



Australian Government
Department of Health
Therapeutic Goods Administration

Cost Recovery Implementation Statement

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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Historical document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 2018-19 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; and
- blood, blood components and biologicals.

While some funding is provided by the Government for meeting the cost of medicines and chemicals scheduling activity, and in the form of an interest equivalency payment against the special account balance (reserves), the overwhelming majority of funding is generated through fees and charges set 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 \(CRG\)](#) 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 manufacturers of medicines and medical devices. Applicable fees and charges are prescribed in the subordinate regulations made under these Acts.

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.

Cost recovery model

A: Pre-market regulatory activities for therapeutic goods

1. Prescription medicines

Medicines are grouped into schedules according to the appropriate level of regulatory control over their availability to consumers.

Higher risk medicines, such as prescription medicines, must be registered on the ARTG before they are made available for supply in Australia. However, certain prescription medicines can be registered provisionally for a period of time. The requirements for a provisional registration of prescription medicines are discussed in detail later in this paper.

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:

Priority and provisional pathways for registration of certain prescription medicines

As part of the implementation of a number of regulatory reforms the TGA has introduced multiple pathways for registration of certain prescription medicines. These pathways are explained in detail in the reforms section of the CRIS.

Applications

All applications for registration of prescription medicines must be preceded by a pre-submission planning form (PPF). The TGA assesses all PPFs to ensure that application dossiers for registration on the ARTG contain all the appropriate and required information. The information provided in the PPF allows resources to be effectively assigned to the evaluation process. If the PPF is insufficient for planning purposes or indicates that mandatory requirements have not been met, the TGA may deem the PPF to be 'not effective' and the application will not proceed to the dossier submission stage. The submission of the PPF improves the quality of applications and helps in meeting legislative timeframes.

Data evaluation

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

- Quality data evaluated by chemists, biochemists, microbiologists and other TGA officers includes:
 - the composition of the drug substance and the drug product;
 - batch consistency;
 - stability data;
 - sterility data (if applicable);
 - the impurity content;
 - non-clinical data evaluated by toxicologists;
 - pharmacology data;
- Toxicology data; and
- Clinical data evaluated by a medical doctor (mostly results of clinical trials).

Decision making

Before making a decision around the suitability of a prescription medicine for registration on the ARTG, the delegate may take into consideration independent expert advice provided by the Advisory Committee on Prescription Medicines.

Regulatory decisions in relation to new chemical entities or fixed dose combination products are published through the Australian Public Assessment Report (AusPAR).

Any person whose interests are affected by the decision may seek a reconsideration of the decision under section 60 of the Act.

Applications to change details of registration

Once a product has been registered, the sponsor can make further applications to change the details of registration. Some examples of the types of change that might be applied for include:

- a change in manufacturer;
- an increase in shelf-life;
- a change in patient population (e.g. allowing children to use the medicine); and
- changing the intended use (usually adding an extra medical condition that can be treated).

Changes may or may not require evaluation of data by the TGA and the prescribed fees apply accordingly. Certain low risk changes to the details of registration can be made through the recently implemented notification system.

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

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

Listing an OTC medicine on the ARTG

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

Brand equivalence statement for registered OTC medicines

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

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

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

3. Complementary medicines

Medicinal products containing such ingredients as herbs, vitamins, minerals, nutritional supplements, homoeopathic and certain aromatherapy preparations are referred to as 'complementary medicines' and are regulated as medicines under the Act. Complementary medicines may be either listed or registered, depending on their ingredients and claims made for the medicine. Most complementary medicines are listed on the ARTG.

Listing a complementary medicine on the ARTG

Listed medicines are low risk medicines that are listed on the ARTG. There are two pathways to list a medicine on the ARTG.

Medicines can be listed via a streamlined electronic listing facility following self-certification by the sponsor of the safety, quality and efficacy of the product. This process for listing products allows for early market access for the lowest risk complementary medicines.

