changes that may be sought include details related to labels, shelf-life, formulation, indications or directions for use. Some of these changes can be made through the notification system.

Listing an OTC medicine in the ARTG

The listing process for an OTC medicine is the same as listing a complementary medicine which is explained in the complementary medicines section of the CRIS.

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 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 two pathways to list a medicine in the ARTG.

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 also required to select the indications for their medicine from the list of permitted indications that is maintained by the TGA. This process for listing products 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
- they can only make indications (for therapeutic use) 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.

Medicines can also be listed in the ARTG following sponsor certification of the safety and quality of the product, coupled with TGA assessment of the efficacy evidence supporting the proposed indications. This pathway, commonly known as ‘Assessed Listing Pathway’ allows sponsors to apply for indications that fall outside the permitted indications list but in all other respects the medicines meet the current eligibility criteria for listed medicines (e.g., contain only permitted ingredients and are manufactured under GMP).

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 considered to be of relatively higher risk than listed complementary medicines, based on their substances or the indications made for the medicine. Registered complementary medicines, like any other registered medicine, are fully evaluated for quality, safety and efficacy prior to being accepted in the ARTG and therefore able to be marketed.

4. Medical devices

The Australian medical devices regulatory framework sets out the requirements for the quality, safety and performance of medical devices, based on a series of Essential Principles. All medical devices must demonstrate compliance 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 allowed into the Australian market.

To recover costs of pre-market and post-market regulatory activities, there are a number of 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 exempt from that requirement, such as exemption under sections 41HA, 41HB or 41HC of the Act. The level of assessment conducted at the point of application for ARTG inclusion depends on the risk classification of the device, the conformity assessment evidence supporting the application, and whether there are any concerns with the application that would require the TGA to request further information for review prior to inclusion.

High-risk medical devices must have an ARTG entry for each device (with the unique product identifier). Lower risk devices can have multiple similar devices included under one ARTG entry (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 higher.

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

All medical devices must comply with regulatory requirements for quality, safety and performance, and manufacturers of devices other than the lowest risk must have a conformity assessment document, covering an assessment of a manufacturer's quality management system and assessment of design dossiers, for the highest risk devices, issued by an independent assessment body or trusted overseas regulator (e.g., European Notified Body, US FDA, etc.).

In addition to the requirement to provide a conformity assessment document with an application for ARTG inclusion, the application process also may involve an assessment of other information 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 compulsory audits an application audit assessment fee is charged
- TGA may also select any other application for inclusion for an audit - an audit assessment fee is not charged for these audits

There are two levels of application audit - Level 1 and Level 2 for non-IVD medical devices and one level of application audit for IVD medical devices. If an application audit is to be conducted, the TGA determines what level of application audit is appropriate for each application. There are different fees for each level of audit assessment, which apply if the audit is compulsory.

Conformity assessments

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 that the device conforms 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 and/or overseas regulators that 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 conformity assessment bodies (also known as Notified Bodies).

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 under Item 1.2, Part 1, Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

A medical device that is intended by the manufacturer to be for export only is classified as a Class I medical device, i.e., 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'. The 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

There is a small number of other therapeutic goods that do not meet the definition of a medical device, medicine or biological and are regulated under Chapter 3 of the Act. These include tampons, menstrual cups, and hard surface disinfectants without specific claims; all of which do not need to be listed in the ARTG. However, 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
- 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 regulatory activities for biologicals involve the following registration and approval activities:

- management of applications for inclusion in the ARTG
- 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
- 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. Under the Act 'blood' means whole blood extracted from human donors and 'blood components' means therapeutic components that have been manufactured from blood (including red cells, white cells, progenitor cells, platelets and plasma). 'Blood components' do not include products derived through fractionation of plasma. Plasma derivatives are prescription medicines subject to full regulation, including compliance with set standards, licensing of manufacture and inclusion in the ARTG after review of manufacturing, pre-clinical and clinical data.

- Some blood and blood components are exempt from regulation by TGA, 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
- 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 two schemes as follows:

a) Special Access Scheme

The Special Access Scheme (SAS) refers to arrangements which provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case-by-case basis. Patients are grouped into three 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

In these circumstances a medical practitioner may be granted authority to become an 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.

The TGA assess applications to grant medical practitioners' authority to prescribe a specified unapproved therapeutic good or class of unapproved therapeutic goods to specified recipients or classes of recipients with a particular medical condition. The medical practitioner becomes an AP and can prescribe that product for that condition to individual patients in their immediate care without further TGA approval.

