



Australian Government

Department of Health

Therapeutic Goods Administration

# Cost recovery implementation statement 2016-17

**TGA** Health Safety  
Regulation

Historical document

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# Introduction

## Purpose of the Cost Recovery Implementation Statement

This Cost Recovery Implementation Statement (CRIS) provides information on how the Therapeutic Goods Administration (TGA) implements cost recovery activities 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 is a part of the Department of Health and contributes to Outcome 5 as outlined in the 2016-17 Portfolio Budget Statements:

### Outcome 5: Regulation, Safety and Protection

Protection of the health and safety of the Australian community and preparedness to respond to national health emergencies and risks, including through immunisation initiatives, and regulation of therapeutic goods, chemicals, gene technology, and blood and organ products.

#### 5.1: Protect the Health and Safety of the Community through Regulation

The Government aims to provide a world class, efficient and timely regulatory system for therapeutic goods. In 2016-17, the TGA will continue to promote best practice regulation through business improvement and regulatory reform, while meeting the Australian Government's expectations under the Regulator Performance Framework.

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 3 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.

### Risk management approach

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 ensure 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.

## Industry 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
- Good manufacturing practices
- Blood, blood components and biologicals

While some funding is provided to the TGA by the Government in the form of an interest equivalency payment against the special account balance (reserves), the bulk of funding is generated through fees and charges charged under cost recovery arrangements.

## Policy and statutory authority to cost recover

Where specific demand for a government activity is created by identifiable individuals or groups, they should be charged for it unless the government has decided to fund that activity. Where it is appropriate for the Australian Government to participate in an activity, it should fully utilise and maintain public resources, through appropriate charging. The application of charging should not, however, adversely impact disadvantaged Australians.<sup>1</sup> The Australian Government's overarching cost recovery policy is that, where appropriate, non-government recipients of specific government activities should be charged some or all of the costs of those activities. The cost recovery policy promotes consistent, transparent and accountable charging for government activities and supports the proper use of public resources<sup>2</sup>.

Cost recovery involves the government entities charging individuals or non-government organisations some or all of the efficient costs of a specific government activity. This may include goods, services or regulation, or a combination of these. The [Australian Government Cost Recovery Guidelines \(CRGs\)](#) set out the overarching framework under which government entities design, implement and review cost recovered activities.

In the 1997-98 Budget, Budget Paper No.2, Part II: Revenue Measures it was stated that the TGA would fully recover all costs from industry from 1998-99. 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 manufacturers of medicines and medical devices.

The *Therapeutic Goods Act 1989* (the Act) provides a legal authority for the TGA to charge for its regulatory 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

<sup>1</sup> Australian Government Charging Framework, 2015, available at [www.finance.gov.au](http://www.finance.gov.au).

<sup>2</sup> Under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act), revenue from cost recovery is a public resource for both corporate and non-corporate Commonwealth entities. Section 8 of the PGPA Act defines 'proper' use or management of public resources as efficient, effective, economical and ethical.

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

## Cost recovery model

### Outputs and business processes of the activity

#### 1. Prescription medicines

Higher risk medicines, such as prescription medicines, must be registered on the ARTG before they are made available for sale in Australia.

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); 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.

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 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. This utilises the following process.

#### Applications

All applications for registration of prescription medicines must be preceded by a pre-planning submission form (PPF). 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
- 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.

## 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 standards in force in Australia. Export only products are required to be listed (not registered) on the ARTG before export.



## Special Access Scheme (SAS)

In the circumstances where patients need access to therapeutic goods that are not on the ARTG, access to the therapeutic good may be arranged through the SAS.

TGA reviews each access under the SAS on a case-by-case basis.

## Clinical trials

TGA reviews the use of unapproved medicines to be made available to patients participating in a clinical trial.

## Compliance monitoring and enforcement

Post-market activities undertaken in relation to prescription medicines include:

- providing access to a comprehensive source of up-to-date consumer medicine information and product information;
- review of Periodic Safety Update Reports to ensure the ongoing suitability of products for registration on the ARTG;
- monitoring risk management plans that detail how safety concerns will be identified and mitigated post-registration;
- ensuring that regular post-market reports are received from sponsors;
- Monitoring any international concerns about a product's safety or efficacy
- laboratory testing program on selected medicines, including random and targeted sampling of approved products;
- publishing a Medicines Safety Update in each edition of the Australian Prescriber;
- managing the problem reporting system for:
  - medicine deficiency or defect
  - adverse reaction to a medicine; and
- undertaking appropriate regulatory action for identified problems. Actions include:
  - informing health care professionals and consumers about the risks of using the product;
  - re-assessing the benefit-risk profile;
  - requiring product labelling changes;
  - requiring design or manufacturing change;
  - requesting post-market studies;
  - restricting access;
  - recalling products; and
  - removing the product from the ARTG.

## 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.

Medicines are grouped into schedules according to the appropriate level of regulatory control over their availability to consumers. 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 process for OTC medicines includes:

- 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 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.

