



Australian Government

Department of Health

Therapeutic Goods Administration

Cost recovery implementation statement

TGA Health Safety
Regulation

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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 2017-18 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, through the Therapeutic Goods Administration (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 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 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.

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 by the Government for meeting the cost of scheduling activity, and 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.¹ 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 resources².

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 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 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

¹ Australian Government Charging Framework, 2015, available at www.finance.gov.au.

² 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

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.

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. This utilises the following process.

Applications

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

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 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.

Brand equivalence statement for registered OTC medicines

TGA receives requests from sponsors for brand equivalence statements for the purpose of 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 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 complementary medicines, like any other registered medicine, are fully evaluated for quality, safety and efficacy prior to being accepted on the ARTG and 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 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, so 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.

5. 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 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 therapeutic devices which are not captured under the new Chapter 4 arrangements. These are largely disinfectants, tampons and menstrual cups.

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.

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 approach to regulation

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 uses a staged risk-management 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 TGA can communicate its regulatory requirements and compliance expectations quickly and directly to a market-entry applicant and can deny market access to applicants who cannot demonstrate compliance with these requirements. Providing regulatory education to applicants at or before this point can help to minimise non-compliance once a product is marketed.

It is the TGA's policy to publish information about regulatory compliance decisions and actions on its website.

The TGA uses a range of tools when taking action on a compliance matter, including:

Guidance

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.

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. All signals, including complaints about a therapeutic good, are recorded and considered, but the TGA cannot investigate all complaints received. Once again, 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, we 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.

Advertising review

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.

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);
- media;
- Therapeutic Goods Advertising Code Council; and
- Complaints Resolution Panel.

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.

The 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 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.

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 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 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.

To obtain a licence for the manufacture, 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.

Monitoring 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: Access to unapproved products

Patient access to unproved 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 legislation access to unapproved goods is available to patients under two schemes as follows:

Special Access Scheme (SAS)

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 two categories under the scheme:

- Category A patients are defined as 'persons 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 patients are all other patients that do not fit the Category A definition.

Authorised prescribers (AP)

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.

Further information on the cost recovery of the two schemes is included in the 'Fee-free regulatory activities' section.

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.

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 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. 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 corporate costs (e.g. finance, human resources, IT, office accommodation) and salaries of staff in support areas (e.g. regulatory practice and support functions).

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 staff to regulatory activities to determine direct cost. Indirect costs are allocated to regulatory activities on the basis of standard costing. More details on the cost of TGA activities 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. 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 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 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 \$6,990.

Fee-free regulatory activities

a) Patient access to unproved therapeutic goods via the SAS and AP schemes

While patient access to certain unapproved therapeutic goods is critical for the health of the Australian public, the TGA does not charge a fee directly 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 or curing a terminally ill patient in highly time sensitive situations. These schemes are incentivised because it is in the public interest to save a life 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 2015-16 there were 42,772 SAS notifications (category A), 25,577 SAS applications (category B) and 899 authorised prescriber applications. The annual cost of the two fee free services is estimated to be \$3 million or around \$43 per application. Recovering this cost through a small application fee levied on patients and or the medical practitioner is unlikely to be cost efficient. Moreover, this would also impact on the access of an unapproved product to the seriously ill patient in a time critical manner.

The costs of these functions are recovered indirectly through the annual charges levied on therapeutic goods approved for supply in Australia which is in line with the Government decision that the TGA recovers the full cost of regulatory activity.

b) Orphan drugs

A medicine, including vaccines or in vivo diagnostic agents, may be eligible for Orphan Drug designation if all four orphan criteria prescribed in regulations 16(3) or 16(4) are satisfied.

The [orphan drug program](#) is an activity undertaken for the public good, with the objective of bringing medicines for rare diseases 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.