The TGA does not charge a fee to the users of these services. These services 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 in their specific circumstances. It is in the public 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 2022-23, there were 37,147 SAS category A notifications, 139,096 SAS category B applications, 45,462 SAS category C applications, and 14,287 AP applications. The annual cost of these fee free services is estimated to be $5.94 million or around $27 per application/ notification. This information will be updated for the 2023-24 financial year in the next update of the CRIS. Cost recovery of this cost through an application fee levied on patients and/or medical practitioners is unlikely to be cost efficient. Moreover, such a process would impact on time critical access of these products to seriously ill patients. Therefore, cost recovery for these activities is not appropriate and the costs are met from 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 can be seen as part of a global movement to address treatment of approximately 7,000 rare diseases. The 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 at 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 2022-23, the TGA assessed 21 orphan drug applications, compared to the total fee-paying applications of 137 for prescription medicines (new chemical entity, major variation and extension of indications). The total cost attributed to the orphan drug program in 2022-23 was $4.99 million.

The costs of the orphan drug program are being met from government appropriation.

B: Compliance, monitoring and enforcement

The TGA's Regulatory Compliance Framework outlines how the TGA manages its compliance functions under its legislation and sets out the overall approach to compliance. The TGA's focus is to ensure compliance and enforcement actions are evidence-based and proportionate to the nature and seriousness of the alleged non-compliance, and the potential risk to public health and safety.

The TGA's compliance functions support the broader regulatory objectives, including consumer protection, and enable a fair market for industry. The TGA monitors, and enforces where necessary, compliance with the legislation, regulations and rules for the import, manufacture, advertising, supply, and export of therapeutic goods.

Risk-based compliance and monitoring

Australians have a right to expect that each of the medicines they take and the medical devices they use meet acceptable levels of safety and quality.

One of the roles of the TGA is to regulate therapeutic products based on a scientific and clinical assessment of the evidence of both the risks and the benefits of those products. It is important to recognise that in doing so, the TGA cannot avoid all risks - that would be impossible - our approach is

about managing risks, so that the impact of any risks identified in relation to a therapeutic product are kept to an acceptable level.

The TGA uses this same risk-based approach in its monitoring and compliance activities. There are different sources of risks in relation to unlawful therapeutic goods:

- 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
- risk of a loss of confidence in the regulatory processes and subsequently loss of confidence in available therapeutic goods.

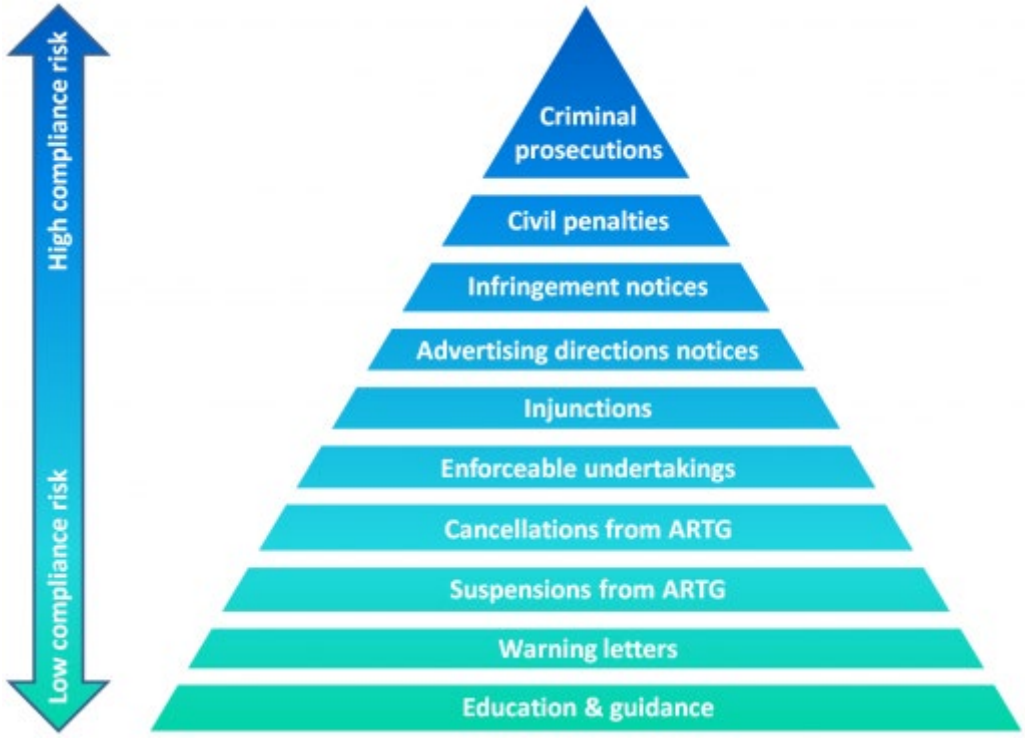
Approach to monitoring

The TGA employs a combination of monitoring strategies to support our compliance programs. Our monitoring programs are both proactive and responsive, including acting upon signals and reports of non-compliance from a number of external sources.