### 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.

### Compliance monitoring and enforcement

The OTC post-market regulatory processes include detection, compliance and enforcement:

- Detection
  - undertaking laboratory testing of products (i.e. chemistry and microbiology);
  - investigating reported adverse events; and
  - reviewing the safety of products or classes of products.

- Compliance
  - monitoring compliance with regulations;
  - maintaining product registers;
  - ensuring compliance with advertising regulations;
  - educating stakeholders;
  - recalling products;
  - issuing alerts to consumers; and
  - updating product information.
- Enforcement
  - investigating potential breaches; and
  - enforcing the regulations.

### 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 via a streamlined electronic listing facility. This process for listing products allows for early market access for low risk complementary medicines. At the time of submitting a listed medicine application, the sponsor must certify that the goods that are the subject of the application meet all of the regulatory requirements.

Unlike registered medicines, there is no evaluation prior to the medicine being listed on the ARTG. The TGA therefore uses a variety of other mechanisms to assure the safety and quality of complementary medicines, such as:

- they may only contain substances that have been previously evaluated and approved as being of low risk;
- they can only make indications (for therapeutic use) for health maintenance and health enhancement or certain indications for non-serious, self-limiting conditions;
- a proportion of listed complementary medicines are reviewed following their listing for compliance with the regulatory requirements; and
- additional substances or ingredients to be used in listed medicines may be evaluated and approved by the TGA on application from the industry. On average, there are 12 such applications received each year.

#### 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 medicines are fully evaluated for quality, safety and efficacy prior to being accepted on the ARTG and able to be marketed.

## Compliance monitoring and enforcement

The post-market compliance review of a listed complementary medicine involves:

- assessing information about the product against the relevant legislative requirements, including, where relevant, the certifications given by the sponsor at the time the product was listed; and
- taking appropriate actions when a breach of the legislative requirements is identified. This action may include cancellation of the listing of the medicine.

The compliance review of a listed complementary medicine may focus on one or several aspects of the medicine. Based on experience and the potential risk that non-compliance represents to the public, the TGA gives greater attention to the following three areas:

- the evidence that a sponsor holds to support the indications;
- the presentation of the medicine; and
- the advertising of the medicine.

On average, approximately 1,800 new complementary medicines are listed on the ARTG each year. Due to resource constraints, the TGA follows a risk management approach to set priorities and direct resources to those reviews that provide the greatest overall benefit for the Australian public. To assist with this determination the TGA gives priority to issues that:

- may result in immediate or potential health risk to consumers;
- could significantly mislead the Australian public, particularly in a way that could have a health impact
- are industry-wide or are likely to become widespread if the TGA does not take action;
- could lead to a loss of stakeholder confidence in regulation or in therapeutic goods;
- may attract adverse scrutiny from media or the public;
- are of national or international significance; and
- involve a new or emerging issue.

Depending on the circumstances, priority will also be given to products that have been relisted after a previous TGA-initiated cancellation or at the request of the sponsor after a previous compliance review, or where the risk or the characteristics of the medicine are of concern.

Listed complementary medicines with potential non-compliance issues may be brought to the TGA's attention from a number of sources, including the public, media, health care professionals or other external sources, referrals from within the TGA, information from other regulatory agencies and information from previous compliance reviews.

Finally, a proportion of newly listed medicines are randomly selected by computer, based on a mathematical model, for compliance review.

## 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 the Essential 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.

Regulatory activities span the life cycle of the medical device, including:

- pre-market (such as applications to include medical devices on the ARTG, conformity assessment applications and use in clinical trials); and
- post-market (such as reporting of adverse events, undertaking recalls and reviewing advertising).

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 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 from complying with the standards under section 14 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 unique device. 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, higher risk medical devices are associated with higher overall costs.

Approval for each medical device is exclusive to the sponsor applying for inclusion, approval for one sponsor cannot be used by other sponsors, even where the medical device is identical.

While all medical devices must comply with minimum requirements for quality, safety and performance, devices other than the lowest risk, must be accompanied by conformity assessment certification following an assessment of a manufacturer's quality management system and assessment of design dossiers where applicable.

In addition to the conformity assessment certification accompanying an application for ARTG inclusion, the application process also involves a review of other information supplied with the application such as the labelling and instructions for use for the device.

## Application audits

Some applications for inclusion of medical devices on the ARTG will undergo an application audit.

- Applications to include certain medical devices in the ARTG must be selected for an application audit—for these mandatory audits an application audit assessment fee is charged.
- The TGA may also select any other application for inclusion for an application 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 application audit, which apply if the audit is mandatory.

## 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 is able to accept the assessment of conformity assessment bodies that are considered to have the appropriate authority and expertise. As the Australian and the European Union (EU) regulatory requirements are similar, certificates issued by EU conformity assessment bodies (also known as Notified Bodies) may be accepted as conformity assessment evidence for the supply of devices in Australia.