While the orphan drug program provides incentive for developing drugs for use by a small patient population, the recently concluded public consultation on the orphan drug program has indicated strong industry support for the orphan drug scheme including a fee waiver. The TGA orphan program can be seen as part of a global movement to address treatment of approximately 7,000 rare diseases worldwide. Orphan drug programs were launched in the US in 1983, in Japan in 1993, and by the European Union in 2000 and offer a wide range of incentives including fee waiver, scientific advice and market exclusivity.

The cost of assessment is met from the evaluation fees for certain types of prescription medicine applications (extensions of indications and new chemical entities). As the sponsors of orphan drugs are also mostly the sponsors of fee paying applications, cross-subsidisation is confined to a small group of sponsors and does not extend to broader industry.

In 2015-16, the TGA assessed 16 orphan drug applications, compared to the total fee paying applications of 117 for prescription medicines (new chemical entity, major variation and extension of indications). The total cost attributed to the orphan drug program in 2015-16 is \$3.1 million.

Once an orphan drug is entered on the ARTG, the annual charge is payable subject to the annual charge exemption (ACE) scheme.

2017-18 Fees and Annual Charges

a) Introduction of an annual charge for in-vitro diagnostic medical devices

A new framework for the regulation of in-vitro diagnostic medical devices (IVDs) was introduced in 2010. Annual charges for IVDs were not levied until the end of the transition period on 30 June 2017. The annual cost of post market monitoring and compliance of IVDs is estimated to be around \$1.6 million. In order to recover these costs an annual charge of \$660 will apply to all classes of IVDs, except for class 4 in-house IVDs. Class 4 in-house IVDs are included in the ARTG only for in-house use by laboratories and not for sale, therefore they will always be exempt from the annual charge under the ACE scheme. Levying an annual charge and then exempting them under the ACE scheme would create unnecessary administrative burden for both sponsors and the TGA.

There are currently 230 sponsors of 2,497 IVDs on the ARTG who will be required to pay the new annual charge, except where exempted under the ACE scheme. The TGA has advised the sponsors of IVDs of the applicable annual charge for 2017-18 ahead of the implementation date.

b) Introduction of a reinstatement fee

The Act provides the Secretary the power to reinstate an entry on the ARTG which was cancelled upon the sponsor's request or due to non-payment of the annual charge. The Act also prescribes that the Secretary may revoke the cancellation and reinstate the entry if the sponsor makes an application to revoke the cancellation and pays the prescribed application fee within 90 days of cancellation.

In order to recover administrative cost of the reinstatement process a two-tier fee structure will apply from 1 July 2017 to applications to reinstate an entry on the ARTG. The reinstatement application fee is set based on the cost of staff effort required in the processing of a typical reinstatement application which involves receipt of the application, payment processing, delegate decision and correction of the ARTG record. The new fees are:

- \$150 for a reinstatement application containing only one entry; and

- if the application contains more than one entry, the fee is \$150 for the first entry plus \$50 for each additional entry.

c) Reduction in annual charges for some medical devices

Before the ACE scheme was implemented on 1 July 2015, replacing the previous LVT exemption scheme, it was recognised that the new scheme would reduce the number of entries that are eligible for an exemption to the annual charge (therefore increasing the number of entries for which an annual charge is payable). In light of this, when the ACE scheme was implemented, annual charge reductions were applied to several types of entries as follows:

- Prescription medicines (non-biologicals) - other than generic medicines: 5%
- Prescription medicines (non-biologicals) - generic medicines: 23%
- Medical devices - class IIA and above: 5%

On introduction, the TGA committed to monitor the impact of the new scheme on the therapeutic goods industry and adjust annual charges, if required, to ensure appropriate cost recovery for each industry sector.

After a year of operation an impact assessment of the new scheme was undertaken which suggested that annual charges revenue from medical devices was higher than forecast, due to a lower than anticipated cancellation of entries. Therefore a further reduction in annual charges for medical devices (other than class 1 medical devices which incur an annual charge of \$80) by 6.5% has been implemented, subject to the general indexation increase of 1.65% to all TGA fees and charges- resulting in an overall reduction in annual charges for most medical devices of 4.96%.

d) Other fees and charges changes for 2017-18

A general increase of 1.65% has been applied to fees and charges from 1 July 2017 to meet estimated cost increases, mainly in employee expenses as a result of salary increases under the Department of Health Enterprise Agreement.