All signals of non-compliance are recorded and considered. The TGA uses triage systems across our compliance functions to determine the priority of the matter and how it will be actioned.

Approach to compliance and enforcement

A range of compliance and enforcement tools are employed to address alleged non-compliance, either individually or in combination, and to encourage compliance with the Act. These are depicted in the diagram below.



The TGA made legislative and regulatory amendments to broaden the enforcement options available to the TGA and provide enhanced sanctions and penalties in relation to advertising offences. The amendments commenced in March 2018 standardising TGA's enforcement and compliance powers modelled on those in the *Regulatory Powers (Standard Provisions) Act 2014* and aligning with contemporary Government policy and other Government regulatory agencies.

The enhanced sanctions and penalties include:

- Substantiation Notices
- Directions Notices
- Cancellation or suspension of therapeutic goods from the ARTG
- Public Warning Notices
- Injunctions
- Infringement Notices
- Enforceable Undertakings
- Civil penalties and
- Criminal prosecution.

A range of tools are used by the TGA when taking action on a compliance matter. 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 SMEs prior to market entry in order to minimise the risk and likelihood of non-compliance. The majority of stakeholders comply with regulatory requirements. Through interaction with the TGA it is possible to foster understanding of the compliance framework within which they operate and thus facilitate compliance.

Prioritisation of compliance and enforcement matters

The TGA cannot pursue all matters that come to our attention. The TGA undertakes intelligence led, risk-based compliance and enforcement activities to ensure compliance with the *Therapeutic Goods Act 1989*.

A risk-based approach is taken to prioritise complaints and other signals of possible non-compliance with regulatory requirements, in order to provide the greatest overall benefit for the Australian public. The actions taken in response to signals of potential non-compliance will depend on the likely risk associated with the non-compliance.

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
- level of compliance of the particular industry sector.

Compliance actions will aim to minimise adverse health consequences for consumers, as a result of public access to inappropriate or dangerous goods and ensure confidence in compliance programs is maintained amongst stakeholders.

The TGA is less likely to pursue matters that are one-off events, unless non-compliance is a deliberate and a blatant breach of the law and/or there are public health consequences.

Other agencies

Where appropriate, the TGA works with other agencies in performing its monitoring and compliance functions. This may involve an exchange of information, or more direct engagement in joint investigatory activities.

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 appearing in broadcast and mainstream print media, billboards, cinema films, the internet etc.

Where a complaint about a product advertisement is received, the TGA will assess the validity of the complaint and, if necessary, ensure that rectifying action is undertaken.

Advertising Education

TGA educates advertisers, consumers, health professionals and industry to promote voluntary compliance with the advertising requirements. We invest in these activities because they are beneficial for advertisers and consumers and are an effective way to achieve overall compliance.

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
- keeps advertisers updated on changes to the requirements.

C: Regulation of manufacturers of therapeutic goods

Good manufacturing practice

In Australia, manufacturers of medical devices are required to have conformity assessment certification (issued either by the TGA or by one of the European Notified Bodies) and demonstrate compliance with Quality System requirements.

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 Quality Systems, 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 to describe 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 on-going program of verifying 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, to help ensure that therapeutic goods supplied in Australia are of appropriate quality and to allow TGA to take appropriate regulatory action where safety concerns are identified.

D: Clinical trials

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

a. CTN Scheme—this involves a notification only with a notification fee (no approval or decision is made by the TGA).

b. CTA Scheme – this 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 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 (including on-costs such as training, superannuation and leave) and supplier costs (e.g., 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 overhead costs such as corporate costs (e.g., finance, human resources, IT, office accommodation) and salaries of staff in support areas (e.g., regulatory practice and support functions).

While most capital assets are funded through the TGA cash reserves, depreciation and amortisation costs are included in costing 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 how the current cost model attributes direct and indirect costs to TGA activities. This model is being reviewed as part of the Department's Portfolio Charging Review.