For certain higher risk medical devices and IVDs, manufacturers must obtain Conformity Assessment Certificates from the TGA for supply to the market in Australia, regardless of whether they have a certificate issued by an EU notified body. In conducting assessments for these products, the assessment will take into account any existing EU conformity assessment evidence. This requirement for TGA conformity assessment 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 certification from TGA to support supply of their medical devices in Australia, rather than relying on certification from an EU notified body.

## Clinical trials

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 programme, and if approval is granted the subsequent trials must be carried out under the terms of the approval and be notified to the TGA.

These schemes are used for clinical trials involving:

- any device not included in the ARTG; and
- use of a device in a clinical trial beyond the conditions of its marketing approval.

## Other therapeutic goods listed and registered on the ARTG

A large majority of medical devices listed and registered on the ARTG prior to 2002 (previously called therapeutic devices) have now been transitioned to the new regulatory framework and are now largely regulated under Chapter 4 of the Act. There is a small number of therapeutic devices which are not captured under the new Chapter 4 arrangements. These are largely disinfectants, tampons and menstrual cups. The fees and charges included in this document for registered and listed devices apply for these products.

## Post-market vigilance and monitoring, and recalls

Once a medical device has been included in the ARTG the device must continue to meet all the regulatory requirements that were required for the approval, including the requirements for safety, quality and performance.



### ***Post-market vigilance***

The TGA has mandatory requirements for all manufacturers and sponsors of medical devices. These requirements are intended to monitor information about medical devices so that appropriate action can be taken. The requirements facilitate the systematic investigation of failures and/or deviations in the way a device performs, in an attempt to prevent an adverse event occurring again. Key post-market mechanisms include:

- Reportable events:

The TGA provides guidance as to the definition of a reportable adverse event for medical devices. There is mandatory reporting within statutory timeframes for sponsors and manufacturers of adverse events that have or could have caused a death, serious injury or serious illness and non-mandatory reporting for other events.

The outcomes of the investigations may result in recalls, hazard and safety alerts, product modification/improvement by a manufacturer, or surveillance audits of manufacturing sites.

### ***Post-market monitoring***

The TGA undertakes post-market reviews of ARTG entries of medical devices to verify compliance with the legislative requirements, such as conditions of inclusion, and to ensure continued safety and performance usually following signals that there may be an issue or a special interest in the device or a type of device.

Sponsors of Class III medical devices must also keep an up to date log of information about the performance of the device and provide annual reports for the first three years after a product receives market authorisation.

The TGA can take action to suspend or cancel a device from the ARTG where, for example, the outcomes of investigations indicate that there is a potential risk of death, serious illness or serious injury if the device continued to be included in the ARTG or if the TGA is satisfied, for instance, that the safety or performance of the device is unacceptable.

### ***Recall actions***

A recall action is an action taken to resolve a problem with therapeutic goods already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation. There are three distinct recall actions - recall, recall for product correction and hazard alert. Not all recall actions result in a product being removed from the market, for example, hazard alerts may be issued in cases involving implantable medical devices, and corrections may be undertaken for products that have software issues.

The TGA coordinates approximately 500 recall actions of medical devices each year. The vast majority of recalls are undertaken voluntarily by the sponsor after consultation with the TGA. For each recall action, the Recalls Unit reviews the proposed recall strategy to address the health hazard and the individual circumstances of each case. Strategies need to reflect the kind of medical device, deficiency identified, risk posed by the deficiency, distribution networks, recovery procedures, resources for corrective action and availability of alternative products. In some cases, recall action is not required but the sponsor may be required to issue a safety alert or some precautionary information in the form of a product notification.

The Recalls Unit monitors the progress of recall action by reviewing the progress reports submitted by the sponsor. In the close-out report, sponsors should provide the root cause of the problem and remedial action undertaken by the manufacturer. The report is reviewed to ensure that the root cause and the corrective action identified are appropriate to prevent the issues from recurring.

## Advertising review

TGA reviews advertisements for medical devices 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.

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

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

- therapeutic goods industry;
- health practitioners;
- consumers;
- advertising industry;
- Australian Competition & Consumer Commission;
- Medsafe (NZ therapeutic goods regulator);
- Media;
- Therapeutic Goods Advertising Code Council; and
- Complaints Resolution Panel.

Advertisements for medical devices do not have to be approved prior to publication or broadcast. However, advertisements must comply with the conditions of inclusion on the ARTG detailed in section 41FN(5) of the Act, Division 3 and 4, Part 2 of the Regulations and the TGAC.

The Complaints Resolution Panel considers complaints about advertisements for medical devices and other therapeutic goods appearing in broadcast and mainstream print media, billboards, cinema films, the internet etc. As advertisements do not require pre-approval, 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.

TGA does not charge for lodging a complaint with the Complaints Resolution Panel. To do so would be contrary to the intent of allowing all complaints about advertising to be appropriately examined. The costs of validating complaints are recovered from sponsors of medical devices via annual charges which are linked to the maintenance of the sponsor's ARTG entry, spreading the cost of the function evenly across all products.