Unlike other medicines, there is no evaluation of these products prior to the medicine being listed on the ARTG. To be eligible for this pathway a medicine must only:

- contain certain low risk ingredients in acceptable amounts that are permitted for use in listed medicine;
- they can only make indications (for therapeutic use) for health maintenance and health enhancement or certain indications for non-serious, self-limiting conditions; and
- be manufactured in accordance with the principles of [Good Manufacturing Practice \(GMP\)](#).

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

Medicines can also be listed in the ARTG following sponsor certification of the safety and quality of the product, coupled with TGA assessment of the efficacy evidence supporting the proposed indications. This is a new listing pathway that will allow sponsors to apply for indications that fall outside the permitted indications list but in all other respects the medicines meet the current eligibility criteria for listed medicines (e.g. contain only permitted ingredients and are manufactured under GMP).

A proportion of listed complementary medicines are reviewed following their listing for compliance with the regulatory requirements.

Applications can be made for evaluation of new substances proposed for suitability for use as an ingredient in listed medicines. New approved ingredients are added to the permitted ingredients list. On average, there are 12 such applications received each year.

Transition arrangements

- The assessed listed medicines pathway has been introduced alongside the permitted indications reform.
- A **three year** transition period commenced on 5 March 2018 for existing listed medicines to be re-listed.
- During the transition period, sponsors of existing listed medicines will need to comply with the new provisions as follows:
 - sponsors of existing listed products with low level indications will be required to transition their products to the new requirements by selecting appropriate indications exclusively from the list of permitted indications;
 - existing listed products with indications not eligible for inclusion in the permitted indications list, will be required to either, transition their products to the new assessed listed medicines pathway, or alternatively, choose low level indications from the permitted indications list.

Registering a complementary medicine on the ARTG

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

4. Medical devices

The Australian medical devices regulatory framework sets out the requirements for the quality, safety and performance of medical devices, based on a series of [Essential Principles](#), rather than a prescriptive framework. All medical devices must demonstrate compliance with the Essential Principles. The extent of evidence required to demonstrate compliance with these principles is based on the risk classification of the device, with higher risk devices undergoing greater assessment prior to being allowed into the Australian market.

In order to recover costs of pre- and post-market regulatory activities, there are a number of fees and charges for medical devices. These include annual charges, application fees, conformity assessment fees and application audit fees.

Applications to include medical devices on the ARTG

Under the Act, medical devices must be included on the ARTG prior to supply in Australia unless exempt from that requirement, such as exemption under sections 41HA, 41HB or 41HC of the Act. The level of assessment conducted at the point of application for ARTG inclusion depends on the risk classification of the device, the conformity assessment evidence supporting the application, and whether there are any concerns with the application that would require the TGA to request further information for review prior to inclusion.

High-risk medical devices must have an ARTG entry for each device (with the unique product identifier). Lower risk devices can have multiple similar devices included under one ARTG entry (a 'kind of medical device'). As the application fee is payable per ARTG entry and the value of the

fee is higher for higher risk medical devices, 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 (however devices can be distributed by multiple distributors on behalf of the same sponsor).

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

In addition to the requirement to provide a conformity assessment document with an application for ARTG inclusion, the application process also may involve an assessment of other information required by the TGA.

Application audits

Some applications for inclusion of medical devices in the ARTG will undergo an audit assessment.

- Applications to include certain medical devices in the ARTG must be selected for an application audit—for these compulsory audits an application audit assessment fee is charged.
- The TGA may also select any other application for inclusion for an audit - an audit assessment fee is not charged for these audits.

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

Conformity assessments

A conformity assessment is a systematic and ongoing examination of evidence and procedures to ensure that manufacturers of medical devices have systems and processes that provide assurance that the device conforms to the Essential Principles for quality, safety and performance.

A manufacturer must implement and maintain a post-market monitoring system for devices after supply, with reportable events reported as specified in the Regulations. A manufacturer's quality system certification may be subject to periodic surveillance audits.