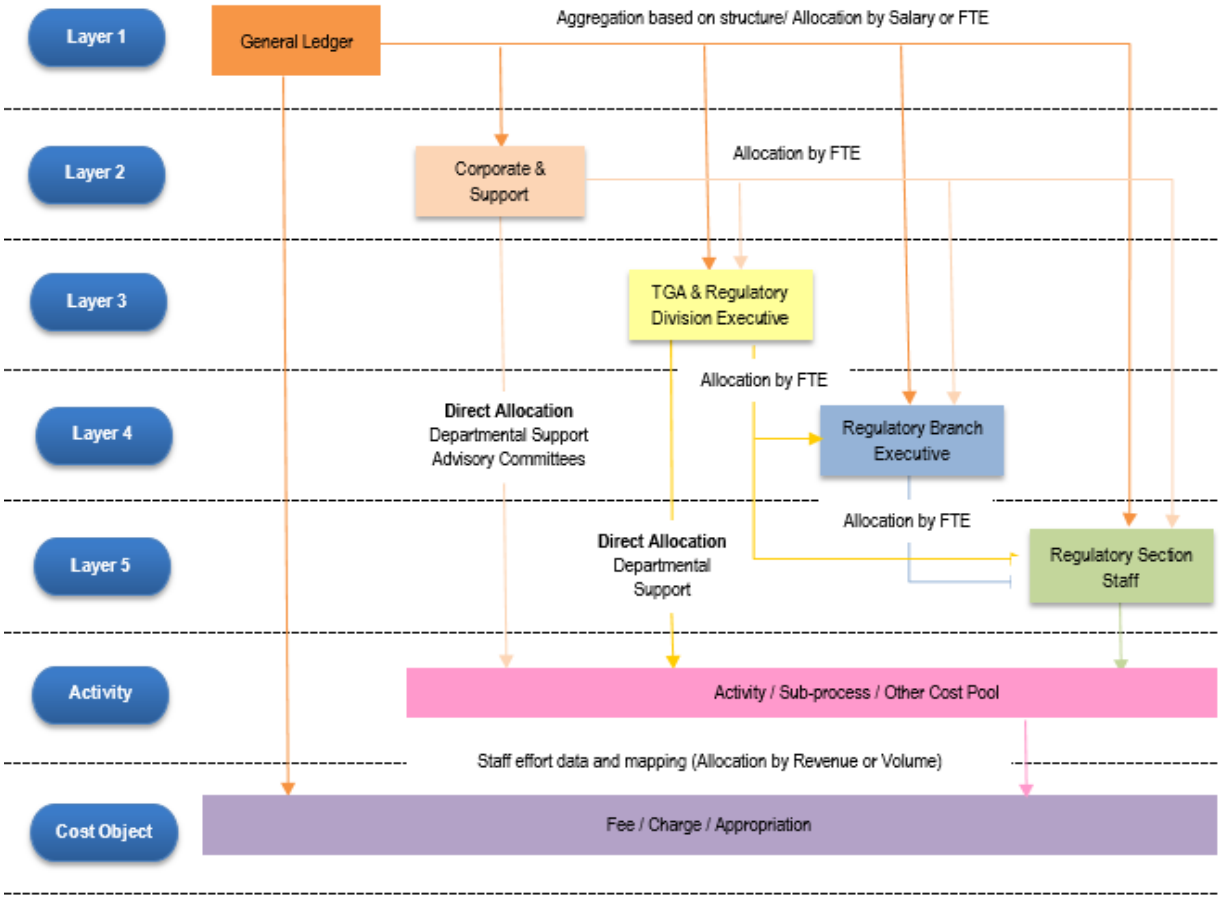
A summary of TGA costs by industry sector can be found in Appendix 1 - Financial performance by industry sector group.

Fees and charges

The characteristics of a government activity determine the type of cost recovery charge used. There are two 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 (e.g., 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 that pays the levy.

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



All therapeutic goods registered, listed or included in the ARTG are subject to annual charges (a type of levy) except for export only products. 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 pharmacovigilance 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 pharmacovigilance and post-market work required (and associated costs) for the regulated good rather than the size of the individual business. For example, the 2023-24 annual charge for a Class I medical device is $103 whereas for a high-risk prescription medicine (biologic) the 2023-2 annual charge is $8,573. This is because post market monitoring cost of a low-risk device (such as band-aid and gloves) is much lower than the costs of a high-risk biologic medicine (blood product and vaccines).

2024–25 Fees and Charges – effective 1 July 2024

Every year in October and November, the TGA reviews its budget outlook, and work on possible changes to fees and charges for the next financial year. For the 2024-25 financial year fees and charges changes comprised of three components:

1. annual indexation of fees and charges
2. changes to annual charges to cost recover investment in the TGA's digital transformation and business system enhancement
3. small number of other changes including:

a. reduction in application audit assessment fee for Class 3 and 4 IVDs, where no laboratory testing is required

b. clinical trial notification fee for each additional site for unapproved medical devices, including IVDs

c. reduction in annual charges for certain prescription medicines containing at least one specified active ingredient (thalidomide, leflunomide, lenalidomide, mifepristone, clozapine and isotretinoin)

d. application fee for requests for consent to supply under section 14/14A of the Act for prescription medicines, including medicinal cannabis products, that are not registered in the ARTG

While not all changes relate to all areas of industry, these changes are discussed in detail as follows:

1. Indexation increase for 2024-25

For FY2024-25, overall costs are estimated to increase by $36 million. Other than mandatory increases to our non-discretionary costs ($14 million), this increase is primarily driven by government-funded activity for the enhanced regulatory model for vaping products. The mandatory cost increases include increase in salary and staff related costs and corporate costs. Employee costs were estimated to increase by $7 million for the 2024-25 financial year mainly related to the 4% pay raise for non-senior executive staff, effective from March 2024 (as per the Department's Enterprise Agreement), This will also include leave provision increases and staff pay increments which are due in August 2024 (all staff with at least 3 months of service and a satisfactory performance rating are eligible for an increment in line with the Department's Enterprise Agreement).

