Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Cost Recovery Implementation Statement

2023-2024

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TGA Health Safety Regulation

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 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 is able to 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 detail in this CRIS.

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 a number of fee-free services for the public good, some of which do not directly relate to any particular 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 from time to time the TGA also receives time limited funding (such as for health emergency or pandemic measures), the vast majority (around 85%) of funding is generated through fees and charges set under the cost recovery arrangements.

Policy and statutory authority to cost recover

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.

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.

	2022-23 $'m	**2023-24 $'m**	**2024-25 $'m**	**2025-26 $'m**	**2026-27 $'m**	**Total $'m**
Department of Health and Aged Care	0.00	14.979	15.214	15.332	15.467	60.992
Total	**0.00**	**14.979**	**15.214**	**15.332**	**15.467**	**60.992**

The funding will allow the TGA to increase its service delivery to industry, using freed up cost recovered funds.

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,

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

application and evaluation fees, conformity assessment fees and inspection fees which are imposed on sponsors and manufacturers of medicines and medical devices.

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 and medical devices. Applicable fees and charges are prescribed in the subordinate regulations made under these Acts.

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 trials – 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 (AusPAR).

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 recently implemented 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 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. 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

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. A medicine with a designation in force for the active, indication, dosage form and sponsor can have subsequent submissions reviewed as part of the program.

The TGA orphan program can be seen as part of a global movement to address treatment of approximately 7,000 rare diseases.

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 orphan drug program is an activity undertaken for the public good, with the objective of assisting sponsors bring medicines for rare diseases or new dose forms for special patient populations to market that may otherwise not be available. The incentive provided is in the form of a fee waiver. Application and evaluation fees (under regulation 45 (12) of the Regulations) 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.

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 several different sources of risks that can arise 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.

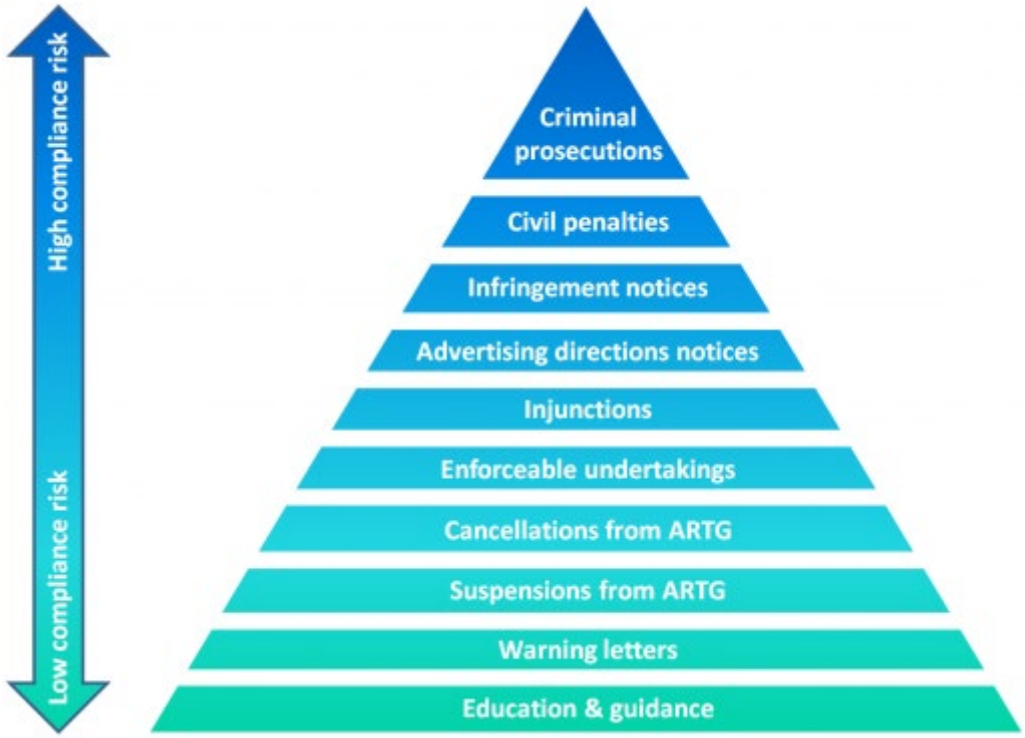
Approach to monitoring

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.