A well-established formula for price indexation has been used in most years, based on the Australian Bureau of Statistics' Consumer Price Index (50%) and Wage Price Index (50%) (both for the year to September). This year the formula resulted in 1.65%. The Office of Best Practice Regulation has advised that a Regulatory Impact Statement is not required for this change.

The amendment regulations were approved by the Executive Council at their meeting of 18 May 2017 to effect the above changes.

A link to the fees and charges applicable from 1 July 2017 is provided in [Appendix 2](#).

Regulatory Reforms: Review of medicines and medical devices regulation

An independent review of medicines and medical devices regulation (the Review) was undertaken to identify:

- 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.

The review panel provided the Government with 58 recommendations of which the Government has accepted 56. In summary, those recommendations are:

- 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 2016-17 Budget measure “Improving the Regulation of Therapeutic Goods in Australia” has provided \$20.4 million (to be met from TGA reserves) to meet the costs of implementation of the above reforms for completion within a period of 24 months. Any increase in ongoing costs will be met via cost recovery arrangements through new, and changes to existing, fees and charges.

The reforms that require new fees from 1 July 2017 are discussed below.

Priority registration of certain medicines

The Review recommended that the TGA implement expedited pathways for the registration of new medicines in certain circumstances. One of the expedited pathways, the Priority Review pathway, to enable faster approval of certain medicines, will be implemented from 1 July 2017. The Priority Review pathway will prioritise the evaluation of novel prescription medicines that meet the eligibility criteria and have a complete data dossier, with a view to reducing the target timeframe for a decision regarding registration of the medicine in the ARTG to 150 working days.

In order to recover the additional costs of the new processes the following new fees will apply for making applications under the Priority Review pathway.

Designation fee

The new registration pathway will not be available for all registration applications but only to those which meet certain criteria. A sponsor of a new medicine will need to make a designation application to the TGA which will be assessed against the relevant eligibility criteria to determine whether the medicine should be granted access to the new pathway. Designation is a new process and an application for this will require payment of a designation fee of \$12,300 per application. The fee is non-refundable regardless of the decision to accept or reject the application.

The fee has been set after taking into account estimated staff time/cost involved in having a pre-submission meeting with the applicant, assessing a designation application against the criteria, seeking expert advice, where needed, and decision making. As some of the designation applications may also accompany an application for designation for orphan drug status (for which a fee is not payable) the new fee has been appropriately loaded to ensure adequate cost recovery. This is consistent with the current practice for recovering the costs of orphan drug applications.

It is anticipated that on average the TGA will receive 18 designation applications every year.

Application and evaluation fee

Once an application has been accepted the applicant may choose to make an application for registration of a New Chemical Entity (NCE) or an extension of indication (EOI) under the new pathway rather than the standard pathway. A higher than standard application and evaluation fees apply for registration applications under the new pathway.

The new application and evaluation fees will be slightly higher because of the additional effort required to complete the Priority Review registration process within a reduced target timeframe of 150 working days.

The application and evaluation fees are based on the staff effort involved in the prescription medicines registration process capturing the estimated average time taken to complete the tasks involved and the classifications of staff that typically carry out these tasks. While there will be some variation in the workload involved between different applications of the same type, as with many assessment processes, costings have been calculated taking into account the likelihood that certain steps will occur, and the minimum and maximum time taken in order to obtain an average fee which will facilitate cost recovery across a broad range of complexity in designation and registration applications. To estimate the fees for the Priority Review pathway, specific tasks within this process have been identified where more time and/or resources will be required to meet the priority timeframe. Estimates of the resource requirements for any new tasks have also been captured.