The corporate and other costs, including depreciation are expected to rise by $7 million (depreciation/amortisation - $6 million and other corporate cost-$1 million), largely due to digital transformation expenditure and increased legal expenses related to vaping reforms.

The indexation factor for 2024-25, based on the previously used formula of the average (composite indexation) of the Consumer Price Index (CPI) and the Wage Price Index (WPI), was 4.7%:

- 50% of CPI Sep 2022 to Sep 2023: 5.4%: 2.7%
- 50% of WPI Sep 2022 to Sep 2023: 4.0%: 2.0%

The indexation increase is consistent with the long-established practice and provides opportunity for efficiency gains through business process improvements. This is also consistent with the Government's policy for cost recovered activities. As the 4.7% increase will not cover all known mandatory cost increases (salary and corporate costs) in 2024-25, the TGA will need to find savings and efficiencies.

2. Mandated increase to annual charges to cost recover investment in the TGA's Digital transformation and business systems enhancements

The October 2022 Budget provided approval for funding of $23.3 million over the two financial years, 2022-23 and 2023-24, to complete digital and business transformation and full implementation of the Unique Device Identification (UDI) system to expand its scope to include medium and high-risk devices. While this money was drawn from the TGA Special Account cash reserves, the Budget decision required this amount to be cost recovered from industry over five years which commenced from 1 January 2024 (six financial years), except for the cost recovery of the UDI system which commences from 1 July 2024.

In the 2023-24 financial year the increase to annual charges (other than for the UDI system) was pro-rated for the 6-month period (50% of a full year attribution). A full year attribution of cost recovery, including for the UDI system, will commence from 1 July 2024.

The table below summarises the increase to annual charges in 2024-25 to cost recover digital transformation investment.

Increase to annual charges in 2024-25	Digital Transformation	AEMS	Devices Digitisation	UDI	Total Increase
Medicines and Biologicals annual charges	1.60%	0.41%			2.01%
Medical Devices Class II and above, including implantables	1.60%		1.08%	1.75%	4.43%
Medical Devices Class I, Im and Is and all classes of IVD devices	1.60%		1.08%		2.68%
Other annual charges i.e., manufacturing licences, OTGs	1.60%				1.60%

Note: Increases required for cost recovery of digital transformation have been adjusted for indexation and other increases in 2023-24 which resulted in lower percentage increases than previously forecasted.

Further changes to fees and charges in 2024–25

i. Application audit assessment fee for Class 3 and 4 IVDs

In the 2023-24 financial year several medical device fees were revised – resulting in some increasing and some decreasing. Class 3 and 4 IVD application audit assessments had significant under recovery mainly during the COVID time and to address the under recovery, the fee for Class 3 and 4 IVD application audit assessment was increased from $7,387 to $22,387.

This fee was based on the estimated cost of undertaking application audit assessment of these classes of IVDs, including the cost of laboratory testing. A review of these applications and associated activities found that not all Class 3 and 4 IVD application audit assessments required laboratory testing.

To align the fees with the costs incurred, there will be two application audit assessment fees for Class 3 and 4 IVDs. A reduced fee of $14,865 if no laboratory testing is required will be implemented with effect from 1 July 2024. The current fee of $23,439 still applies where laboratory testing is required.

ii. Clinical Trial Notification fees for additional unapproved medical devices site

Under the Act, clinical trials conducted in Australia are subject to TGA regulatory controls to ensure the safety of participants. The CTN schemes provide for the lawful importation into and/or supply in Australia of ‘unapproved’ therapeutic goods for use solely for experimental purposes in humans (i.e., clinical trials). The overall decision as to whether a CTN is required in relation to the use of the therapeutic goods is the responsibility of the trial sponsor.

Fees are currently applied to notify the TGA of an additional clinical trial site for unapproved medicines, biologicals, and medical devices (including IVDs). While these are long-standing fees, the fee for notification of an additional site for medical devices was omitted from the Therapeutic Goods (Medical Device) Regulations 2002.

A fee of $429 for each notification of an additional site for unapproved medical devices (including IVDs) will be implemented with effect from 1 July 2024. This fee would implement a CTN fee involving unapproved medical devices to make it consistent with the existing fee for an additional clinical trial site for a clinical trial involving an unapproved medicine or biological.

iii. Removal of higher annual charge for certain medicines

When annual charges were significantly lowered for most generic medicines in 2015, a higher annual charge was prescribed for prescription medicines that contain one of the named ingredients:

- Thalidomide
- Leflunomide
- Lenalidomide
- Mifepristone
- Clozapine
- Isotretinoin

The main reason for a higher annual charge for specified medicines was due to significant risk management activities associated with them. Risk minimisation programs for these medicines are now well established and requires less regulatory oversight.

