Australian Government
Department of Health
Therapeutic Goods Administration

# Cost Recovery Implementation Statement

## 2020-2021

Version 1.0, February 2021

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[1], 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) devices, and biologicals onto the Australian Register of Therapeutic Goods (ARTG) and the ongoing monitoring and surveillance of them.

## Description of the activity

The TGA protects the health and safety of the community by regulating therapeutic goods for safety, effectiveness/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; and
- 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 on the ARTG. Medical devices and biologicals must be 'included' on 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 of which are minor, some 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's Outcome 5 - Program 5.1: Protect the Health and Safety of the Community Through 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 in-vitro diagnostic (IVD) devices;
- blood, blood components and biologicals; and
- good manufacturing practices (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. Some (and not all) of the costs of these services are met from the Government appropriation. A review of the TGA fees and charges is underway to determine the costs and the appropriate funding source of the TGA activities.

While some funding is also provided by the Government for meeting secretariat costs for medicines and chemicals scheduling regulation, and in the form of an interest equivalency payment against the special account balance (reserves), the vast majority (around 96%) of funding is generated through fees and charges set under 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.

The 2016-17 Budget measure "Improving the Regulation of Therapeutic Goods in Australia" provided $20.4 million (from TGA reserves) to meet the costs of implementation of a number of regulatory reforms for completion within a period of 24 months. Any increase in ongoing costs will be met via cost recovery arrangements through new and revised fees and charges.

In the 2019-20 Mid-year Economic & Fiscal Outlook (MYEFO) as part of ongoing measure Improving Access to Medicines Item 7, the Government agreed to provide funding of $33 million over the financial years 2019-20 to 2022-23. This includes an ongoing funding of $15 million per annum from 2022-23 for meeting the costs of fee-free services provided for the public good and other costs which cannot be appropriately cost recovered. While the Government asked that the TGA resources are maintained at existing levels, a review of TGA fees and charges to determine the costs of chargeable and non-chargeable activities in accordance with the Australian Government Charging Framework is underway.

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 and medical devices.

The *Therapeutic Goods Act 1989* (the Act) provides a 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

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

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

# Australian National Audit Office audit on Application of Cost Recovery Principles

In 2018-19, the Australian National Audit Office (ANAO) conducted a cross-entity performance audit on application of cost recovery principles in the Commonwealth. The Department of Health (Health) for the TGA was one of the selected entities subject to the performance audit. The objective of this audit was to assess whether the selected regulatory entities effectively applied the cost recovery principles of the Australian Government's cost recovery framework.

The audit found the TGA's cost recovery policies and methodology were largely compliant with the CRGs, although it had scope to improve the effectiveness of cost recovery arrangements. The key TGA specific recommendations were:

1. Ensure that the TGA's CRIS is fully compliant with the CRGs and cost recovery performance at the regulatory activity level is reported annually in the CRIS
2. Health seeks a decision from Government in relation to funding of TGA's fee-free services
3. Implement ongoing stakeholder engagement strategies for cost recovery arrangements in consultation with stakeholders and include performance measures for engagement on cost recovery in the CRIS.

While specific information recommended by the ANAO is included in this CRIS, further improvements are being made to it to ensure that the TGA's CRIS remains fully compliant with the CRG as per Recommendation 1 of the ANAO.

Recommendation 2 has been implemented: the Government has agreed to provide funding of $33 million over four years from 2019-20 to cover the costs of such activities which are not appropriate to be cost recovered. In addition, TGA is conducting a review of all its fees and charges.

Information about the stakeholder engagement strategy has been included in the CRIS as part of implementing recommendation 3. A survey for measuring performance of stakeholder engagement was conducted in October 2020.

The complete ANAO report is available on the ANAO website.

# 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 on 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 on the ARTG before they are supplied in Australia. These are implemented through:

- the Special Access Scheme (SAS);
- the authorised prescriber scheme; and
- the clinical trials systems (CTX and CTN).

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 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

Regulatory decisions are made within a framework of guidelines. The guidelines must maintain currency with scientific and technical developments.

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 on the ARTG

Before being placed on 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 on 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:
  - the composition of the drug substance and the drug product;
  - batch consistency;
  - stability data;
  - sterility data (if applicable);
  - the impurity content;
  - non-clinical data evaluated by toxicologists;

  - pharmacology data;
- Toxicology data; and
- 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 on the ARTG, the delegate may take into consideration independent expert advice provided by the Advisory Committee on Prescription 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); and
- changing 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) on the ARTG before export.

## Regulatory Reforms – Opioid prescriptions

A number of regulatory reforms to address inappropriate/excessive use of certain opioid medicines was introduced in late 2019; implementation will be complete in 2021. A broad education strategy and campaign to address regulatory changes and other related matters for increasing awareness of practitioners and consumers is proposed to commence on 25 January 2021.

In order to reduce the burden due to regulatory changes and to assist sponsors to make changes to their products, a fee waiver has been provided for variations to pack sizes and product information. Some of the 2019-20 MYEFO funding covers the costs related to such applications.

# 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 on the ARTG depending on the level of risk associated with making the product available and accessible to consumers.

## Registering an OTC medicine on 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 on 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 good manufacturing practice (GMP) is in place;
- requesting advice from the Advisory Committee on non-prescription medicines;
- advising the sponsor of the outcome of the application process; and
- 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 on 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.

## Brand equivalence statement for registered OTC medicines

The TGA receives requests from sponsors for brand equivalence statements for the purpose of Pharmaceutical Benefits Scheme (PBS) listing either as part of an application to register an OTC medicine or after a medicine has been registered on the ARTG.

Applications to register an OTC medicine infrequently include requests for a brand equivalence statement. As TGA provides advice for the purpose of PBS listing at the time of approval for registration a separate fee is not charged for this service.

Requests that are received after a medicine has been registered on the ARTG may or may not require evaluation of clinical data - typically bioequivalence data. Post-registration requests for brand equivalence statements that do not require supporting clinical data are charged a lower fee than the fee charged for a request that requires supporting clinical data or a justification for not providing such data.

## 3. Complementary medicines

Medicinal products containing such ingredients 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 on the ARTG.

### Listing a complementary medicine on the ARTG

Listed medicines are low risk medicines that are listed on the ARTG. There are two pathways to list a medicine on 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. 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 on 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 Good Manufacturing Practice (GMP).