## 5. Good manufacturing practices

In Australia, manufacturers of therapeutic goods are required to hold a licence, except for manufacturers of certain medical devices who have European conformity certification (CE Mark). To obtain the licence, a manufacturer must demonstrate that they have the ability to comply with manufacturing principles, 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 insure that the products manufactured will possess the required quality.



The GMP related regulatory activities undertaken are as follows:

## **Licensing**

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 compliance**

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 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.

## **Investigation and enforcement**

The TGA undertakes appropriate actions to promote and ensure compliance with the applicable GMP standards by manufacturers. Where a licensed Australian manufacturer poses unacceptable safety or quality risks, sanctions available range from (but are not limited to) revocation or suspension of the manufacturing licence to restriction of the type, kind or quantity of goods that can be manufactured for the Australian market at that site. Where required, sanctions are decided on a case-by-case basis after consideration of the circumstances involved and the best interests of the Australian consumer. Where the manufacturer is based outside of Australia, limits are placed on the ability of sponsors to make the products available on the Australian market.

## **Information and education**

The TGA promotes compliance with the manufacturing standards by producing guidelines and other informational materials primarily targeted at manufacturers whose products are supplied in Australia. These resources are made available through the TGA website. In addition, the TGA conducts seminars and information briefings to raise awareness of regulatory requirements, particularly when changes are proposed.

TGA contributes strongly to international programs to improve and harmonise manufacturing practices in developing regions through international meetings, seminars and training events.

## **Policy development and services to government**

The TGA provides services to Government in relation to the regulation of manufacturers, including specific technical and policy advice that is considered to be integral to the regulation of manufacturers.

Broader policy advice provided by the Department of Health is not subject to fees and charges.

## **6. Blood, blood components and biologicals**

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

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.

Manufacturers of blood components 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) and to submit a technical master file which demonstrates compliance to relevant standards.

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).

## Compliance monitoring and enforcement

- Post-market controls include ongoing manufacturing inspections, managing adverse event reporting, investigations and recalls.
- The TGA also provides information and support to the regulated industry and consumers and is responsible for the maintenance of the regulatory framework.

## Design of cost recovery charges

### Costs of TGA activities

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

**Direct costs:** can be easily traced to a cost object 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 oncosts, such as training, superannuation and leave) and supplier costs (e.g. office supplies).

**Indirect costs:** are the costs that cannot be easily linked to a cost object or for which the costs of tracking this outweigh the benefits. Indirect costs are apportioned to a cost object using the internal costing methodology. Common indirect costs include overhead costs such as salaries of staff in corporate (e.g. finance, human resources, IT) areas, or accommodation costs (e.g. rent, maintenance, utilities).

In 2015, a software solution was installed to improve TGA's activity based costing (ABC) capability. The first staff work effort survey was conducted in 2015 to attribute the time of regulatory staff to regulatory activities. Due to a significant restructure of TGA on 1 July 2015, the work effort survey is being undertaken again.

### 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 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.

**Cost recovery levies:** charges 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 except for export only products and IVD medical devices. Annual charges are used to recover the costs of pharmacovigilance and other post market monitoring and compliance activities where:

- they cannot reasonably be assigned to individual sponsors;
- they maintain the integrity of the regulated industry to the benefit of all sponsors; and
- assigning costs to individual sponsors would deter sponsors from disclosing important public health information, such as reporting adverse events.

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 for the regulated good rather than the size of the individual business. For example, the annual charge for a class 1 medical device (other than a class 1 medical device that has a measuring function or is supplied in a sterile state) is \$80 whereas for a high risk prescription medicine (biologic) the annual charge is \$6,725.

## 2016-17 fees and charges

TGA fees and charges are reviewed annually to ensure full cost recovery. An increase of 2.25 per cent was applied for 2016-17 to meet estimated cost increases mainly in employee expenses as a result of a 2 per cent salary increase in the Department of Health Enterprise Agreement.

A well-established formula has been used in most years, based on the Australian Bureau of Statistics' Consumer Price Index (50 per cent) and Wage Price Index (50 per cent) (both for the year to September). This year the formula resulted in 2.25 per cent. The Office of Best Practice Regulation has advised that a Regulatory Impact Statement was not required for this change.

The amendment regulations were approved by the Executive Council at their meeting of 5 May 2016. As a result all TGA fees and charges will increase by 2.25 per cent from 1 July 2016, subject to rounding. In addition, a small number of other, minor, changes relating to fees for biologicals were also approved. These changes are:

- to clarify that the fees applying under the Regulations for requests by sponsors to vary an entry in the Register for a biological do not apply where the variation would result in the creation of a separate and distinct biological (a new application for marketing approval must be made in such a case);
- to allow sponsors of Class 3 and 4 biologicals to pay a lower fee (\$1,050 from 1 July 2016 rather than that fee and an evaluation fee of \$16,800) for a request to vary an entry in the Register if the request does not involve the evaluation of quality and manufacturing information (this higher fee has not been charged to date); and
- to set separate evaluation fees for 'safety-related' variations to an entry in the ARTG for Class 3 or 4 biologicals (these are changes resulting only in reducing the class of persons for whom the biological is suitable, or in adding a warning or precaution not involving a comparison with any other goods in relation to quality, safety or efficacy), and setting different fees depending on whether the request involves evaluation by the TGA.