Therefore, effective from 1 July 2024 a lower annual charge of $4,238 will be implemented for prescription medicines that contain one of the above-named ingredients.

iv. Consent to supply prescription medicines fees (medicinal cannabis)

The quality standard for medicinal cannabis, Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017 was updated in December 2022 to include requirements for labelling of medicinal cannabis products and for manufacturers overseas to hold equivalent GMP authorisations as domestic manufacturers. These changes were effective from 1 July 2023.

Since the update to the requirements for imported medicinal cannabis to be manufactured at sites that hold the GMP evidence specified in section 13(3) of TGO 93, the TGA has received 6 section 14/14A application for consent to supply medicinal cannabis products that do not meet TGO 93.

There is currently no fee prescribed for the assessment of these applications. Based on staff effort required for assessment of these applications and using the activity-based costing the following application fee will be implemented with effect from 1 July 2024:

- Application fee - $3,712

Summary of changes to fees and charges in 2024-25

To summarise, in 2024-25:

- all fees and charges increased by an inflation-based indexation of 4.7% – capped at the previously used indexation formula, other than some medical device fees (refer section 1 - Indexation increase for 2024-25)
- there will be increases to annual charges for cost recovery for the final phase of digital and business transformation (refer section 2(i) - Cost recovery of final phase of the digital business transformation);
- there will be an increase to Medical Devices Class II and above, (including implantable) annual charges for the UDI system (refer section 2(ii) - Cost recovery of further investment in the UDI system and device specific digitisation).

The impact of the changes to 2024-25 fees and charges (other than the small number of changes discussed above) are summarised in the table below:

	Inflation Based Increase	Cost Recovery – Digital Transformation	Cost Recovery - UDI	Total Increase
All TGA fees	4.70%			4.70%
Medicines and Biologicals	4.70%	2.01%		6.71%
Medical Devices Class II and above, including implantables	4.70%	2.68%	1.75%	9.13%
Medical Devices Class I, Im and Is and all classes of IVD devices	4.70%	2.68%		7.38%
Others i.e., manufacturing licences and Other Therapeutic Goods	4.70%	1.60%		6.30%

The TGA summary of fees and charges can be found on TGA website.

Risk Assessment

A cost recovery risk assessment for the annual increases to fees and charges was undertaken in June 2024 resulting in an overall medium risk rating for TGA's cost recovery arrangements. The cost recovery risk rating of medium is based on assessment of the criteria using the Charging Risk Assessment template for existing charging activity. The key medium risks for cost recovery are that levies will increase by 6 to 10 percent, and the total cost recovered revenue will increase by more than $10 million. The source of recovery is 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
- 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
- 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)
- identifying, assessing, and evaluating the risks posed by manufacturing processes before a manufacturer is issued with a licence to manufacture therapeutic goods (licensing of manufacturers)
- identifying, assessing, and evaluating the risks 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 long-standing 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 focus on the forthcoming financial year. The TGA asks peak bodies to bring any proposals for fees and charges to the attention of their members. Around the same time, the TGA 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 taken into account in developing impact analyses, and any relevant cost recovery arrangements. The TGA uses a number of forums to consult and disseminate information regarding the TGA cost recovery, including:

- the TGA Consultative Committee consultation forum with industry and non-industry bodies involved in the manufacture, use and consumption of therapeutic goods
- the TGA Industry Forum is a sub-committee of the TGA Consultative Committee, providing consultation and feedback on industry specific issues
- 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 good manufacturing practice and
- the Regulatory and Technical Consultative Forums 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 is 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 licenses. 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 fee and charges from 2019-20 onwards. In addition to inviting the three additional medical industry bodies, the TGA also brought forward the bilateral meetings to December each year to provide more notice of changes to sponsors.

The TGA's stakeholder engagement strategy was also included in the consultation paper on the 2024-25 fees and charges proposal to seek comments from stakeholders with a view to further improve the strategy. However, no specific comments were received.

Consultation on the 2024-25 fees and charges

Consistent with previous practice, the TGA consulted with the following thirteen industry representative groups in November/ December 2023 through a series of bilateral meetings:

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

While most peak bodies were supportive to annual indexation increase which is based on the established formula, concerns were again raised in respect of additional annual charge increases to cost recover $23.7 million investment in TGA's digital and business systems given that the money was drawn from the TGA Special Account cash reserve paid by industry in the past. However, it was explained to the peak bodies that as discussed and agreed in December 2022 bilateral meetings and the consultation paper on the 2023-24 fees and charges proposal this decision for mandated increase to annual charges to cost recover investment in the TGA's Digital transformation and business systems enhancements had already been made by Government.