For the majority of medical devices and IVDs the TGA accepts documents issued by the assessment bodies and/or overseas regulators that provide evidence that that body has assessed the manufacturer's compliance with the conformity assessment procedures or procedures comparable to conformity assessment and found it to be acceptable. As the Australian and the European Union (EU) regulatory requirements are similar, many manufacturers of medical devices authorised for supply in Australia, have EC Certificates issued by EU conformity assessment bodies (also known as Notified Bodies).

For certain high risk medical devices and IVDs, manufacturers must obtain Conformity Assessment Certificates issued by the TGA, regardless of whether they have a market authorisation/approval issued by an overseas regulator/assessment body. This requirement for TGA conformity assessment certificate applies to medical devices containing medicinal substances or materials of animal, microbial, recombinant or human origin and Class 4 IVDs.

Manufacturers may also choose to seek conformity assessment certificate from TGA for medical devices supplied in Australia, rather than relying on overseas certification.

Export

Sponsors wanting to export medical devices from Australia must meet regulatory requirements set out in the legislation. Before a sponsor can export a medical device from Australia, the device must:

- be included in the ARTG; or
- be exempt under Item 1.2, Part 1, Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

A medical device that is intended by the manufacturer to be for export only is classified as Class I medical device, i.e. there is no requirement for the manufacturer of such device to have a certification/approval issued by an assessment body and/or regulator. The labelling or packaging of such device should contain the words 'for export only'. The export only medical devices are still required to comply with the essential principles.

If a medical device is imported/manufactured and supplied in Australia, and exported from Australia, the device is classified in accordance with the classification rules provided in Schedule 2 or 2A of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

5. Other therapeutic goods listed and registered on the ARTG

All medical devices listed and registered on the ARTG (including invitro diagnostic) prior to 2002 (previously called therapeutic devices) have been transitioned to the new regulatory framework and are now regulated as included devices under Chapter 4 of the Act. The full transition period for in vitro diagnostic (IVD) medical devices ended on 30 June 2017.

There is a small number of other therapeutic goods that do not meet definition of a medical device, medicine or biological, that are regulated under Chapter 3 of the Act.

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.

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

The enhanced sanctions and penalties include:

- Substantiation Notices;
- powers to issue directions about advertisements or generic information;
- cancellation or suspension of therapeutic goods from the ARTG;
- Public warning Notices;
- injunctions;
- Infringement Notices;
- Enforceable Undertakings;
- preparation of a brief of evidence for criminal prosecution; and
- civil action.

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, the TGA may:

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

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

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

Other agencies

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

Advertising review

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

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; and
- Therapeutic Goods Advertising Consultative Committee.

From 1 July 2018, the TGA became the single body responsible for handling complaints about therapeutic goods advertising to the public. It will consider complaints about advertisements for medical devices and other therapeutic goods appearing in broadcast and mainstream print media, billboards, cinema films, the internet etc. The majority of activity in this area is related to assessing the validity of complaints about current advertisements that are claimed as not meeting the requirements.

The TGA does not charge for lodging a complaint about an advertisement. 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 medical devices who are required to have conformity assessment certification (either issued by the TGA or by one of the European Notified Bodies). To obtain the licence, a manufacturer must demonstrate that they have the ability to comply with good manufacturing principles (GMP), which include relevant Codes of GMP and Quality Systems, and have appropriate facilities to manufacture safely. Overseas manufacturers of therapeutic goods supplied to Australia must provide evidence of compliance with equivalent GMP standards or otherwise undergo on-site inspections in the same manner as manufacturers based in Australia.

GMP is a generally accepted term internationally to describe a set of principles and procedures that, when followed by manufacturers of medicines and biologicals, helps to ensure that the products manufactured will possess the required quality.

The GMP related regulatory activities undertaken are as follows:

Licensing

The TGA usually undertakes on-site inspections of Australian manufacturers prior to the issue of a licence to ensure that the manufacturer can comply with the manufacturing principles set under the Act and has suitable premises to undertake the proposed manufacturing steps. The extent of the inspection depends on the size and complexity of the manufacturing processes.