The fees for the standard pathway and Priority Review pathway are included in table below:

Application type	Costing	Application Fee	Evaluation Fee	Total
New Chemical Entity	Standard Pathway	\$46,900	\$188,200	\$235,100
	Priority Review pathway	\$49,800	\$199,000	\$248,800
	Difference in fees	\$2,900	\$10,800	\$13,700
Extension of Indication	Standard Pathway	\$28,000	\$111,700	\$139,700
	Priority Review pathway	\$29,600	\$118,400	\$148,000
	Difference in fees	\$1,600	\$6,700	\$8,300

Because the expedited pathway will be a new process, it is difficult to provide a definitive estimate of the total costs as there are many unknown factors such as:

- how many applications for designation will be received;
- how many of these applications will be eligible for the Priority Review pathway;
- how many will also be eligible for orphan designation; and
- how many applications will ultimately be registered through the pathway.

The new fees and the impact of introduction of the new pathway will be monitored and reassessed within 2 years.

Risk based approach for certain minor variations to registered medicines

The Review recommended that the TGA should apply a more risk-based approach to managing variations to registered medicines. This approach should provide for notification of variations in circumstances where the variation does not impact the quality, safety or efficacy of the medicine. The sponsor will be required to notify the TGA of the variation within a given timeframe.

In order to implement this recommendation the TGA has implemented a new notification system for minor variations to registered medicines. Under the new notification process, the sponsor will be able to notify the TGA of certain changes to their goods. This notification will need to occur before the change is made.

In submitting the notification, the sponsor will need to make a declaration that certain conditions are met and, in some circumstances, provide evidence, as outlined in the relevant guidance. Once the relevant fees have been processed, the sponsor would receive an automatic acknowledgment and can then proceed to implement the change. There will be no assessment of the notification or 'wait' time before acknowledgment.

While this process will reduce manual staff effort, the new notification fee is set to recover the costs of associated activities in:

- building and maintaining the IT system;
- providing sponsor support;
- ensuring currency of records; and
- auditing notifications to ensure variations are being notified appropriately.

Based on the estimated costs of the above activities, a notification fee of \$780 per notification has been set. This represents a reduction of more than 50% on the current minor variation fees for prescription medicines (\$1,625) and OTC medicines (\$1,565) respectively.

It is estimated that around 2/3rd of current 'Safety Related Notifications' variation applications for prescription medicines, or around 850 annually, will come in as notifications under the new system. For over the counter medicines it is expected that 1/3rd of the current C1 variation applications could be made under the new system. The estimated volume is around 175 notifications each year. As a result of this change, a reduction of around \$0.85 million in revenue is estimated in a financial year.

Consultations

Extensive consultation was undertaken in 2014-15 with consumers, industry and health professionals as part of the Review. Further public and targeted consultation, including in relation to the above regulatory requirements, has been conducted since late 2016. In relation to

priority approval for medicines, public consultation in November and December 2016 sought feedback on the main elements of the arrangements, including the proposed criteria for qualifying for the new pathway.

On notifiable variations, consultation was conducted with stakeholders including peak bodies and industry sponsors in November 2016 on the proposed variations and processes for notifying the TGA of these changes.

Submissions from peak bodies (e.g. Medicines Australia) and industry sponsors, patient advocacy groups and healthcare professional bodies overall indicated support for the above reforms.

Consultation on the new fees was conducted with peak therapeutic bodies in February 2017 along with the other changes to fees and charges proposed for 2017-18. Peak bodies welcomed the reduced fee for notifications and raised no concerns in relation to designation fees and application and evaluation fees under the Priority Review pathway.

The amendment regulations to prescribe the above fees were approved by the Executive Council at their meeting of 27 June 2017.

A link to the fees and charges (including the above fees) applicable from 1 July 2017 is provided in [Appendix 2](#).