In its review of advertising, the TGA works with the following stakeholders:

- therapeutic goods industry
- health practitioners
- consumers
- advertising industry
- Australian Competition & Consumer Commission
- media.

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 trials participants.

Design of cost recovery charges

Costs of TGA activities

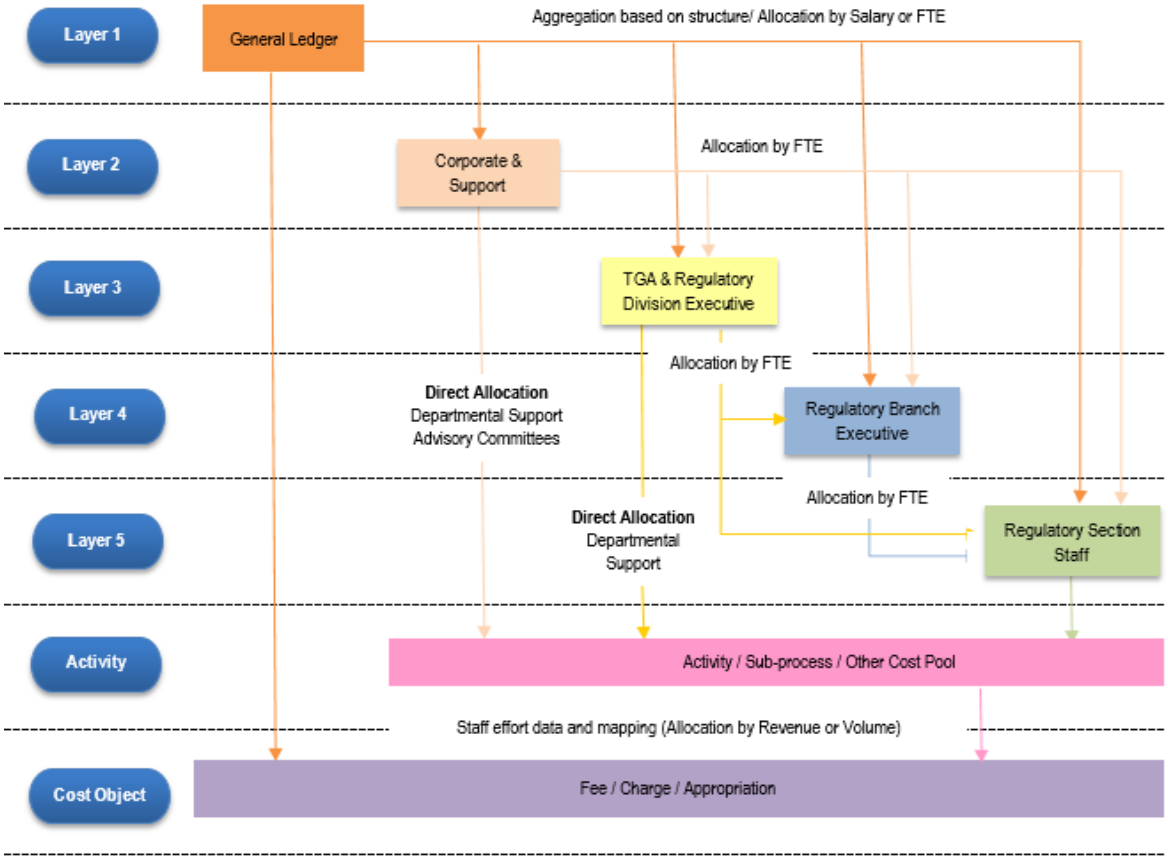
In line with the Australian Government Charging Framework costs are categorised into the following groups for cost allocation:

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 direct or 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.



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

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.

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
- 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 2022-23 annual charge for a Class I medical device is $92 whereas for a high-risk prescription medicine (biologic) the 2022-23 annual charge is $7,685. 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).

2023–24 Fees and Charges – effective 1 July 2023

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 2023-24 financial year fees and charges changes comprised of four 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. additional changes to annual charges to cost recover investment in the TGA laboratory modernisation fit out
4. changes to some medical device fees

1. Indexation increase for 2023-24

The single largest component of the TGA costs is salary, contractors and other staff related costs. Employee costs were estimated to increase by $4.1 million for the 2023-24 financial year mainly related to the 3% pay raise for non-senior executive staff that took effect from March 2023 (as per the Department's Enterprise Agreement). This also included leave provision increases and staff pay increments which were due in August 2023 (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, were estimated to increase by $6.1 million in 2023-24 mainly due to inflation-based increases to corporate charge back ($2.2 million) and the yearly increase apportioned for depreciation/amortisation ($3.5 million) on digital transformation projects.