Under the recent reforms, sponsors who apply to list a new medicine will be required to select the indications for their medicine from the list of permitted indications that is maintained by the TGA.

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 is a new listing pathway that will allow 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. In 2019-20, there were ten such applications actioned.

#### *Transition arrangements*

- The assessed listed medicines pathway has been introduced alongside the permitted indications reform.
- A **three year** transition period commenced on 5 March 2018 for existing listed medicines to be re-listed.
- During the transition period, sponsors of existing listed medicines will need to comply with the new provisions as follows:
  - sponsors of existing listed products with low level indications will be required to transition their products to the new requirements by selecting appropriate indications exclusively from the list of permitted indications; and

  - existing listed products with indications not eligible for inclusion in the permitted indications list, will be required to either, transition their products to the new assessed listed medicines pathway, or alternatively, choose low level indications from the permitted indications list.

- To assist industry to make the early transition to permitted indications, sponsors are allowed to make the transitional application without payment of a fee during the transition period. While the TGA was able to absorb these costs for the first 18 months of the transition period, at the 2019-20 MYEFO, a decision was made by the Australian Government to fund fee waivers for the remaining period from October 2019 to March 2021.

### Registering a complementary medicine on 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 on 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, rather than a prescriptive framework. All medical devices must demonstrate compliance with the Essential Principles. The extent of evidence 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.

In order to recover costs of pre 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 on the ARTG

Under the Act, medical devices must be included on 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, representing higher overall costs associated with higher risk medical devices.

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 conformity assessment document, covering an assessment of a manufacturer's quality management system and assessment of design dossiers, where applicable, 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.
- The 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).

For certain high risk medical devices and IVDs, manufacturers must obtain Conformity Assessment Certificates issued by the TGA, regardless of whether they have a market authorisation/approval issued by an overseas regulator/assessment body. This requirement for TGA conformity assessment certificate applies to medical devices containing medicinal substances or materials of animal, microbial, recombinant or human origin and Class 4 IVDs. Manufacturers may also choose to seek conformity assessment certificate from TGA for medical devices supplied in Australia, rather than relying on overseas certification.

## 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 Class I medical device, i.e. there is no requirement for the manufacturer of such device to have a

certification/approval issued by an assessment body and/or regulator. The labelling or packaging of such device 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/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 and registered on the ARTG

All medical devices listed and registered on the ARTG (including in vitro diagnostic) prior to 2002 (previously called therapeutic devices) have been transitioned to the new regulatory framework and are now regulated as included devices under Chapter 4 of the Act. The full transition period for in vitro diagnostic (IVD) medical devices ended on 30 June 2017.There is a small number of other therapeutic goods that do not meet definition of a medical device, medicine or biological and are regulated under Chapter 3 of the Act. These include tampons and menstrual cups; and hard surface disinfectants.

The TGA is implementing reforms in the regulation of other therapeutic goods. As a result of this, tampons and menstrual cups are no longer required to be listed on the ARTG. Hard surface disinfectants that are currently listed (hospital grade without specific claims) will be exempt from the requirements of entry in the ARTG. Registered hard surface disinfectants with specific claims will be moved from registered to listed other therapeutics goods. These reforms will reduce unnecessary regulatory burden and sponsors would be required to pay lower annual charges for these products.

## 6. Biologicals

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

Some examples of tissue therapies currently being used are:

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

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

- chondrocytes used for cartilage regeneration;
- isolated pancreatic islet cells for the treatment of diabetes; and
- mesenchymal progenitor cells for the treatment of musculoskeletal defects and in a range of other clinical applications such as cardiovascular repair.

### Inclusion on 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; and
- manufacturers of Class 2, 3 and 4 biologicals are required to demonstrate compliance with manufacturing principles equivalent to the Australian Code of Good Manufacturing for human blood and blood components, human tissues and human cellular therapy products (2013).

## 7. Blood and blood components

Blood, blood components and plasma derivatives are regulated under the Act. 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; and
- manufactured by a blood collection centre for a medical practitioner for therapeutic application to a particular patient under the practitioner's care.

## 8. Regulatory activities provided for the public good

### a) 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:

### 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.

## Authorised prescribers

In these circumstances a medical practitioner may be granted authority to become an Authorised Prescriber (AP) of a specified unapproved therapeutic good (or class of unapproved therapeutic goods) to specific patients (or classes of recipients) with a particular medical condition.

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 'Authorised Prescriber' 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. 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 2019-20, there were 42,232 SAS category A notifications, 63,026 SAS category B applications, 16,234 SAS category C applications, and 1,419 AP applications. The annual cost of these fee free services is estimated to be $3.12 million or around $26 per application/notification. Recovering this cost through a large number of small application fee levied on patients and or the medical practitioner is unlikely to be cost efficient in an administrative sense. Moreover, this would also impact on the access of these products to the seriously ill patient in a time critical manner.

While the costs of these functions were previously recovered indirectly through the annual charges levied on therapeutic goods approved for supply in Australia, as per the 2019-20 MYEFO decision Government has agreed to fund this activity in future.

## b) 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 2019-20, the TGA assessed 22 orphan drug applications, compared to the total fee paying applications of 142 for prescription medicines (new chemical entity, major variation and extension of indications). There were no orphan drug designations for registration of new generic products, compared to seventy-seven fee paying applications in 2019-20. The total cost attributed to the orphan drug program in 2019-20 is $4.4 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 were cross-subsidised by the prescription medicine industry thus far, however recognising growth in demand and cross subsidisation issues, the Government has now agreed to fund this program in future. However, as the number of orphan drug applications continues to rise, additional costs of this program would need to be absorbed within cost recovery revenue until further funding is provided by the Government.

# B: Compliance, monitoring and enforcement

The TGA's Regulatory Compliance Framework outlines how the TGA manages its compliance function under its legislation and sets out the overall approach to compliance. This also outlines the TGA's general approach to ensuring uniform and proportionate responses where non-compliance with regulatory requirements is identified.

The TGA actively monitors the quality, safety and performance of therapeutic goods when they become available to consumers to promote the on-going compliance of the products with TGA's regulatory requirements and has an ongoing program of verifying the suitability of manufacturers to produce therapeutic goods for supply in Australia. The TGA also actively monitors unlawfully supplied products and takes appropriate regulatory action where these are identified.