A link to the fees and charges applicable from 1 July 2016 is provided in [Appendix 2](#).

# Financial and non-financial performance

## a) Financial performance

	2014-15 Actual \$'m	2015-16 Forecast \$'m	2016-17 Budget \$'m	2017-18 Estimate \$'m	2018-19 Estimate \$'m
<b>A: Revenue<sup>3</sup></b>					
Revenue from Government	6.995	2.227	1.800	1.800	1.800
Sale of goods and services	130.764	133.908	138.384	142.035	147.568
Other revenue and gains	1.027	0.249	0.200	0.200	0.200
<b>Total A</b>	<b>138.786</b>	<b>136.385</b>	<b>140.384</b>	<b>144.035</b>	<b>149.568</b>
<b>B: Expenses<sup>4</sup></b>					
Employee expenses	83.552	79.108	94.308	96.284	98.236
Suppliers	42.071	44.587	45.498	43.165	41.405
Depreciation and amortisation	5.620	4.368	8.190	8.190	9.927
Write-down and impairment of assets	2.205	0.510			
Other expenses and losses	0.001	0.001			
<b>Total B</b>	<b>133.448</b>	<b>128.574</b>	<b>147.996</b>	<b>147.639</b>	<b>149.568</b>
<b>Surplus (deficit)</b>	<b>5.338</b>	<b>7.811</b>	<b>(7.612)</b>	<b>(3.604)</b>	<b>0.000</b>

TGA's activities are primarily cost recovered from industry. However, the TGA received appropriation funding in 2014-5 for aligning Australia's and New Zealand's regulation of therapeutic goods. In addition, the TGA continues to receive appropriation funding in the form of an interest equivalency payment for funds held in the TGA special account (reserves).

While our financial performance is within the target budget range when compared to budget, the surplus in 2014-15 was largely the result of lower than expected employee expenses due to lower staffing levels and stable employee remuneration over recent financial years.

<sup>3</sup> Excludes Office of Drug Control

<sup>4</sup> Excludes Office of Drug Control

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). Depreciation is also accumulated for the replacement of assets. The Government expects the TGA to manage within its cost recovery resources and therefore investment, such as the Business Improvement Program, must also come from the responsible management of these reserves. The target for the reserve balance is set to be at least one quarter of operating expenses. During 2015-16 our reserves will remain above that target but then reduce 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.

Financial performance by industry sector group is included in [Appendix 1](#).

## b) Non- financial performance

The TGA reports to stakeholders at six monthly intervals on performance against a set of agreed KPIs. The KPIs have been endorsed by the Australian Therapeutic Goods Advisory Council following consultation with the TGA-Industry Consultative Committee. For more information on the TGA’s KPIs please visit: [TGA key performance indicators](#).

The KPIs are high-level indicators of performance against our strategic intent. Within that matrix of KPIs is a requirement for measuring whether 'business operations are consistent and meet agreed service and timeliness standards'. Measures of specific business activities will continue to be documented in our half-yearly performance reports.

These reports are provided to members of the TGA-Industry Consultative Committee to enable us to report on specific parameters of relevance to industry stakeholders and to enable stakeholders to provide performance feedback. They provide detailed quantitative information about our performance on the timeliness of business activities as well as information for industry about the volumes of work performed. Key highlights for 2014-15 were:

- The TGA worked closely with industry on new initiatives to help improve the efficiency of a number of application and administrative processes. This included implementing a new business services portal to provide industry with self-service technology to conduct simple regulatory transactions with the TGA.
- For medicines, the pilot to introduce the electronic Common Technical Document (eCTD) format for over-the-counter and prescription medicines was completed, eliminating the need for paper applications. Other initiatives included releasing an electronic smart form for sponsors to notify the TGA of prescription medicines shortages, reducing the reliance on phone, email and letter communication.
- Medical devices initiatives included implementation of regulatory changes to allow Australian medical device manufactures to obtain market approval for most products using European notified bodies’ conformity assessment.
- The TGA substantially met all performance targets in relation to completing applications for registration of therapeutic goods within the legislated timeframes.



# Fees and charges and other reforms

## a) Annual charges exemption scheme

The annual charges exemption (ACE) scheme replaced the low value turnover (LVT) scheme on 1 July 2015 following a review of the operation of the LVT which included a public consultation and Regulatory Impact Statement.