The indexation factor for 2023-24, based on the previously used formula of the average (composite indexation) of the Consumer Price Index (CPI) and the Wage Price Index (WPI), was 5.2%:

- 50% of CPI Sep 2021 to Sep 2022: 7.3%: 3.65%
- 50% of WPI Sep 2021 to Sep 2022: 3.1%: 1.55%

All fees and charges, other than those mentioned in 4. Changes to some medical device fees (below) and conformity assessment certificate fees, increased by the calculated indexation factor of 5.2%. 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 5.2% increase will not cover all known standard cost increases (salary and corporate costs) in 2023-24, the TGA will need to find savings and efficiencies.

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

The October 2022 Budget provided 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 will be drawn from the TGA Special Account cash reserves, the Budget decision requires this amount to be cost recovered from industry over five years commencing from 1 January 2024 (six financial years), except for the cost recovery of the UDI system which will commence from 1 July 2024.

In the 2023-24 financial year the recovery will be 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 in 2024-25. The components of the digital transformation being recovered as a result of the Government decision are:

i. Cost recovery of final phase of the digital business transformation - $14.7 million

An investment of $14.7 million will enhance TGA's business systems, including establishing a single product portal. This investment will address requests by medicine and medical device sponsors to establish a "tell us once" business system. Industry product sponsors will have a single account to do business with the TGA and with other areas of the Department. This will deliver reductions in regulatory burden and costs for businesses, and potentially support faster access by patients to products. Sponsors will be able to manage and control their own information, including tracking their applications through the review process and responding to requests for information in a timelier manner. Sponsors will also be able to use contemporary methods of providing medical device data to the TGA, including through machine-to-machine interfaces. This will create efficiency improvements through automating and modernising manual processes. For industry it will provide a clear and consistent interaction with Government for the regulation and reimbursement of their products.

Cost recovery of this investment required an annual increase of 3.57% to all annual charges, commencing from 2023-24 for six financial years. As cost recovery will commence from 1 January 2024, for the first financial year (2023-24) this increase will only be 50% (1.78%), with a full annual increase of 3.57% for the next four financial year. The sixth financial year will require a 1.78% increase.

ii. Cost recovery of investment in Adverse Event Management System - $2.2 million

The $2.2 million further investment in the Adverse Event Management System (AEMS) over the next two financial years will improve the management of medicine and biological safety.

The investment will make it easier for health professionals to report adverse events and streamline how relevant data is shared with industry and jurisdictions.

The TGA is creating a self-serve portal for medicine and biologicals sponsors to access adverse event data relevant to their products from TGA systems. Sponsors will have greater, easier, and faster access to the adverse event data needed to fulfill their pharmacovigilance responsibilities. The TGA receives about 130 manual requests from industry per month for this data. The investment will remove this manual step. Sponsors will be able to use their existing TGA credentials to find and extract non-public de-identified case data for uploading into their own pharmacovigilance systems. The investment will also reduce barriers to report medicine and biological adverse events for health professionals directly from the systems doctors use in general practice.

For this component, an annual increase 0.92% was required to medicines and biologicals annual charges. Like the other annual charge increase, 50% of the increase was required in 2023-23 which equates to 0.46%.

iii. Cost recovery of further investment in the UDI system and device specific digitisation - $6.4 million

The 2020 Budget provided investment of $7.7 million for initial development of a UDI system. The initial investment only covered development of a UDI system for implanted medical devices and establishment of a UDI database with linkages to enable data provision to the database. However, to have a single supply chain and safety management system and following stakeholder feedback, the UDI platform will be expanded with a further $2.5 million investment over 2022-23 and 2023-24 to also include all medium and high-risk devices, not just those that are implanted in patients. In addition, $3.9 million will be invested in further device specific digitisation.

The UDI system will allow faster, and more accurate identification of devices included in a recall and help prevent recalled or expired products from being used. The use of UDI will also enable accurate details about the device to be recorded within digital health records or patient implant cards. The UDI system will allow faster identification and correcting of problem devices and support better linking of device data across siloed systems including the UDI system, the ARTG, recalls and adverse events.