## 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 therapeutic goods - they can be product risks (risks that are inherent to the product), compliance risks (risks occurring from products failing to meet requirements), and unlawful products (risks of unauthorised products).

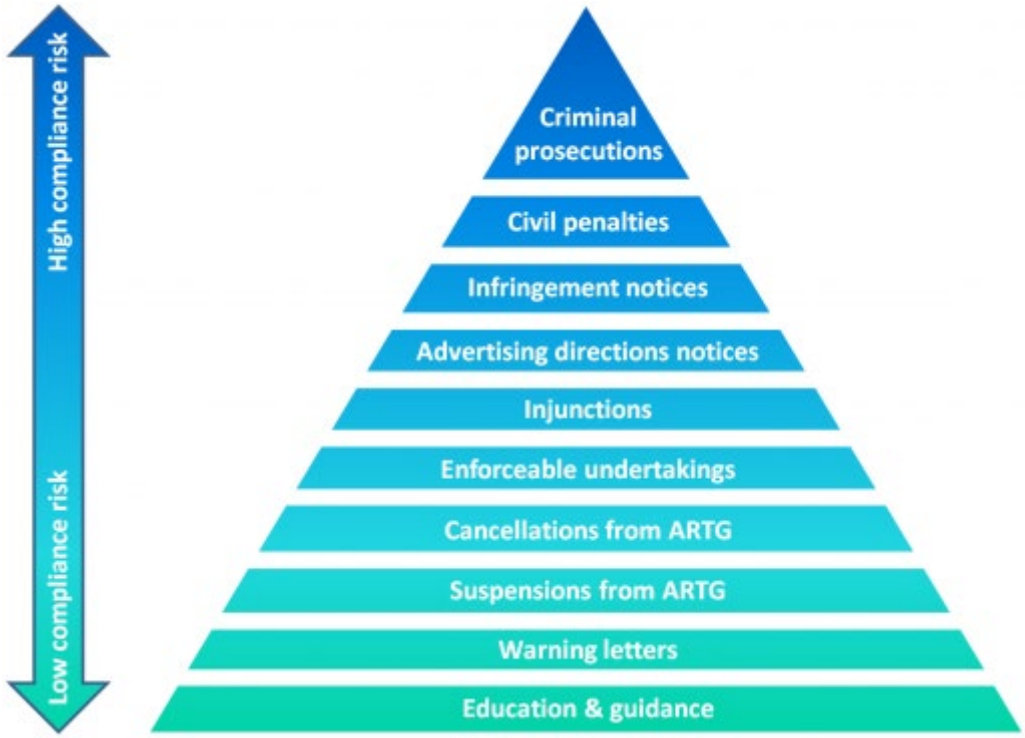
## Approach to monitoring

The TGA employs a combination of monitoring strategies to support its compliance program. Underpinning all forms of monitoring is the legislated requirement for sponsors to monitor the performance of their products in the marketplace and, where higher risk products or serious health issues are involved, to report problems to the TGA in a timely manner.

The TGA uses its strategies to monitor the market for signals of potential non-compliance across the range of regulatory areas covered by the Act. The TGA employs a uniform risk-based approach to determining the significance of any signals detected and the appropriate regulatory response.

## Approach to compliance

The TGA takes a risk-based approach to compliance that attempts to identify entities at risk of unintentional or deliberate non-compliance and enable the development of appropriate strategies to prevent non-compliance. The below diagram depicts TGA's approach to compliance.




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.

The TGA uses a range of tools when taking action on a compliance matter. It publishes information about regulatory compliance activity on its website.

## Regulatory education

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.

## Consumer health literacy and confidence in the regulatory scheme

Overall, Australian health literacy including consumer awareness of the TGA's role and activities and regulation of and information about therapeutic goods is very low. A central objective of Australia's National Medicines Policy is the quality use of medicines, which includes their appropriate selection. Yet unlike other regulators, the TGA provides very little public information about therapeutic goods, and almost none relating to medical devices and biologicals. Today, consumers are becoming more involved in decisions surrounding their treatment and healthcare, and have greater access to information and therapeutic goods than ever before.

## Restriction/Warnings

There may be a need for the TGA to act in the interests of consumers to restrict or revise an indication for use of a therapeutic good. Sometimes this may be based on information from other jurisdictions.

## Suspension/Sanctions

The identification of more serious contraventions of the TGA Act and/or Regulations may require therapeutic goods to be suspended from the ARTG or sanctions, such as enforceable undertakings, to be applied.

## Cancellation/Prosecution

Some products may be seized and/or cancelled from the ARTG in the event of deliberate non-compliance or discovery of non-compliant systems or activity associated with the therapeutic good. The discovery of activities with criminal intent in relation to therapeutic goods - e.g. counterfeit medicines - is dealt with under provisions of the Act and Regulations, not necessarily only through the imposition of civil penalties but also, on occasion, through criminal prosecution.

## Prioritisation of compliance and enforcement matters

The TGA's monitoring programs receive signals of possible non-compliance with regulatory requirements from many sources. 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.

The following criteria are indicative of the factors guiding the prioritisation of monitoring and compliance actions:

- issues that may have adverse health consequences for consumers as a result of public access to inappropriate or dangerous goods; and
- issues that may affect the TGA's reputation among key stakeholders leading to a loss of confidence in the regulatory processes and subsequently loss of confidence in available therapeutic goods.

In cases where the TGA decides not to engage in regulatory action in relation to non-compliance, the TGA may:

- provide information to the party to help deal with the issue and gain a better understanding of the Act;
- postpone or cease investigations, where insufficient information is available, with a view to a later investigation once more information is available;

- draw the possibilities of contraventions of legislation to the attention of the party and provide information to encourage rectification and future compliance;
- place relevant parties on notice about TGA's concerns and the possibility of future actions and investigation should non-compliance continue; and
- deal with a matter informally, where parties have attempted to correct possible contraventions and provide information to prevent recurrence.

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

The TGA reviews advertisements for therapeutic goods, where permitted, to ensure compliance with the conditions of inclusion on the ARTG that are detailed in the Regulations and the Therapeutic Goods Advertising Code (TGAC). These advertisements may be in, but are not limited to, broadcast and mainstream print media, billboards, cinema films or the internet.