The ACE scheme is more equitable, reduces red tape for business and provides administrative efficiencies for the TGA. It recognises that TGA's post-market monitoring costs are incurred for products that have been placed into the market and allows sponsors to enter their products in the ARTG in advance of their marketing with no annual charge (until turnover commences). For more information on the ACE please visit: [Annual charge exemption scheme](#).

When the ACE scheme was introduced the TGA undertook to monitor the impact of the new scheme on the therapeutic goods industry. In December 2015 a preliminary assessment of the financial impact of the ACE scheme on industry sponsors across a range of business areas showed, at that point in time, a forecast increase of \$2.5 million or 5 per cent in annual charges in 2015-16 under the ACE scheme. The [preliminary assessment report](#) is available on the TGA website.

At the time of undertaking the preliminary assessment the ACE scheme had been in operation for only a few months (July 2015 to October 2015), and the full impact and effectiveness of the ACE scheme will not be known until it has been in operation for a minimum of 2 years. The impact of the introduction of the ACE scheme will continue to be monitored as the scheme matures and changes will be made, as required, to ensure appropriate cost recovery for each sector.

## b) Review of medicines and medical devices regulation

An independent review of medicines and medical devices regulation was announced on 24 October 2014. The aim of the review was to examine the TGA's regulatory framework and processes with a view to identifying:

- areas of unnecessary, duplicative, or ineffective regulation that could be removed or streamlined without undermining the safety or quality of therapeutic goods available in Australia; and
- opportunities to enhance the regulatory framework so that Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods.

In its two staged report (stage 1 released on 31 March 2015 and stage 2 released on 31 July 2015), the review panel provided the Government with 58 recommendations. In summary, the report recommended:

- 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.

In 2016-17 the TGA will manage a comprehensive reform agenda based on the 2016-17 Budget measure “improving the Regulation of Therapeutic goods in Australia”.

## Risk assessment

A cost recovery risk assessment for the proposed reform program was undertaken in May 2015 resulting in a medium risk rating.

The cost recovery risk rating of medium 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 (although implementation is to be funded from reserves), the source of recovery is through fees and levies, they involve an existing Act of Parliament (for TGA charges to be reviewed) and many stakeholders will be affected.

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 to be addressed by:

- continued improvements in regulatory and administrative functions;
- implementing best practice in activity based costing (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).



## Stakeholder engagement

TGA consults with industry associations separately on regulatory matters and cost impacts relating to specific sectors. Industry associations are also consulted in the process of regulatory development and reform, and feedback is taken into account in developing regulatory impact statements, and in developing cost recovery arrangements. Meetings are held with key industry representative bodies each year to discuss financial forecasts and as a part of the consultation process on cost recovery. The TGA also reports to stakeholders against a set of agreed Key Performance Indicators (KPIs).

Consultation on the proposed fees and charges for 2016-17 was undertaken at bilateral meetings with the following industry representative groups in February and March 2016.

1. Medicines Australia
2. The Generic and Biosimilar Medicines Association
3. AusBiotech
4. Medical Technology Association of Australia
5. IVD Australia
6. Australian Dental Industry Association
7. The Australian Self-Medical Industry
8. Complementary Medicines Australia
9. Accord Australasia

## Key forward events

### Portfolio charging review

The Department of Health will undertake a portfolio charging review in the 2017-18 Budget context. The review will encompass TGA's cost recovery activities, and include such things as: identifying any policy, legal and operational issues and risks related to existing cost recovery activities; evaluating the relevance of charging activities and consistency with the planned policy outcomes of the Australian Government; assessing the potential to charge for new or existing activities; and stating whether charging should continue for existing activities or be changed, and on what basis.

Key forward events schedule	Next scheduled update
Actual financial and performance results for 2015-16	Reported in the Department of Health's Annual Report
Scheduled portfolio charging review	2017-18
Forward (financial) estimates	30 June 2017

## CRIS approval and change register

Date of CRIS change	Approver	CRIS change
01/07/2014	Secretary Department of Health	CRISs for 1 July 2014
01/07/2014	Assistant Minister for Health	CRISs for 1 July 2014
01/07/2015	Secretary Department of Health (noted by Assistant Minister for Health)	Individual sector based CRISs updated for 1 July 2015, except for the over the counter medicines CRIS which was updated on 1 January 2016 to reflect fee changes on 1 January 2016
01/07/2016	Secretary Department of Health	Consolidated CRIS updated for 1 July 2016

# Appendix 1 - Financial performance by industry sector group

## 1. Prescription medicines

Volumes <sup>5</sup>	2014-15 Actual	2015-16 Forecast	2016-17 Budget	2017-18 Estimate	2018-19 Estimate
Biological prescription medicines	461	550	550	550	550
Non-biological prescription medicines – higher charge	N/A	475	475	475	475
Non-biological prescription medicines – lower charge	4,842	5,901	5,901	5,901	5,901