The $2.5 million additional investment in the UDI system will be recovered from the medical device industry through an increase of 1.97% to annual charges for medical devices Class II and above, commencing from 2024-25, as cost recovery for this is mandated to commence from 1 July 2024.

The $3.9 million investment in device specific digitisation will allow electronic access to patient information leaflets, streamlined notification and change request processing for industry, and identification of software devices. The funding will be recovered from medical device industry through an increase of 2.46 % (annually) to annual charges of all classes of medical devices, including IVD medical devices. However, for 2023-24 this increase is only 50% (1.23%), with full increase to commence from 2024-25.

The table below summarises the increase to annual charges in 2023-24 to cost recover digital transformation investment.

Increase to annual charges in 2023-24	Digital Transformation	AEMS	Devices Digitisation	Total Increase
Medicines and biologicals	1.78%	0.46%		2.24%
Medical devices and IVDs	1.78%		1.23%	3.01%
Other annual charges i.e., manufacturing licences, OTGs	1.78%			1.78%

3. Laboratory modernisation fit out costs

Last year the TGA relocated to purpose-built facilities in Fairbairn, ACT. The new laboratory building has a flexible and modern design that allows for reconfiguration and efficiency in the laboratory spaces which facilitates more efficient workflows for testing. It also has enhanced security for test samples improving the handling and tracking of products that come to the TGA for analysis. The new modern workspaces allow staff across scientific disciplines to work together more effectively which is critical for solving complex post-market problems or work on highly complex products.

While the relocation of the TGA to the new office building was cost neutral for the TGA, an additional investment was required for the laboratory fit out. For this investment the Department is required to make an additional payment of $4.85 million annually to the landlord for the initial lease term of 15 years. The Department has agreed to charge back only 70% of this amount to the TGA (aligning with the approximate proportion of laboratory activity related to industry product testing) with remaining 30% to be absorbed by the Department.

To cost recover the 70% component (or $3.4 million annually) from industry an additional increase of 4.12% was required to all annual charges.

4. Changes to some medical device fees

i. Increase/decrease of certain fees

Demand for medical devices has seen an unprecedented number of new sponsors and new applications over the past two years, as well as the need to deliver activities that are not necessarily covered by direct fees. Many new entrants to the medical devices industry, have limited knowledge of regulation, quality management, and certification processes. Efforts have focused on supporting those manufacturers (including significant investment in domestic manufacturing capability) and sponsors seeking regulatory approval for devices used in the response to the COVID-19 pandemic.

In parallel, the TGA has continued to progress reforms as outlined in *An Action Plan for Medical Devices*, including alignment with the significant changes occurring in the European Union, which requires recertification of devices in most instances and the flow on implications for existing Australian market approvals. Important reforms, extensive education sessions and clarifications to how emerging technologies are regulated in Australia such as personalised medical devices (including 3D printed devices) and software medical devices have been critical activities where the TGA is unable to charge fees. We also reviewed our:

- business-as-usual evaluation and post market activities
- activities that had not been reviewed for many years where the fees charged were not commensurate with the effort needed.

and identified a number of processes and activities that could change to streamline processes and deliver efficiencies.

The workload in relation to medical devices pre-market activity continues to be significant. The TGA processed 7,624 medical device (including IVD), disinfectant and variation applications in 2021-22. A recent review of the average time taken to carry out regulatory activities found discrepancies between costs and fees for:

- disinfectant evaluations
- certain new and variation application
- application audits
- conformity assessment certification activities.

To adequately recover associated costs, the below changes to medical device fees have been implemented from 1 July 2023.

Description	Previous fee $	New Fee $
Conformity Assessment Certificate Application	1,077	1,416
Device Class 1 Sterile – Application for Inclusion	1,098	575
Device Class 1 Measuring – Application for Inclusion	1,098	575
Variation to ARTG inclusion entry if entry is incomplete or incorrect		
IVD Class 3	482	1,750
IVD other classes	482	1,000
Other Medical Devices	482	1,000
Application Audit Assessment – Level 2		
Medical Device Class III (non IVDs)	7,582	16,000
Other Medical Devices (non IVDs)	7,582	4,000
Application Audit Assessment fee for Class 3 IVDs	7,387	22,387
Application Audit Assessment fee for Class 4 IVDs (non-immunohaematology reagent) - This is a newly introduced fee	0	22,387
Application Audit Assessment fee for Class 4 IVDs (immunohaematology reagent) - This is a newly introduced fee	0	16,621
Application Audit Assessment fee for Class 4 in-house IVDs	68,434	22,387
Listed Disinfectant – application fee	482	2,200
Listed Disinfectant – variation fee	482	1,400