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 medical devices and other therapeutic goods appearing in broadcast and mainstream print media, billboards, cinema films, the internet etc. The majority of activity in this area is related to assessing the validity of complaints about current advertisements that are claimed as not meeting the requirements.

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;
- Medsafe (NZ therapeutic goods regulator); and
- Media.

## C: Regulation of manufacturers of therapeutic goods

### Good manufacturing practices

In Australia, manufacturers of therapeutic goods are required to hold a licence, except for manufacturers of medical devices who are required to have conformity assessment certification (issued either by the TGA or by one of the European Notified Bodies). To obtain the licence, a manufacturer must demonstrate that they have the ability to comply with good manufacturing principles (GMP), which include relevant Codes of GMP and Quality Systems, and have 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.

The GMP related regulatory activities undertaken are as follows:

### Licensing

The TGA usually undertakes on-site 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. 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 reviews the use of unapproved medicines and medical devices to be made available to patients participating in a clinical trial. There are two schemes under which clinical trials involving medical devices may be conducted:

- Clinical Trial Notification (CTN) Scheme—this involves a notification only with a nominal notification fee (no approval or decision is made by the TGA)
- Clinical Trial Exemption (CTX) Scheme—this process comprises an assessment of summary data and usage guidelines for a proposed clinical development program, and if approval is granted the subsequent trials must be carried out under the terms of the approval and be notified to the TGA, and
- a pilot program for Good Clinical Practice (GCP) inspection program was completed in the 2019-20 financial year. The GCP inspections program strengthens the clinical trials environment by addressing a gap in regulatory oversight of the conduct of Australian clinical trials. The TGA has assessed the effectiveness of the pilot program and is implementing an ongoing GCP inspection program that will strengthen Australia as an attractive clinical trial destination for both local therapeutic goods sector and in attracting internationally sponsored clinical trials.

# 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:

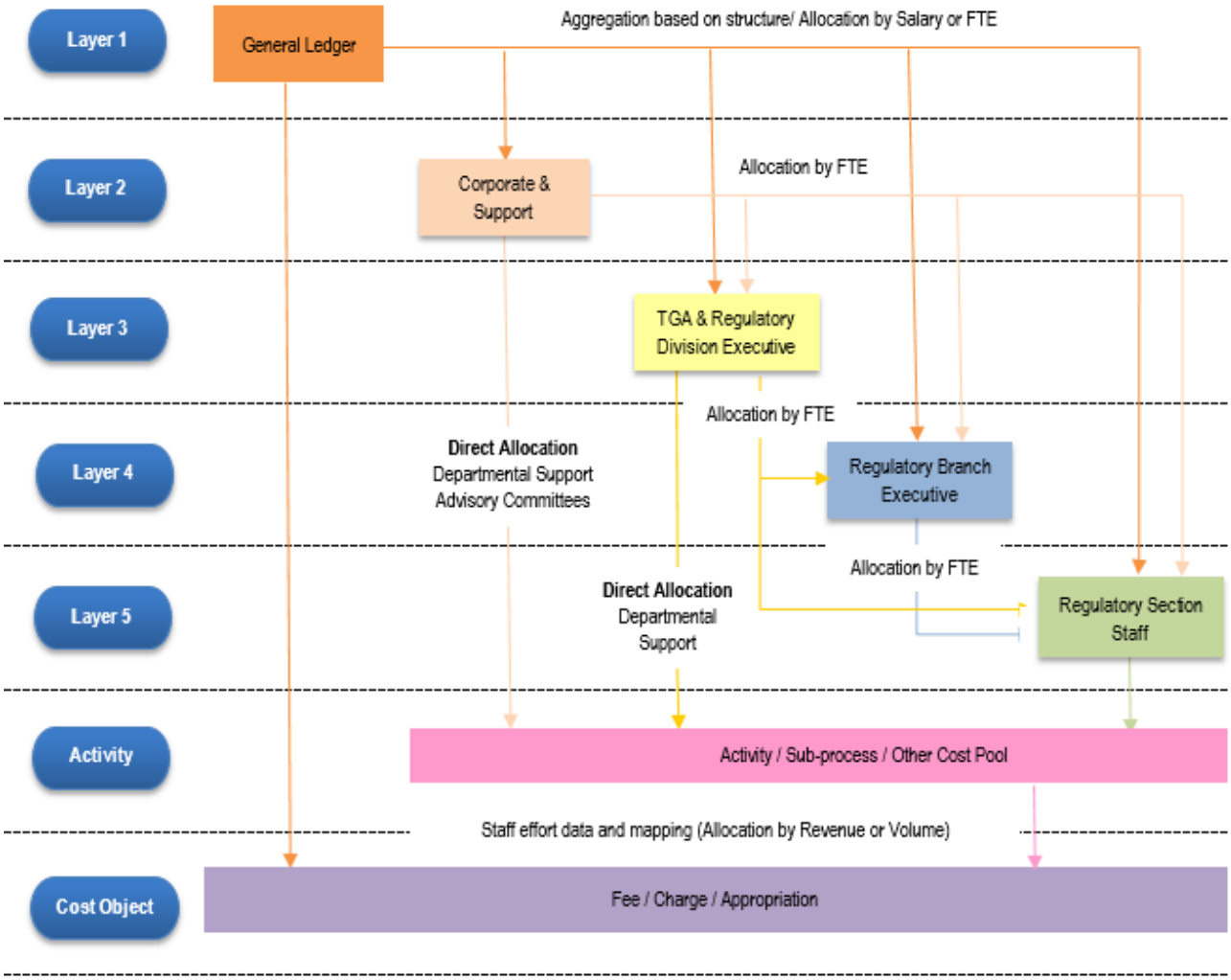
**Direct costs:** can be easily traced to a cost object[3] with a high degree of accuracy. The allocation of direct costs to a cost object is relatively straightforward. The most common direct costs are staff salaries (including on-costs such as training, superannuation and leave) and supplier costs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

**Indirect costs:** are the costs that cannot be easily linked to a cost object or for which the costs of tracking outweighs 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 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.

The TGA uses a software solution 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 on the basis of 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. The current cost model is being reviewed as part of review of TGA fees and charges.




[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."