Revenue and expenses	2014-15 Actual \$'m	2015-16 Forecast \$'m	2016-17 Budget \$'m	2017-18 Estimate \$'m	2018-19 Estimate \$'m
<b>A: Revenue</b>					
Cost recovery revenue	65.6	68.7	70.8	72.7	75.5
<b>Total A</b>	<b>65.6</b>	<b>68.7</b>	<b>70.8</b>	<b>72.7</b>	<b>75.5</b>
<b>B: Expenses<sup>6</sup></b>					
Direct	35.4	34.7	40.0	39.9	40.5
Indirect	22.8	22.3	25.8	25.7	26.0
<b>Total B</b>	<b>58.1</b>	<b>57.0</b>	<b>65.8</b>	<b>65.6</b>	<b>66.5</b>
<b>Surplus (deficit)</b>	<b>7.4</b>	<b>11.7</b>	<b>5.0</b>	<b>7.0</b>	<b>9.0</b>

<sup>5</sup> Number of entries on the ARTG subject to annual charge.

<sup>6</sup> Due to restructure in the corporate area, TGA is undertaking a review of its activity based costing model to reflect the new structure. The direct and indirect expenses are derived based on the ratio from the previous model.

## 2. Over the counter medicines

Volumes <sup>7</sup>	2014-15 Actual	2015-16 Forecast	2016-17 Budget	2017-18 Estimate	2018-19 Estimate
Over the counter medicines	2,064	2,451	2,451	2,451	2,451

Revenue and expenses	2014-15 Actual \$'m	2015-16 Forecast \$'m	2016-17 Budget \$'m	2017-18 Estimate \$'m	2018-19 Estimate \$'m
<b>A: Revenue</b>					
Cost recovery revenue	7.7	8.0	8.2	8.4	8.8
<b>Total A</b>	<b>7.7</b>	<b>8.0</b>	<b>8.2</b>	<b>8.4</b>	<b>8.8</b>
<b>B: Expenses<sup>8</sup></b>					
Direct	5.1	5.0	5.7	5.7	5.8
Indirect	2.9	2.8	3.3	3.3	3.3
<b>Total B</b>	<b>7.9</b>	<b>7.8</b>	<b>9.0</b>	<b>9.0</b>	<b>9.1</b>
<b>Surplus (deficit)</b>	<b>(0.3)</b>	<b>0.2</b>	<b>(0.8)</b>	<b>(0.5)</b>	<b>(0.3)</b>

<sup>7</sup> Number of entries on the ARTG subject to annual charge.

<sup>8</sup> Due to restructure in the corporate area, TGA is undertaking a review of its activity based costing model to reflect the new structure. The direct and indirect expenses are derived based on the ratio from previous model.

### 3. Complementary medicines

Volumes <sup>9</sup>	2014-15 Actual	2015-16 Forecast	2016-17 Budget	2017-18 Estimate	2018-19 Estimate
Registered complementary medicines	131	127	127	127	127
Listed complementary medicines	8,262	9,491	9,491	9,491	9,491

Revenue and expenses	2014-15 Actual \$'m	2015-16 Forecast \$'m	2016-17 Budget \$'m	2017-18 Estimate \$'m	2018-19 Estimate \$'m
<b>A: Revenue</b>					
Cost recovery revenue	11.4	12.6	13.0	13.3	13.8
<b>Total A</b>	<b>11.4</b>	<b>12.6</b>	<b>13.0</b>	<b>13.3</b>	<b>13.8</b>
<b>B: Expenses<sup>10</sup></b>					
Direct	13.7	13.4	15.5	15.4	15.6
Indirect	9.0	8.8	10.2	10.1	10.3
<b>Total B</b>	<b>22.7</b>	<b>22.2</b>	<b>25.6</b>	<b>25.6</b>	<b>25.9</b>
<b>Surplus (deficit)</b>	<b>(11.3)</b>	<b>(9.6)</b>	<b>(12.7)</b>	<b>(12.3)</b>	<b>(12.1)</b>

<sup>9</sup> Number of entries on the ARTG subject to annual charge.

<sup>10</sup> Due to restructure in the corporate area, TGA is undertaking a review of its activity based costing model to reflect the new structure. The direct and indirect expenses are derived based on the ratio from previous model.

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

Volumes <sup>11</sup>	2014-15 Actual	2015-16 Forecast	2016-17 Budget	2017-18 Estimate	2018-19 Estimate
Included medical devices	39,124	40,480	40,480	40,480	40,480
Other therapeutic goods	448	340	340	340	340

Revenue and expenses	2014-15 Actual \$'m	2015-16 Forecast \$'m	2016-17 Budget \$'m	2017-18 Estimate \$'m	2018-19 Estimate \$'m
<b>A: Revenue</b>					
Cost recovery revenue	32.0	31.7	32.7	33.5	34.8
<b>Total A</b>	<b>32.0</b>	<b>31.7</b>	<b>32.7</b>	<b>33.5</b>	<b>34.8</b>
<b>B: Expenses<sup>12</sup></b>					
Direct	12.9	12.6	14.6	14.6	14.8
Indirect	11.2	11.0	12.7	12.6	12.8
<b>Total B</b>	<b>24.1</b>	<b>23.6</b>	<b>27.3</b>	<b>27.2</b>	<b>27.6</b>
<b>Surplus (deficit)</b>	<b>7.9</b>	<b>8.1</b>	<b>5.4</b>	<b>6.3</b>	<b>7.3</b>

<sup>11</sup> Number of entries on the ARTG subject to annual charge.