In order to obtain broader feedback from industry and other stakeholders, the TGA also undertook a public consultation. The four-week consultation ended on 23 February 2024.

15 submissions were received, including 10 from industry representative bodies and 5 from sponsors or manufacturers. Of these submissions:

- 8 relate to medical devices and IVDs, 3 prescription medicines, 2 complementary/ listed and over the counter medicines, and one each for personal hygiene and biotechnology products.
- 12 submissions including from peak and major sponsors supported the proposed 4.7 per cent indexation increase to the TGA fees and charges.
- 3 submissions, including 2 from peak bodies, did not support the indexation increase to the TGA fees and charges.
- Digital transformation and UDI cost recovery was foreshadowed in last year's fees and charges consultation and industry remained concerned of the decision already taken by the government.
- No significant concerns were raised in relation to the small number of other fees and charges changes.

The feedback from the submissions was put forward to the Government for consideration along with the proposed fees and charges for 2024-25. Government approved the above changes to the TGA fees and charges for 2024-25, commencing from 1 July 2024.

[4] Optical Distributors & Manufacturers Association of Australia couldn't attend this year's bilateral meeting. Therefore, the bilateral meeting presentations were provided to them for their feedback.

Financial and non-financial performance

a) Financial performance

Financial Outcomes - financial performance in previous financial years

Details	2019-20 Actual $'m	2020-21 Actual $'m	2021-22 Actual $'m	2022-23 Actual $'m	2023-24 Estimate $'m
Revenue from Government	8.53	13.76	16.19	21.44	34.73
Sale of goods and services	168.04	169.49	178.62	187.50	190.31
Other revenue and gains	-	1.49	3.72	9.81	0.67
Total A	**176.58**	**184.74**	**198.52**	**218.75**	**225.71**
Employee expenses	86.73	88.08	96.08	109.36	146.73
Suppliers	74.84	84.37	100.71	101.73	73.81
Depreciation and amortisation	8	9.97	10.43	5.40	5.92
Write-down and impairment of assets	1.6	0	0.25	4.52	0.43
Total B	**171.16**	**182.43**	**207.46**	**216.50**	**226.89**
Surplus (deficit)	**5.42**	**2.32**	**(8.94)**	**2.25**	**(1.18)**
Retained surplus	47.68	50.00	41.06	43.31	42.13
% of Retained surplus to TGA budget	27%	27%	21%	20%	19%

Until 2018-19, the TGA's activities were primarily cost recovered from industry except for the cost of the medicines and chemicals scheduling function for which an appropriation was provided by the Government. In addition, the TGA continued to receive appropriation 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 the Government for activities that are not appropriate for cost recovery from the industry.

In 2022-23 the TGA had a surplus of $2.25 million. Revenue was above budget by $5.7 million primarily due to adjustments for a previous 'make good provision' for the TGA building. Expenses were above budget by $0.37 million due to increases in corporate expenditure: unbudgeted property costs, other corporate costs (Poisons Standard Management system, Advertising Compliance Software) and write-off of other assets (lab equipment, fit out and steam steriliser) by $12.5 million. This was offset by a reduction in supplier expenditure (Contractors, contract for services and domestic and international travel) by $10.51 million and employee expenses of $1.62 million. The appropriation funding for 2022-23 included $15 million for fee free services and $5.9 million for COVID-19 assistance.

TGA's financial performance is discussed with industry representative bodies at the annual bilateral meetings.

The TGA aims to maintain reserves to provide a buffer for volatility in revenue streams (e.g., applications, assessments, evaluations, inspections) and respond to major external or unplanned impacts (recalls, product tampering). The target for the reserve balance has been set at around 25% of the yearly operating budget in previous years, or around $50 million. There is no statutory requirement for the 25% figure. The TGA's cash reserves at 30 June 2023 were $8.2 million which is significantly below the target reserve level.

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.

Government has approved funding of $23.28m for business Digital Transformation Project (DTP) as well as enhanced implementation of Australia's UDI system for the safety and traceability of medical devices in Australia. These funds are drawn from TGA cash reserves. The Government decision mandates cost recovery of the operational and capital expenses from industry over 6 years commencing in 2023-24 totalling $23.28m. This will allow the TGA to rebuild its cash reserves in coming years.

The below table reflects the TGA's known position in May 2024 as published in the 2024-25 Portfolio Budget Statements (PBS).

Financial estimates for budget and three forward years as published in the PBS

Financial Estimates	2024-25 Budget $'m	2025-26 Estimate $'m	2026-27 Estimate $'m	2027-28 Estimate $'m
Cost Recovery and Other Revenue	202.53	206.23	210.13	204.96
Government Appropriation	57.62	34.24	32.64	17.07
Expenses	263.08	241.23	243.53	222.79
Surplus (Deficit)		**(0.76)**	**(0.76)**	**(0.76)**
Cumulative Balance	**39.21**	**38.45**	**37.69**	**36.93**

Financial performance by industry sector group is included in Appendix 1.