**"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."

For example, application, evaluation and inspection fees. TGA has limited authority under the Act to waive or reduce fees.

**"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 products registered, listed or included on 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 annual charge for a class I medical device is ninety dollars whereas for a high-risk prescription medicine (biologic) the annual charge is $7,410. 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).

## Regulatory reforms: Review of medicines and medical devices regulation

In order to ensure that Australia continues to be well positioned to respond to emerging global trends, in 2015, an expert panel undertook an independent review of medicines and medical devices regulation to identify areas of unnecessary, duplicative, or ineffective regulation that could be streamlined and opportunities to enhance the regulatory framework.

To achieve long-term sustainable reform, a strategic and systems-based approach and the response to the Expert Panel Review of Medicines and Medical Devices Regulation was released in September 2016. It supported 56 of the 58 Review recommendations. In summary, those recommendations were:

- expanding the pathways by which sponsors can seek marketing approval for a medicine or medical device, including making provision for utilisation of assessments conducted by comparable overseas regulators, and for expedited assessments in defined circumstances;
- identifying comparable overseas regulators using transparent criteria;

- enhancing post-market monitoring of medicines and medical devices and streamlining post-market requirements for products in the ARTG;
- improving transparency and predictability of processes and decisions, to ensure Australians have timely access to high quality, safe and efficacious products;
- expanding the pathways by which sponsors can approve an ingredient for use in a listed medicine, and for marketing approval of a listed complementary medicine;
- enhancing the transparency and predictability of processes and evidence requirements associated with ingredient approvals and complementary medicine marketing approvals;
- improving and clarifying the interface and synergies between the market approval of therapeutic goods and advertising requirements that ensure consumer protections are balanced with the availability of information for consumers and health professionals to make informed spending and health decisions; and
- enhancing and streamlining the advertising framework to facilitate and maximise compliance and the management of complaints.

The majority of the reforms have been implemented, while some longer-term reforms are still progressing, including particular reforms that commenced later in the implementation. The staged approach allowed adequate transition times to safeguard the continued availability of therapeutic goods on the Australian market.

Consistent with the 2016-17 Budget decision, the reforms implementation costs were met from the TGA reserves. Therefore, it had no impact on industry. The ongoing costs, if any, are being recovered through fees and charges levied as per the Australian Government Charging Framework.

# 2020–21 Fees and Annual Charges – effective 1 July 2020

## A. Indexation increase for 2020-21

In January 2020, the TGA budget forecast for 2020-21 suggested that an increase of 4.3% would be required to the TGA fees and charges to absorb the anticipated increase in known costs only, while maintaining the TGA resources at existing level. The majority of the increase in costs was because of the estimated increases in staff and contractor expenses due to salary increase as per the Enterprise Agreement ($3.8 million), and corporate costs and depreciation ($3.3 million).

This forecast assumed constant demand for the TGA services in 2020-21, however, following the outbreak of the COVID-19 pandemic, a significant downturn is expected for certain TGA activities. In addition, medical devices revenue will reduce by approximately $2.6 million because of lower annual charges for certain classes of medical devices (discussed later in the CRIS). The increase in medical devices applications as a result of COVID19 has stabilised and the full impact of the COVID19 is not known yet.

With a view to minimise the impact on industry, an increase of 1.95% was approved by Government to most fees and charges from 1 July 2020 which was based on an indexation factor as follows:

- 50% of cost price index Sep 2018 to Sep 2019 of 1.7% : 0.85%
- 50% of wage price index Sep 2018 to Sep 2019 of 2.2%: 1.1%.

The 1.95% increase is consistent with the long-standing practice which industry is well familiar with. Indexation of fees and charges is also consistent with government policy. The indexation-based increase to fees and charges not only provides certainty to sponsors but also offers

opportunities for efficiency gains through TGA's business process improvements. The TGA would need to achieve significant internal efficiencies to absorb additional costs in 2020-21.

In applying the indexation factor, fees and charges are rounded to the nearest $10 for items less than $10,000 and to the nearest $100 for items $10,000 and above. Due to the rounding policy and low indexation increase, a number of low-level fees remained unchanged for 2020-21.

## B. Revision in fees for consent to supply goods that do not comply with applicable standards

Under sections 14 and 14A of the Act, sponsors can seek the Secretary's consent to supply medicines and biologicals that do not comply with the applicable standards. Similar provisions exist in sections 41MA and 41MAA for seeking the Secretary's consent to supply medical devices that do not comply with the Essential Principles. Generally, non-compliance relates to labelling and changes to the details (name/address etc.) of the sponsor or manufacturer. The Secretary's delegate grants consent when the sponsor/manufacturer can provide evidence of an appropriate risk mitigation strategy.

Different fees applied for medicine (including biologicals) and medical device consent applications until 2019-20 – even though the processes are broadly similar. Sponsors of medical devices also raised a concern that the current fee was too high especially for a single application with a large number of products covered by different ARTG entries.

While the previous fee was set at the appropriate level where a consent application contained a single ARTG entry, the cost of processing an application containing multiple entries rises marginally for each additional entry included in the same application, and not proportionately to the increase in the number of entries.

To address the above issues, we introduced a revised fee structure for obtaining the Secretary's consent for all types of therapeutic goods from 1 July 2020 as follows:

- application containing one entry - $490; and
- application containing more than one entry involving the same non-compliance issues for such entries - $490 for the first entry plus $100 per additional entry included in the application.

This fee structure is compliant with the CRGs and would benefit majority of sponsors of consent applications. For example, for a medical device sponsor, an application with 10 device entries would only require payment of a fee of $1,390. This is a saving of $3,220 on the previous fee (10 x $460 previous fee per application = $4,600). The overall impact on the TGA revenue is not significant.

## C. Fee for early scientific advice for generic medicines

Early scientific advice is designed to assist companies to confirm the data requirements prior to submitting an application for registration of a new generic medicine where current guidance is not suitable due to the unique technical complexities of the product. The targeted external consultation in 2019 consistently supported the introduction of early scientific advice on proposed justifications for bio waivers for prescription medicines and a fee that is commensurate with the effort and resources required to evaluate the requests.

A fee of $8,570, which is based on staff effort as per activity-based costing, was implemented from 24 July 2020. This is an optional step (and associated fee) for applications for registration of certain generic medicines although sponsors can continue to submit their applications through the current processes without the proposed step and associated fee.