Financial and non-financial performance

a) Financial performance

	2015-16 Actual \$'m	2016-17 Forecast \$'m	2017-18 Budget \$'m	2018-19 Estimate \$'m	2019-20 Estimate \$'m
A: Revenue					
Revenue from Government	2.142	2.574	2.388	2.367	2.371
Sale of goods and services	141.489	139.006	142.341	146.448	148.613
Other revenue and gains	0.198	0.120	0.120	0.120	0.120
Total A	143.829	141.700	144.849	148.935	151.104
B: Expenses					
Employee expenses	78.683	79.200	80.782	82.396	84.042
Suppliers	44.601	63.353	60.836	59.116	59.206
Depreciation and amortisation	4.672	6.020	6.835	7.423	7.856
Write-down and impairment of assets	0.105	0.027			
Total B	128.060	148.600	148.453	148.935	151.104
Surplus (deficit)	15.769	(6.900)	(3.604)	0.000	(0.000)

TGA's activities are primarily cost recovered from industry except for the cost of the scheduling function for which an appropriation is provided by the Government. 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).

The surplus in 2015-16 was the result of underspends in employee expenses due to lower staffing levels, and higher revenue because the number of products cancelled from the ARTG were lower than anticipated upon introduction of the ACE scheme.

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 in new, or replacement of existing, business systems, must also come from the responsible management of these reserves. The target for the reserve balance is set at around 20% of operating expenses. While in 2015–16 the TGA's reserves remained above that target they 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.

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

b) Non- financial performance

The Australian Government has developed a framework to measure the performance of regulators. The [Regulator Performance Framework](#) comprises six outcome-based key performance indicators (KPIs) to articulate the Government's overarching expectations of regulator performance:

1. Regulators do not unnecessarily impede the efficient operation of regulated entities
2. Communication with regulated entities is clear, targeted and effective
3. Actions undertaken by regulators are proportionate to the regulatory risk being managed
4. Compliance and monitoring approaches are streamlined and coordinated
5. Regulators are open and transparent in their dealings with regulated entities
6. Regulators actively contribute to the continuous improvement of regulatory frameworks.

This framework has been applied since 1 July 2015 with the first assessment period being the 2015-16 financial year. The TGA reports annually³ to stakeholders on performance against a set of agreed KPIs. A series of qualitative and quantitative outputs and evidence to assess the TGA's achievement of the KPIs and associated measures were developed in consultation with the Australian Therapeutic Goods Advisory Council and the TGA-Industry Consultative Committee (TICC). These KPIs were endorsed by the then Assistant Minister and published on the TGA website in June 2015. For more information on the TGA's KPIs please visit: [TGA key performance indicators](#).

The TGA's self-assessment against the KPIs was externally validated by the TICC which comprises industry and consumer representatives. In terms of feedback on whether the self-assessment process provided sufficient, reliable and current evidence to support our overall performance rating of met, TICC members either agreed or somewhat agreed. Members noted that this is the first report of its kind, and although the majority of the evidence matrices are appropriate and an effective tool for assessing our compliance against the KPIs, the matrices should be subject to continuous improvement to ensure relevance.

Overall the TGA has met the requirements of the Framework through meeting KPIs 1, 3, 5 and 6 with 'strong performance' against these measures and through substantially meeting KPIs 2 and 4. The [2015-16 report](#) is published on TGA's website, a brief summary is provided below.

³ More detailed information about TGA's regulatory and corporate activities can be found in the annual [Performance Statistics Report](#).