We also removed the safety evaluation fees for disinfectants with a new ingredient (current fee $19,699), as it is simpler to continue to recover costs through the application and variation fees.

ii. Non-indexation of conformity assessment fees

Conformity assessment fees are charged for assessment services provided in relation to an application for a medical device conformity assessment certificate. Data for the 2022-23 financial year indicated a systematic under-recovery of the costs incurred by the TGA in providing conformity assessment services. This is primarily because of the TGA's fee reduction policies, which reduced the fees for these services below the level of cost recovery.

Accordingly, there is a need to further review and update fee reduction approach to these fees, to examine and ensure that the fees charged for these services will facilitate full cost recovery. However, as this change can be accommodated through a review of the current approach, the conformity assessment fees has not been increased for the 2023-24 financial year (i.e., they were not subject to the 5.2 per cent increase).

iii. Waiver or refunds for transitional medical devices

Under reforms introduced by the Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019, a number of specified kinds of medical devices (transitional medical devices) were reclassified to support the harmonisation, where possible, with regulation of medical devices with the European Union, e.g., spinal implantable medical devices. Separately, a number of medical devices that are subject to the reclassification reforms are also included in the legislative instrument that underpins the Prostheses List (PL), which is made under the *Private Health Insurance Act 2007*. The PL is itself the subject of a number of reforms, although these are not aligned with or connected to the medical device reclassification reforms, and the PL will be renamed in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (Rules). Relevantly, the inclusion of a medical device in the PL or the Rules is dependent on that medical device being included in the ARTG. However, because of the PL reforms, there is expected to be a period in 2024 when there will be no new entries added to the Rules.

Sponsors of reclassified medical devices who have successfully included their medical devices in the ARTG at the new classification, therefore, may need to maintain the former ARTG entry for those medical devices to ensure their continuing inclusion in the Rules, with the effect that such sponsors will need to maintain two entries in the ARTG for a period of time (expected to be the 2023-24 financial year).

Having two entries in the ARTG means that affected sponsors will incur two sets of annual charges under the Therapeutic Goods (Charges) Regulations 2018. Amendments have been included in the Regulations to provide for a waiver and refund of charges in relation to the former ARTG entry for transitional medical devices that is needed for the devices to remain on the Rules.

Summary of changes to fees and charges in 2023-24

To summarise, in 2023-24:

- all fees and charges increased by an inflation-based indexation of 5.2% – capped at the previously used indexation formula, other than some medical device fees (refer section 1 and 4)
- mandatory increase to annual charges for cost recovery for final phase of digital and business transformation – 50% of the required increase – 1.78% to 3.01% (refer 2)
- additional increase to annual charges for additional chargeback for the TGA laboratory fit out– 4.12% (refer section 3)
- changes to certain medical device fees (refer section 4)

	Inflation Based Increase	Cost Recovery – Digital Transformation and Others	TGA Building Lease Charge Back (50%)	Total Increase
All TGA fees	5.2%			5.2%
Medicines and biologicals annual charges	5.2%	2.24%	4.12%	11.56%
Medical devices and IVDs annual charges	5.2%	3.01%	4.12%	12.33%
Other annual charges i.e., manufacturing licences, OTGs	5.2%	1.78%	4.12%	11.1%

Further changes to fees and charges in 2023–24

The new prescription medicine application and evaluation fees have been introduced to facilitate a streamlined process for applications for strain updates to certain vaccines (COVID-19, respiratory syncytial virus (RSV) and seasonal flu). The new fees will be applicable where the vaccine is closely related to an existing vaccine that is included in the ARTG in relation to the applicant.

The work effort required for the vaccine strain update applications is similar to the work effort for minor variation applications for prescription medicines under the *Therapeutic Goods Act 1989*. Therefore, the application and evaluation fees that currently applies to minor variation applications for prescription medicines will also apply to the new vaccine strain update applications. The new fees will support vaccine strain updates for COVID 19 vaccines. The regulation amendment to give effect to the below fees were approved by the Executive Council at its meeting of 23 November 2023, and commenced on 28 November 2023.

a. Application fee - $1,241
b. Evaluation fee - $4,954

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

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 2023-24 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 2023-24 fees and charges

Consistent with previous practice, the TGA consulted with the following thirteen industry representative groups in December 2022 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 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 that this decision had already been made by Government.