### D. Lower annual charges for certain medical devices in 2020-21

In response to significant decreases in income by parts of the medical devices industry supplying to elective surgery (as a result of its suspension during the height of the COVID-19 pandemic), the Government agreed to provide some relief from TGA charges to the sponsors with the most affected products. This relief is provided to higher risk medical devices that have been particularly affected by the hold on elective surgery. These are Class IIa, IIb, III or AIMD medical devices that are listed prostheses as defined in the Private Health Insurance (Prostheses) Rules (No.1) 2020, as in force on 8 April 2020 (e.g. implantable defibrillators, cardiac pacemakers and Cochlear implants). The *Therapeutic Goods (Charges) Regulations 2018* prescribe 50 per cent lower annual charges for the above classes of medical devices that would otherwise have applied, to help alleviate the impact of reductions in elective surgeries because of COVID-19.

As a result of this, the annual charge for 2020-21 (only) for the inclusion in the ARTG and where the device is a listed prosthesis will be:

a. for all kinds of medical devices that are Class IIa and Class IIb medical devices - $470; and

b. for all kinds of medical devices that are Class III and Class AIMD medical devices - $600.

Currently there are 297 AIMD, 2,534 Class III and 1,867 Class IIa and IIb medical devices that are listed prosthesis. The impact on the TGA revenue in 2020-21 will be a reduction in revenue by approximately $2.6 million.

A summary of fees and charges for 2020-21 can be found on TGA website.

# Stakeholder consultation

## 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 regulatory development and reform, and feedback is taken into account in developing regulatory impact statements, 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 regulation, 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 a Regulation Impact Statement for amendments to fees and charges for therapeutic goods and manufacturing licenses. This is consistent with advice from the Office of Best Practice Regulation. 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.

The TGA also reports to stakeholders against a set of agreed Key Performance Indicators.

Based on stakeholder feedback, the TGA enhanced its consultation process for fee and charges from 2019-20 onwards. In addition to inviting 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 2020-21 fees and charges proposal to seek comments from stakeholders with a view to further improve the strategy. However, no specific comments were received.

## Stakeholder engagement survey

As part of implementing the recommendations from the Application of Cost Recovery Principles report issued by ANAO in May 2019, the TGA undertook a targeted survey in October 2020 to gain feedback on the TGA's engagement on cost recovery matters from sponsors and industry bodies. This survey was in addition to the annual stakeholder survey conducted by the TGA to obtain feedback from the wider stakeholder community including health professionals and consumers. The survey was distributed to a sample of around 6,000 sponsors who paid TGA fees or charges in the last two years and have provided their email address and the thirteen peak industry bodies which attend the annual bilateral meetings.

Out of the 831 response received (response rate 14%), approximately 65% were from medical devices sector, 15% from complementary medicines,12% from combined prescription and over the counter medicines sector and 2% from blood, tissues and biological sector. The rest indicated 'Other' as the best representation of the sector. Around 87% of the respondents were aware the costs of the TGA's regulatory activities is recovered through fees and charges levied on the therapeutic goods industry in accordance with the Australian Government Charging Framework. Overall, the quantitative data showed high level of satisfaction in the consultation process.

The TGA will look at increasing direct communication to sponsors through direct emails, webinars and other forums. The TGA will explore ways to enable more sponsors to provide input to the yearly consultation on fees and charges. This will include providing sponsors with direct notice about the publication of a consultation paper and presenting information in a manner that will improve understanding of the policy basis and considerations for the TGA's proposed fees and charges.

# Consultation on the 2020-21 fees and charges

Consistent with previous practice, the TGA consulted with thirteen industry representative groups in December 2019 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;
- Australian Self Medication Industry;
- Complementary Medicines Australia;
- Accord Australasia;
- Optical Distributors & Manufacturers Association of Australia[4];
- Assistive Technology Suppliers Australasia;
- Australian Medical Device Distribution Association; and
- MTP Connect.

In order to obtain broader feedback from industry and other stakeholders, the TGA undertook a public consultation of its fees and charges through its website, which ended on 28 February 2020.

The majority of the industry bodies indicated their support for the increase to fees and charges by the indexation factor at the bilateral meetings and six industry bodies took the opportunity to present their industry view in the public consultation. Eight submissions were received through the public consultation – six from industry bodies and two from sponsors of therapeutic goods. Three of the submissions from industry bodies confirmed their support to increase the fees and charges by 1.95%. One peak body supported the indexation-based increase at the bilateral meeting in December 2019, however later requested that the Government not apply any increase because of the likely impact of the COVID-19 pandemic on business and the economy.

Two industry bodies in the medical devices sector were not supportive of the increase to TGA's fees and charges due to the increasing costs of doing business and inability to pass on such costs to their customers to remain competitive in the market. A not-for-profit organisation sponsoring clinical trials, did not support the increase in fees and requested to abolish fee increases for not for profit academic organisations.

The feedback from the submissions was put forward to Government for consideration along with the proposed fees and charges for 2020-21.Feedback was taken into account and with a view to minimise impact on industry only indexation increase of 1.95% in fees and charges was approved despite more than 4% increase in expenses in 2020-21.

[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 performance in previous financial years**

| Details | 2015–16 Actual $'m | 2016–17 Actual $'m | 2017–18 Actual $'m | 2018–19 Actual $'m | 2019-20 Actual $'m [5] |
|---|---|---|---|---|---|
| Revenue from Government | 3.177 | 2.574 | 2.439 | 2.257 | 8.534 |
| Sale of goods and services | 141.539 | 139.037 | 152.905 | 159.000 | 168.044 |
| Other revenue and gains | 0.148 | 0.012 | 0.001 | 0.048 | - |
| **Total A** | **144.864** | **141.623** | **155.345** | **161.305** | **176.578** |
| Employee expenses | 66.158 | 78.781 | 75.802 | 93.619 | 86.728 |
| Suppliers | 57.849 | 61.686 | 62.837 | 57.556 | 74.838 |
| Depreciation and amortisation | 4.672 | 4.286 | 6.846 | 7.518 | 7.995 |
| Write-down and impairment of assets | 0.105 | 1.961 | 2.895 | 1.448 | 1.599 |
| **Total B** | **128.784** | **146.715** | **148.380** | **160.141** | **171.160** |
| **Surplus (deficit)** | **16.080** | **(5.092)** | **6.965** | **1.164** | **5.418** |
| Retained surplus | 48.680 | 43.589 | 50.554 | 51.717 | 47.683 |
| % of Retained surplus to TGA budget | 34% | 31% | 33% | 32% | 27% |

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 (reserves). From 2019-20 onwards, an additional funding was approved by the Government for activities that are not appropriate for cost recovery from the industry.