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 this TGA Performance Report cover the period 1 July 2022 to 30 June 2023, and contribute to annual publications that track our progress against the priorities we have established for the financial year.

Key forward events

Key forward events schedule	Next scheduled update
Update actual financial information for 2024-25	November 2024

CRIS approval and change register

Date of CRIS change	Approver	CRIS change
8/6/2023	Deputy Secretary, TGA, Health Products Regulation Group (HPRG)	CRIS approved for introducing changes to fees and charges from 1 July 2023
27/11/2023	A/g First Assistant Secretary, Regulatory Practice & Support, HPRG	CRIS update for financial information
25/6/2024	Deputy Secretary, TGA, HPRG	CRIS approved for revised fees and charges from 1 July 2024

Appendix 1 - Financial performance by industry sector group

1. Prescription medicines

Revenue and expenses	2018-19 Actual $'m	2019-20 Actual $'m	2020-21 Actual $'m	2021-22 Actual $'m	2022-23 Actual $'m
Cost recovery revenue	74.8	80.6	88.0	92.6	87.1
Total A	74.8	80.6	88.0	92.6	87.1
Direct	41.5	44.6	48.0	57.0	51.3
Indirect	30.4	30.7	30.3	31.1	33.9
Total B	71.9	75.3	78.3	88.1	85.2
Surplus (deficit)	2.9	5.3	9.7	4.5	1.9

2. Over the counter medicines

Revenue and expenses	2018-19 Actual $'m	2019-20 Actual $'m	2020-21 Actual $'m	2021-22 Actual $'m	2022-23 Actual $'m
Cost recovery revenue	10.3	9.9	8.6	7.9	8.4
Total A	10.3	9.9	8.6	7.9	8.4
Direct	3.7	4.2	4.4	4.7	4.5
Indirect	3.0	3.2	3.3	3.0	3.0
Total B	6.7	7.4	7.7	7.7	7.4
Surplus (deficit)	3.6	2.5	0.8	0.2	1.0

3. Complementary medicines

Revenue and expenses	2018-19 Actual $'m	2019-20 Actual $'m	2020-21 Actual $'m	2021-22 Actual $'m	2022-23 Actual $'m
Cost recovery revenue	15.1	16.6	17.9	16.8	15.7
Total A	15.1	16.6	17.9	16.8	15.7
Direct	10.2	11.2	10.8	11.7	11.2
Indirect	7.6	8.5	8.3	7.5	7.4
Total B	17.8	19.7	19.1	19.2	18.6
Surplus (deficit)	(2.7)	(3.1)	(1.2)	(2.4)	(2.9)

4. Medical devices, including IVD medical devices

Revenue and expenses	2018-19 Actual $'m	2019-20 Actual $'m	2020-21 Actual $'m	2021-22 Actual $'m	2022-23 Actual $'m
Cost recovery revenue	41.1	46.3	45.5	47.5	46.8
Total A	41.1	46.3	45.5	47.5	46.8
Direct	22.0	26.6	31.5	39.8	34.3
Indirect	18.2	17.4	18.6	19.1	22.6
Total B	40.2	44.0	50.1	58.9	57.0
Surplus (deficit)	0.9	2.3	(4.6)	(11.4)	(10.1)

5. Good manufacturing practices

Revenue and expenses	2018-19 Actual $'m	2019-20 Actual $'m	2020-21 Actual $'m	2021-22 Actual $'m	2022-23 Actual $'m
Cost recovery revenue	12.4	15.2	15.8	17.2	19.5
Total A	12.4	15.2	15.8	17.2	19.5
Direct	8.6	8.9	8.8	9.5	9.2
Indirect	5.9	6.9	6.8	6.3	6.1
Total B	14.5	15.8	15.6	15.8	15.3
Surplus (deficit)	(2.1)	(0.6)	0.2	1.4	4.2

6. Blood, blood components and biologicals

Revenue and expenses	2018-19 Actual $'m	2019-20 Actual $'m	2020-21 Actual $'m	2021-22 Actual $'m	2022-23 Actual $'m
Cost recovery revenue	2.7	2.7	2.8	3.7	3.0
Total A	2.7	2.7	2.8	3.7	3.0
Direct	2.3	2.6	2.8	3.0	2.8
Indirect	1.9	1.8	2.0	1.8	1.8
Total B	4.2	4.4	4.8	4.8	4.6
Surplus (deficit)	(1.5)	(1.7)	(2.0)	(1.1)	(1.6)

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	RPSD RE Cost Recovery Management Section	June 2024

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