Self-assessment rating and summary of overall performance

KPI	Performance rating	Comments
KPI 1. Regulators do not unnecessarily impede the efficient operation of regulated entities	Met	<p>The performance rating of met is supported by successful participation in formal stakeholder forums and participation at industry events. This has led to smaller face-to-face workshops and increased opportunities for our staff to improve their knowledge of emerging technologies and provide industry with an opportunity to increase understanding of our regulatory requirements.</p> <p>Additionally, we have implemented a number of initiatives under the Business Improvement Program aimed at reducing compliance costs to industry.</p>
KPI 2. Communication with regulated entities is clear, targeted and effective	Substantially met	<p>The performance rating of substantially met is based on medical device timeframes for application audits not being met, although these timeframes are not mandated in legislation. The legally-mandated timeframes for medical device conformity assessment were met in 100% of cases.</p>
KPI 3. Actions undertaken by regulators are proportionate to the regulatory risk being managed	Met	<p>The performance rating of met is supported by our risk management approach in regulating therapeutic products, including identifying entities at risk of unintentional or deliberate non-compliance, and the collection of intelligence in relation to alleged breaches of the <i>Therapeutic Goods Act 1989</i> and the <i>Therapeutic Goods Regulations 1990</i>.</p> <p>Evidence of actions undertaken by regulators that are proportionate to the regulatory risk is also outlined in our laboratories targeted testing of medicines and medical devices according to the risk they pose to the public, monitoring of the market for signals of potential non-compliance and the scheduling of manufacturer inspections based on compliance records.</p> <p>Additionally, we can communicate regulatory requirements and compliance expectations quickly and directly to market-entry applicants.</p>

KPI	Performance rating	Comments
KPI 4. Compliance and monitoring approaches are streamlined and coordinated	Substantially met	The performance rating of substantially met is because we do not yet have a fully mature compliance and enforcement framework with graduated sanctions and penalties. While we have a sound compliance structure in place, we do not yet have a range of regulatory tools which allow us to use the full range of compliance approaches. This is being addressed under the reform program.
KPI 5. Regulators are open and transparent in their dealings with regulated entities	Met	The performance rating of met is demonstrated through our continued efforts towards raising awareness of our regulatory framework through industry workshops and the publication of educational material, as well as maintaining telephone and email based information lines. We also publish regular performance activity reports on our website.
KPI 6. Regulators actively contribute to the continuous improvement of regulatory frameworks	Met	The performance rating of met is supported by our stakeholder engagement through market research, continued business improvements and interactions with other regulators.

Risk assessment

A cost recovery risk assessment for the regulatory reform program was undertaken resulting in a medium risk rating for TGA's cost recovery arrangements. The cost recovery risk rating of medium is based on assessment of the criteria using the Charging Risk Assessment (CRA) template. The key medium to high risks for cost recovery are that the amount to cost recover exceeds \$20 million, 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 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

The 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 changes to fees and charges for 2017-18 was undertaken at bilateral meetings with the following industry representative groups in February 2017:

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

Key forward events

Key forward events schedule	Next scheduled update
Consultations on new and revised cost recovery arrangements for regulatory reforms	2017-18
Actual financial and performance results for 2016-17	Reported in the Department of Health's Annual Report
Forward (financial) estimates	30 June 2018

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
01/07/2016	Secretary Department of Health	Consolidated CRIS updated for 1 July 2016
30/6/2017	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

Appendix 1 - Financial performance by industry sector group

1. Prescription medicines

Volumes ⁴	2015-16 Actual	2016-17 Forecast	2017-18 Budget	2018-19 Estimate	2019-20 Estimate
Biological prescription medicines	580	486	486	486	486
Non-biological prescription medicines – higher charge	522	493	493	493	493
Non-biological prescription medicines – lower charge	6,536	5,640	5,640	5,640	5,640

Revenue and expenses	2015-16 Actual \$'m	2016-17 Forecast \$'m	2017-18 Budget \$'m	2018-19 Estimate \$'m	2019-20 Estimate \$'m
A: Revenue					
Cost recovery revenue	71.7	69.6	71.2	73.2	74.3
Total A	71.7	69.6	71.2	73.2	74.3
B: Expenses⁵					
Direct	36.9	39.7	41.8	43.1	43.7
Indirect	26.3	28.3	29.8	30.7	31.2
Total B	63.2	68.0	71.6	73.8	74.9
Surplus (deficit)	8.5	1.6	(0.4)	(0.6)	(0.6)

⁴ Number of entries on the ARTG subject to the annual charge.