The surplus in 2019-20 was $5.42 million above the approved budget. The revenue ended up above budget by $7.49 million primarily due to increase in medical device applications and appropriation revenue. Expenses were above budget by $1.76 million due to increase in

[5] Extract from Department of Health 2019-20 Annual Report

corporate expenditure by $5.99 million, offset by reduction in employee expenses of $4.24 million, compared to budget. The appropriation funding for 2019-20 included $2.78 million for the opioids campaign and $3.47 million for the fee free services.

Detailed financial performance information is discussed with industry representative bodies at bilateral meetings held each year.

The TGA aims to maintain reserves to provide a buffer for volatility in revenue streams (the number and type of evaluation applications) and respond to major external or unplanned impacts (recalls, product tampering). The target for the reserve balance is set at around 25% of operating budget. While until 2014-15 accumulated reserves remained within the target level, since 2015–16 these have remained above that target although reduced in 2016-17 as a result of the costs of implementing the 2016-17 Budget measure "Improving the Regulation of Therapeutic Goods in Australia" which involves expenditure of $20.4 million from TGA reserves over four years. The surplus in 2017-18 allowed the TGA to recoup earlier than planned a part of the $20.4 million drawn from its reserves.

In view of the 2020-21 Budget decisions to make investments of $22.8 million in the TGA business systems and UDI, retained surplus would drop in coming years.

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.

**Financial estimates for budget and three forward years**

| Financial Estimates | 2020-21 Budget $'m | 2021–22 Estimate $'m | 2022–23 Estimate $'m | 2023–24 Estimate 'm |
|---|---|---|---|---|
| Revenue from Cost Recovered activities *(see Note 1 for 2020-21 Budget)* | 167.470 | 173.378 | 175.061 | 179.494 |
| Government Appropriation | 11.979 | 8.727 | 15.564 | 15.523 |
| Expenses *(see Note 2 for 2020-21 Budget)* | 180.615 | 183.536 | 192.057 | 195.494 |
| Surplus(Deficit) | **(1.166)** | **(1.431)** | **(1.432)** | **(0.477)** |

** Revenue from Government includes the current government appropriation for Scheduling function and interest appropriation for TGA Special Account along with the 2019-20 MYEFO funding provided by the Government.*

*Notes

1. *Assumes constant volumes, includes 1.95% increase and takes into account $2.576 million reduction in medical devices revenue due to lower annual charges in 2020-21 certain classes of medical devices. However this doesn't take into account the potential loss of revenue of $9.2 million due to COVID 19 as follows:*
    a. *Loss of overseas GMP inspection revenue due to pause on international travel until 31 December 2020 $3.058 million; and*
    b. *Decline in new prescription medicines applications because of halt on clinical trials $6.1 million.*
2. *Known increase in expenses in 2020-21, maintaining existing resources, is estimated to be $7.1 million as follows:*

a. *Increase in salary and contractor expenses is mainly due to a 2% increase in salary, and increment advancement as per Enterprise Agreement - $3.8 million;*

b. *Increase in corporate expenses - $2.5 million;*

c. *Increase in depreciation $0.8 million.*

*We need to find internal savings of $3.703 million to absorb increase in non-discretionary costs because TGA revenue and appropriation would only increase by $3.397 million in 2020-21.*

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 Annual Performance Statistics Report and the Half Yearly Performance Snapshot. We also report annually on our performance against the Regulator Performance Framework through the TGA Self-Assessment (Key Performance Indicators) Report.

The statistics contained within this report cover the period 1 July 2018 to 30 June 2019, and contribute to annual publications that track our progress against the priorities we have established for the financial year.

# Risk assessment

A cost recovery risk assessment for the annual increases to fees and charges was undertaken in April 2020 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; and
- potential for misunderstanding of how fees and charges are calculated.

These risks are addressed by:

- continued improvements in regulatory and administrative functions;
- implementing best practice in ABC methodology;
- working closely with stakeholders and industry representatives to mitigate the cost impact to business; and
- ensuring charging practices are aligned to our services and are transparent and defensible.

From a regulatory perspective risk management is applied to regulating therapeutic goods by:

- identifying, assessing, and evaluating the risks posed by therapeutic goods before they can be approved for use in Australia (pre-market assessment or evaluation);
- 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); and
- 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 |
|---|---|
| Fees and charges for 2021-22 | 1 July 2021 |
| Portfolio Charging Review | 2022 |

# CRIS approval and change register

| Date of CRIS change | Approver | CRIS change |
|---|---|---|
| 01/07/2016 | Secretary Department of Health | Consolidated CRIS updated for 1 July 2016 |
| 30/06/2017 | Secretary Department of Health | CRIS updated for introducing new fees for a number of regulatory reforms and other changes to fees and charges from 1 July 2017 |
| 20/12/2017 | Secretary Department of Health | CRIS updated for introducing new fees for Priority Review pathway for medical devices from 1 January 2018 |
| 28/03/2018 | Secretary Department of Health | CRIS updated for introducing new fees for a number of regulatory reforms from 19 March 2018 |
| 24/06/2018 | Secretary Department of Health | CRIS update for introducing changes to fees and charges from 1 July 2018 |
| 12/10/2018 | First Assistant Secretary, Regulatory Practice & Support, HPRG | CRIS update for lowering the application fee for export only medical devices |
| 05/02/2019 | Deputy Secretary, HPRG | CRIS update for financial information |
| 11/06/2019 | Deputy Secretary, HPRG | CRIS certified for introducing changes to fees and charges from 1 July 2019 |
| 19/06/2019 | Minister for Health | CRIS approved for introducing changes to fees and charges from 1 July 2019 |
| 27/11/2019 | First Assistant Secretary, Regulatory Practice & Support, HPRG | CRIS update for financial information |
| 25/01/2021 | Minister of Health | CRIS for 2020-21 |