There was also significant opposition to an increase in charges to cover a loan made to the Department to support the move of the TGA laboratory to the Fairbairn site. Industry emphasised that this impact on industry charges had not been raised with them prior to the Department's decision to move to the new site.

In order to obtain broader feedback from industry and other stakeholders, the TGA also undertook a public consultation. The four-week consultation ended on 21 March 2023.

36 submissions were received, including 11 from industry representative bodies, 22 from sponsors or manufacturers and 3 from others. Of these:

- 28 submissions including from peak and major sponsors supported the proposed 5.2 per cent indexation increase to the TGA charges.
- several submissions opposed (or were silent) additional increases to the TGA charges for cost recovery of the digital transformation costs (as per the October 2022 Budget decision) and additional property costs in relation to the TGA's relocation to a new site in Fairbairn, including setting up a new laboratory.
- the medical device industry raised a number of concerns about the proposed increases to specific medical device fees for assessing applications, in particular, level 2 audits, disinfectants and diagnostic tests. They claimed that the TGA should increase the efficiency should instead fully rely on overseas approvals, rather than undertaking its own assessments.

[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.

The feedback from the submissions was put forward to the Government for consideration along with the proposed fees and charges for 2023-24. Government approved the above changes to the TGA fees and charges for 2023-24, commencing from 1 July 2023. It was noted despite significant increases in 2023-24, the TGA fees and charges are significantly lower than the fees and charges of a number of comparable overseas regulators.

Financial and non-financial performance

a) Financial performance

Financial performance in previous financial years

Details	2018–19 Actual $'m	2019-20 Actual $'m	2020-21 Actual $'m	2021-22 Actual $'m	2022-23 Actual $'m
Revenue from Government	2.26	8.53	13.76	16.19	21.44
Sale of goods and services	159.00	168.04	169.49	178.62	187.50
Other revenue and gains	0.05	-	1.49	3.72	9.81
Total A	**161.31**	**176.58**	**184.74**	**198.52**	**218.75**
Employee expenses	93.62	86.73	88.08	96.08	109.36
Suppliers	57.56	74.84	84.37	100.71	101.73
Depreciation and amortisation	7.52	8	9.97	10.43	5.40
Write-down and impairment of assets	1.45	1.6	0	0.25	0
Total B	**160.14**	**171.16**	**182.43**	**207.46**	**216.50**
Surplus (deficit)	**1.16**	**5.42**	**2.32**	**-8.94**	**2.25**
Retained surplus	51.72	47.68	50.00	41.06	40.21
% of Retained surplus to TGA budget	32%	27%	27%	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 is 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 $23.278m 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 $23.278m. This will allow the TGA to rebuild its cash reserves in coming years.

The below table reflects the TGA's known position in May 2023 as published in the 2023-24 Portfolio Budget Statements (PBS).

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

Financial Estimates	2023–24 Budget $'m	2024–25 Estimate $'m	2025–26 Estimate $'m	2026-27 Estimate $'m
Cost Recovery and Other Revenue	191.79	205.32	215.58	226.36
Government Appropriation	34.93	30.53	30.19	30.19
Expenses	228.66	233.91	242.25	253.95
Surplus (Deficit)	**1.94**	**1.94**	**3.52**	**2.60**

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 2021 to 30 June 2022, and contribute to annual publications that track our progress against the priorities we have established for the financial year. The TGA's performance report containing the statistics for the period 1 July 2022 to 30 June 2023 will be released shortly.

c) Risk assessment

A cost recovery risk assessment for the annual increases to fees and charges was undertaken in May 2022 resulting in an overall low risk rating for TGA's cost recovery arrangements. The cost recovery risk rating of low is based on assessment of the criteria using the Charging Risk Assessment (CRA) template. The key medium to high risks for cost recovery are that the amount to cost recover exceeds $20 million and 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)

Key forward events

Key forward events schedule	Next scheduled update
Update 2024-25	June 2024

CRIS approval and change register

Date of CRIS change	Approver	CRIS change
8/6/2023	Deputy Secretary, 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

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

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Reference/Publication #