⁵ Following the internal organisation restructure (industry sector based) within the TGA, a new activity based costing model has been developed in 2016-17 based on a staff effort survey undertaken in 2016-17. The allocation of direct and indirect expenses is based on the ratio from the most recent 2016-17 model. The TGA will continue to review the costing model and apply changes when necessary.

2. Over the counter medicines

Volumes ⁶	2015-16 Actual	2016-17 Forecast	2017-18 Budget	2018-19 Estimate	2019-20 Estimate
Over the counter medicines	2,667	2,417	2,417	2,417	2,417

Revenue and expenses	2015-16 Actual \$'m	2016-17 Forecast \$'m	2017-18 Budget \$'m	2018-19 Estimate \$'m	2019-20 Estimate \$'m
A: Revenue					
Cost recovery revenue	6.7	7.7	7.9	8.1	8.3
Total A	6.7	7.7	7.9	8.1	8.3
B: Expenses⁷					
Direct	2.8	3.4	3.1	3.2	3.3
Indirect	2.3	2.9	2.6	2.7	2.8
Total B	5.1	6.2	5.8	6.0	6.1
Surplus (deficit)	1.6	1.5	2.1	2.2	2.2

⁶ Number of entries on the ARTG subject to the annual charge.

⁷ Following the internal organisation restructure (industry sector based) within the TGA, a new activity based costing model has been developed in 2016-17 based on a staff effort survey undertaken in 2016-17. The allocation of direct and indirect expenses is based on the ratio from the most recent 2016-17 model. The TGA will continue to review the costing model and apply changes when necessary.

3. Complementary medicines

Volumes ⁸	2015-16 Actual	2016-17 Forecast	2017-18 Budget	2018-19 Estimate	2019-20 Estimate
Registered complementary medicines	132	133	133	133	133
Listed complementary medicines	11,003	10,238	10,238	10,238	10,238

Revenue and expenses	2015-16 Actual \$'m	2016-17 Forecast \$'m	2017-18 Budget \$'m	2018-19 Estimate \$'m	2019-20 Estimate \$'m
A: Revenue					
Cost recovery revenue	15.7	14.0	14.3	14.7	14.9
Total A	15.7	14.0	14.3	14.7	14.9
B: Expenses⁹					
Direct	7.2	7.8	8.1	8.4	8.5
Indirect	5.2	5.7	5.9	6.1	6.2
Total B	12.4	13.5	14.0	14.5	14.7
Surplus (deficit)	3.3	0.5	0.3	0.2	0.3

⁸ Number of entries on the ARTG subject to the annual charge.

⁹ Following the internal organisation restructure (industry sector based) within the TGA, a new activity based costing model has been developed in 2016-17 based on a staff effort survey undertaken in 2016-17. The allocation of direct and indirect expenses is based on the ratio from the most recent 2016-17 model. The TGA will continue to review the costing model and apply changes when necessary.

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

Volumes ¹⁰	2015-16 Actual	2016-17 Forecast	2017-18 Budget	2018-19 Estimate	2019-20 Estimate
Included medical devices	44,878	45,471	45,471	45,471	45,471
IVD medical devices	N/A	N/A	2,492	2,492	2,492
Other therapeutic goods	359	279	279	279	279

Revenue and expenses	2015-16 Actual \$'m	2016-17 Forecast \$'m	2017-18 Budget \$'m	2018-19 Estimate \$'m	2019-20 Estimate \$'m
A: Revenue					
Cost recovery revenue	34.3	36.0	36.8	37.8	38.4
Total A	34.3	36.0	36.8	37.8	38.4
B: Expenses¹¹					
Direct	17.1	19.3	19.4	20.0	20.3
Indirect	12.2	13.7	13.8	14.3	14.5
Total B	29.4	33.0	33.3	34.3	34.8
Surplus (deficit)	4.9	3.0	3.5	3.5	3.6

¹⁰ Number of entries on the ARTG subject to the annual charge.