<sup>12</sup> Due to restructure in the corporate area, TGA is undertaking a review of its activity based costing model to reflect the new structure. The direct and indirect expenses are derived based on the ratio from previous model.

## 5. Good manufacturing practices

Volumes <sup>13</sup>	2014-15 Actual	2015-16 Forecast	2016-17 Budget	2017-18 Estimate	2018-19 Estimate
Low level GMP licence	116	104	104	104	104
High level GMP licence	162	163	163	163	163

Revenue and expenses	2014-15 Actual \$'m	2015-16 Forecast \$'m	2016-17 Budget \$'m	2017-18 Estimate \$'m	2018-19 Estimate \$'m
<b>A: Revenue</b>					
Cost recovery revenue	12.1	11.1	11.5	11.8	12.2
<b>Total A</b>	<b>12.1</b>	<b>11.1</b>	<b>11.5</b>	<b>11.8</b>	<b>12.2</b>
<b>B: Expenses<sup>14</sup></b>					
Direct	9.3	9.1	10.5	10.5	10.7
Indirect	3.6	3.5	4.0	4.0	4.1
<b>Total B</b>	<b>12.9</b>	<b>12.6</b>	<b>14.6</b>	<b>14.5</b>	<b>14.7</b>
<b>Surplus (deficit)</b>	<b>(0.7)</b>	<b>(1.5)</b>	<b>(3.1)</b>	<b>(2.8)</b>	<b>(2.5)</b>

<sup>13</sup> Number of entries on the ARTG subject to annual charge.

<sup>14</sup> Due to restructure in the corporate area, TGA is undertaking a review of its activity based costing model to reflect the new structure. The direct and indirect expenses are derived based on the ratio from previous model.

## 6. Blood, blood components and biologicals

Volumes <sup>15</sup>	2014-15 Actual	2015-16 Forecast	2016-17 Budget	2017-18 Estimate	2018-19 Estimate
Blood primary site	5	5	5	5	5
Blood secondary site	79	79	79	79	79
Single step manufacturer of human tissue	10	24	24	24	24
Class 2 biological products	14	15	15	15	15

Revenue and expenses	2014-15 Actual \$'m	2015-16 Forecast \$'m	2016-17 Budget \$'m	2017-18 Estimate \$'m	2018-19 Estimate \$'m
<b>A: Revenue</b>					
Cost recovery revenue	2.0	2.2	2.3	2.3	2.4
<b>Total A</b>	<b>2.0</b>	<b>2.2</b>	<b>2.3</b>	<b>2.3</b>	<b>2.4</b>
<b>B: Expenses<sup>16</sup></b>					
Direct	1.8	1.8	2.0	2.0	2.1
Indirect	1.5	1.5	1.7	1.7	1.7
<b>Total B</b>	<b>3.3</b>	<b>3.2</b>	<b>3.7</b>	<b>3.7</b>	<b>3.8</b>
<b>Surplus (deficit)</b>	<b>(1.3)</b>	<b>(1.0)</b>	<b>(1.5)</b>	<b>(1.4)</b>	<b>(1.4)</b>

<sup>15</sup> Number of entries on the ARTG subject to annual charge.

<sup>16</sup> Due to restructure in the corporate area, TGA is undertaking a review of its activity based costing model to reflect the new structure. The direct and indirect expenses are derived based on the ratio from previous model.



## 7. Other activities

Revenue and expenses	2014-15 Actual \$'m	2015-16 Forecast \$'m	2016-17 Budget \$'m	2017-18 Estimate \$'m	2018-19 Estimate \$'m
<b>A: Revenue</b>					
Revenue	8.0	2.1	2.0	2.0	2.0
<b>Total A</b>	<b>8.0</b>	<b>2.1</b>	<b>2.0</b>	<b>2.0</b>	<b>2.0</b>
<b>B: Expenses</b>					
Expense	4.4	2.1	2.0	2.0	2.0
<b>Total B</b>	<b>4.4</b>	<b>2.1</b>	<b>2.0</b>	<b>2.0</b>	<b>2.0</b>
<b>Surplus (deficit)</b>	<b>3.6</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>

## **Appendix 2 - Schedule of fees and charges w.e.f 1.7.2016**

2016-17 TGA fees and charges can be found using the URL below:

<https://www.tga.gov.au/schedule-fees-and-charges>

Historical document

Historical document

**Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia

Email: [info@tga.gov.au](mailto:info@tga.gov.au) Phone: 1800 020 653 Fax: 02 6203 1605

<https://www.tga.gov.au>

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