The TGA participates in international harmonisation activities to ensure that GMP requirements applied in Australia are best practice.

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 unapproved therapeutic goods

There are circumstances where patients may require access to certain medicines or medical devices that have not been approved for supply in Australia. Under the 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 three categories under the scheme:

Category A is a notification pathway which can be accessed by a prescribing medical practitioner or a health practitioner on behalf of a prescribing medical practitioner for patients who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.

Category B is an application pathway which can be accessed by health practitioners for patients who do not fit the Category A definition and where the unapproved good is not deemed to have an established history of use and cannot therefore be accessed through Category C. An approval letter from TGA is required before the good may be accessed. Approvals for medicines accessed through this pathway are typically only issued to medical and dental practitioners.

Category C is a notification pathway which allows health practitioners to supply goods that are deemed to have an established history of use without first seeking prior approval. The goods deemed to have an established history of use are specified in a list along with their indications and the type of health practitioner authorised to supply these products for the respective indications.

Authorised prescribers (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); and
- 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.

Historical document

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 I medical device (other than a class I medical device that has a measuring function or is supplied in a sterile state or Class 1 IVD) is \$90 whereas for a high risk prescription medicine (biologic) the annual charge is \$7,120.

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 2016-17 there were 51,639 Special Access Notification (SAS) notifications (category A), 26,905 SAS applications (category B) and 1,042 authorised prescriber applications (noting category C commenced in 2017-18). The annual cost of these free services is estimated to be \$3 million or around \$35 per application/notification. 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) The orphan drug program

A medicine, may be eligible for orphan drug designation if all orphan criteria prescribed in regulations 16J(3) or 16J(4) are satisfied. A medicine with a designation in force for the active, indication, dosage form and sponsor can have subsequent submissions reviewed as part of the programme.

The [orphan drug program](#) is an activity undertaken for the public good, with the objective of assisting sponsors bring medicines for rare diseases or new dose forms for special patient populations to market that may otherwise not be available. The incentive provided is in the form of a fee waiver. Application and evaluation fees (under regulation 45 (12) of the Regulations) for the assessment of orphan drugs are not charged by the TGA but the quality, efficacy and safety of orphan drugs are assessed at the same standard as for other registered medicines.

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 2016-17, the TGA assessed 20 orphan drug applications, compared to the total fee paying applications of 122 for prescription medicines (new chemical entity, major variation and extension of indications). In addition, there were 2 orphan drug designations for registration of new generic products, compared to 95 fee paying applications in 2016-17. The total cost attributed to the orphan drug program in 2017-18 is \$3.77 million.

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

Regulatory reforms: Review of medicines and medical devices regulation

In 2015, 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 56 have been accepted. 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” provided \$20.4 million (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 required changes to fees and charges which were implemented throughout 2017-18 are briefly 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, was implemented from 1 July 2017. The pathway prioritises the evaluation of novel prescription medicines that meet the eligibility criteria and have a complete data dossier, with a target timeframe of 150 working days for a decision regarding registration of the medicine in the ARTG.

In order to recover the additional costs of the new processes a determination fee applies for making applications under the priority review pathway. The application and evaluation fees for registration under this pathway are higher than the fees under the standard pathway.

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

Because the priority pathway is 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 determination 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 using the fee waiver under the orphan drug program.

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

Prescription medicine provisional approval pathway

The Review recommended that the TGA implement expedited pathways for the registration of new medicines in certain circumstances. The pathway allows sponsors to apply for time-limited provisional registration (maximum of 2 years in the first instance and renewable further twice) on the ARTG on the basis of preliminary clinical data. It provides earlier access to certain promising new medicines where the TGA assess that the benefit of early availability of the medicine outweighs the risk inherent in the fact that additional data are still required. Under the provisional approval pathway, medicines could come to the market up to two years sooner than under the current framework.