¹¹ Following the internal organisation restructure (industry sector based) within the TGA, a new activity based costing model has been developed in 2016-17 based on a staff effort survey undertaken in 2016-17. The allocation of direct and indirect expenses is based on the ratio from the most recent 2016-17 model. The TGA will continue to review the costing model and apply changes when necessary.

5. Good manufacturing practices

Volumes ¹²	2015-16 Actual	2016-17 Forecast	2017-18 Budget	2018-19 Estimate	2019-20 Estimate
Low level GMP licence	105	111	111	111	111
High level GMP licence	163	161	161	161	161

Revenue and expenses	2015-16 Actual \$'m	2016-17 Forecast \$'m	2017-18 Budget \$'m	2018-19 Estimate \$'m	2019-20 Estimate \$'m
A: Revenue					
Cost recovery revenue	11.2	10.3	10.5	10.8	11.0
Total A	11.2	10.3	10.5	10.8	11.0
B: Expenses¹³					
Direct	7.8	9.2	8.8	9.1	9.2
Indirect	5.4	6.4	6.1	6.3	6.4
Total B	13.2	15.6	14.9	15.4	15.6
Surplus (deficit)	(2.0)	(5.3)	(4.4)	(4.6)	(4.6)

¹² Number of entries on the ARTG subject to the annual charge.

¹³ Following the internal organisation restructure (industry sector based) within the TGA, a new activity based costing model has been developed in 2016-17 based on a staff effort survey undertaken in 2016-17. The allocation of direct and indirect expenses is based on the ratio from the most recent 2016-17 model. The TGA will continue to review the costing model and apply changes when necessary.

6. Blood, blood components and biologicals

Volumes ¹⁴	2015-16 Actual	2016-17 Forecast	2017-18 Budget	2018-19 Estimate	2019-20 Estimate
Blood primary site	5	5	5	5	5
Blood secondary site	79	75	75	75	75
Single step manufacturer of human tissue	24	17	17	17	17
Class 2 biological products	20	19	19	19	19
Class 3 biological products	5	6	6	6	6

Revenue and expenses	2015-16 Actual \$'m	2016-17 Forecast \$'m	2017-18 Budget \$'m	2018-19 Estimate \$'m	2019-20 Estimate \$'m
A: Revenue					
Cost recovery revenue	2.2	2.4	2.5	2.6	2.6
Total A	2.2	2.4	2.5	2.6	2.6
B: Expenses¹⁵					
Direct	1.6	1.5	1.8	1.9	1.9
Indirect	1.3	1.2	1.4	1.5	1.5
Total B	2.9	2.6	3.2	3.3	3.4
Surplus (deficit)	(0.6)	(0.2)	(0.7)	(0.8)	(0.8)

¹⁴ Number of entries on the ARTG subject to the annual charge.

¹⁵ Following the internal organisation restructure (industry sector based) within the TGA, a new activity based costing model has been developed in 2016-17 based on a staff effort survey undertaken in 2016-17. The allocation of direct and indirect expenses is based on the ratio from the most recent 2016-17 model. The TGA will continue to review the costing model and apply changes when necessary.

7. Other activities

Revenue and expenses	2015-16 Actual \$'m	2016-17 Forecast \$'m	2017-18 Budget \$'m	2018-19 Estimate \$'m	2019-20 Estimate \$'m
A: Revenue					
Revenue	2.0	1.6	1.7	1.7	1.7
Total A	2.0	1.6	1.7	1.7	1.7
B: Expenses					
Other Expense	2.0	2.7	2.0	1.7	1.7
MMDR Expense	N/A	6.9	3.6	N/A	N/A
Total B	2.0	9.6	5.6	1.7	1.7
Surplus (deficit)	0.0	(8.0)	(4.0)	0.0	0.0

Appendix 2 - Schedule of fees and charges 1 July 2017

2017-18 fees and charges can be found using the URL below:

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

Therapeutic Goods Administration

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Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605

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

Reference/Publication #