# Appendix 1 - Financial performance by industry sector group

## 1. Prescription medicines

| Revenue and expenses | 2015–16 Actual $'m | 2016–17 Actual $'m | 2017–18 Actual $'m | 2018–19 Actual $'m | 2019-20 Actual $'m |
|---|---|---|---|---|---|
| Cost recovery revenue | 71.7 | 68.5 | 72.9 | 74.8 | 80.6 |
| **Total A** | **71.7** | **68.5** | **72.9** | **74.8** | **80.6** |
| Direct | 36.9 | 40.0 | 39.4 | 41.5 | 44.6 |
| Indirect | 26.3 | 28.3 | 28.8 | 30.4 | 30.7 |
| **Total B** | **63.2** | **68.4** | **68.2** | **71.9** | **75.3** |
| **Surplus (deficit)** | **8.5** | **0.1** | **4.7** | **2.9** | **5.3** |

# 2. Over the counter medicines

| Revenue and expenses | 2015–16 Actual $'m | 2016–17 Actual $'m | 2017–18 Actual $'m | 2018–19 Actual $'m | 2019-20 Actual $'m |
|---|---|---|---|---|---|
| Cost recovery revenue | 6.7 | 7.8 | 9.0 | 10.3 | 9.9 |
| **Total A** | **6.7** | **7.8** | **9.0** | **10.3** | **9.9** |
| Direct | 2.8 | 3.0 | 2.9 | 3.7 | 4.2 |
| Indirect | 2.3 | 2.6 | 2.4 | 3.0 | 3.2 |
| **Total B** | **5.1** | **5.7** | **5.3** | **6.7** | **7.4** |
| **Surplus (deficit)** | **1.6** | **2.1** | **3.7** | **3.6** | **2.5** |

# 3. Complementary medicines

| Revenue and expenses | 2015–16 Actual $'m | 2016–17 Actual $'m | 2017–18 Actual $'m | 2018–19 Actual $'m | 2019-20 Actual $'m |
|---|---|---|---|---|---|
| Cost recovery revenue | 15.7 | 13.8 | 14.5 | 15.1 | 16.6 |
| **Total A** | **15.7** | **13.8** | **14.5** | **15.1** | **16.6** |
| Direct | 7.2 | 7.3 | 6.9 | 10.2 | 11.2 |
| Indirect | 5.2 | 5.6 | 5.3 | 7.6 | 8.5 |
| **Total B** | **12.4** | **12.9** | **12.1** | **17.8** | **19.7** |
| **Surplus (deficit)** | **3.3** | **0.9** | **2.4** | **(2.7)** | **(3.1)** |

# 4. Medical devices, including in-vitro diagnostic (IVD) devices

| Revenue and expenses | 2015–16 Actual $'m | 2016–17 Actual $'m | 2017–18 Actual $'m | 2018–19 Actual $'m | 2019-20 Actual $'m |
|---|---|---|---|---|---|
| Cost recovery revenue | 34.3 | 37.2 | 40.6 | 41.1 | 46.3 |
| **Total A** | **34.3** | **37.2** | **40.6** | **41.1** | **46.3** |
| Direct | 17.1 | 19.6 | 20.6 | 22.0 | 26.6 |
| Indirect | 12.2 | 13.8 | 16.9 | 18.2 | 17.4 |
| **Total B** | **29.4** | **33.3** | **37.6** | **40.2** | **44.0** |
| **Surplus (deficit)** | **4.9** | **3.9** | **3.0** | **0.9** | **2.3** |

# 5. Good manufacturing practices

| Revenue and expenses | 2015–16 Actual $'m | 2016–17 Actual $'m | 2017–18 Actual $'m | 2018–19 Actual $'m | 2019-20 Actual $'m |
|---|---|---|---|---|---|
| Cost recovery revenue | 11.2 | 9.9 | 13.2 | 12.4 | 15.2 |
| **Total A** | **11.2** | **9.9** | **13.2** | **12.4** | **15.2** |
| Direct | 7.8 | 8.7 | 8.8 | 8.6 | 8.9 |
| Indirect | 5.4 | 5.7 | 6.2 | 5.9 | 6.9 |
| **Total B** | **13.2** | **14.4** | **14.9** | **14.5** | **15.8** |
| **Surplus (deficit)** | **(2.0)** | **(4.5)** | **(1.7)** | **(2.1)** | **(0.6)** |

# 6. Blood, blood components and biologicals

| Revenue and expenses | 2015–16 Actual $'m | 2016–17 Actual $'m | 2017–18 Actual $'m | 2018–19 Actual $'m | 2019-20 Actual $'m |
|---|---|---|---|---|---|
| Cost recovery revenue | 2.2 | 2.6 | 2.4 | 2.7 | 2.7 |
| **Total A** | **2.2** | **2.6** | **2.4** | **2.7** | 2.7 |
| Direct | 1.6 | 2.0 | 2.0 | 2.3 | **2.6** |
| Indirect | 1.3 | 1.6 | 1.7 | 1.9 | 1.8 |
| **Total B** | **2.9** | **3.6** | **3.6** | **4.2** | **4.4** |
| **Surplus (deficit)** | **(0.7)** | **(1)** | **(1.2)** | **(1.5)** | **(1.7)** |

# 7. Other activities (such as laboratory, medicines and chemical scheduling etc.)

| Revenue and expenses | 2015–16 Actual $'m | 2016–17 Actual $'m | 2017–18 Actual $'m | 2018–19 Actual $'m | 2019-20 Actual $'m |
|---|---|---|---|---|---|
| Revenue | 2.0 | 1.7 | 2.7 | 4.9 | 5.1 |
| **Total A** | **2.0** | **1.7** | **2.7** | **4.9** | **5.1** |
| Other Expense | 2.0 | 2.7 | 2.6 | 4.9 | 4.5 |
| MMDR Expense | N/A | 6.9 | 4.1 | N/A | |
| **Total B** | **2.0** | **8.6** | **6.7** | **4.9** | **4.5** |
| **Surplus (deficit)** | **0.0** | **(6.9)** | **(4.0)** | **(0.0)** | **0.6** |

**Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
**https://www.tga.gov.au**

Reference/Publication #