Extension of provisional determination

Sponsors may only apply for one six month extension of an approved provisional determination.

Provisional registration application

If the applicant makes an application for registration of a New Chemical Entity (NCE) or an extension of indication (EOI) and an applicable provisional determination is in force in relation to the applicant, the medicine and the indication, then the application is for provisional registration of the medicine.

In order to recover the additional costs of the new processes a determination fee applies for making applications under the provisional registration pathway. A higher than standard application and evaluation fees apply for registration applications under the provisional pathway to reflect additional activities for example:

- additional checking as part of the dossier acceptance process that the information supplied as part of the dossier supports the provisional designation that was previously granted;
- assessment of rolling clinical data;
- additional collaboration between evaluation sections;
- additional expert advice during evaluation (actual advice plus procurement effort);

- submissions may also be considered by ACM/ACV during first or second round assessment; and
- additional time for RMP evaluation.

Extension of provisional registration

Sponsors may request up to two extensions of up to two years each during the provisional registration period (maximum of 6 years). Assessment of applications for extension of provisional registration may include:

- checking progress against commitments;
- re-assessment of conditions of registration; and
- product information change (only if required).

Transition from provisional registration to full registration

Application and evaluation fees apply to transition provisionally registered goods to the ARTG as registered goods. The fee is set based on associated processes and activities being similar to a standard extension of indication application, taking into account additional activities undertaken by the evaluators and the clinical delegate to assess and make decisions about the application under section 29(9) of the Act. This section outlines how the TGA will consider whether all or part of the provisionally registered indication should continue to be provisionally registered, at the time of deciding on the application for full registration. Additional effort has also been included to obtain expert advice (if required) and for communication activities including updates to the website and the update of the ARTG.

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.

As this process reduces manual staff effort, the notification fee is lower by around 50% than the minor variation application fee. It is estimated that around two thirds 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 one-third 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.

Complementary medicines pre-market assessment pathways

The Review made 19 recommendations to improve the regulation of complementary medicines. The following recommendations from the Review are relevant to the development and revision of fees:

- introduction of a new assessment pathway for listed complementary medicines that sits between the existing low risk listed medicine pathway and the higher risk registered medicine pathway (Recommendation 39). The introduction of a new 'assessed listed medicines' pathway requires the introduction of new application and evaluation fees to recover the administrative and evaluation costs associated with its use;
- use of reports from comparable overseas regulators for the assessment of new ingredients, new registered medicines and products assessed through the new listing pathway (Recommendation 36, 39 and 40). The evaluation of complementary medicines using comparable overseas regulator reports requires less assessment than for de novo evaluations and consequently requires the introduction of additional categories of evaluation. The level of work effort associated with evaluating medicines via these new categories needs to be reflected in the application and evaluation fees;
- review and appeal rights for evaluation of new complementary medicine ingredients (Recommendation 47). The introduction of an application fee for ingredient assessments will contribute to higher quality applications which support the introduction of appeal rights for ingredient assessments;
- the establishment of a list of permitted indications for listed complementary medicines (Recommendation 38) requires a process to add new indications. It is proposed that these applications will incur an application fee only as these assessments will not involve evaluation of data. To support a smooth transition and minimise regulatory burden for industry, it is proposed that sponsors of existing listed products who apply to update their ARTG entry to select permitted indications will not be charged an application fee during the first 18 months from commencement of the new legislative package;
- the introduction of legislated timeframes for assessment of complementary medicines and their ingredients (Recommendation 41) will create the need for a refund mechanism if the TGA fails to meet legislated timeframes. The removal of page count based fee structure may also improve application quality, with consequent improvements to assessment timeframes; and
- the use of a risk-based approach to the management of variations. We are proposing to develop risk based application categories for variations to medicines assessed via the assessed listed medicines and registered complementary medicines pathways (Recommendation 42).

The application and evaluation fees for complementary medicines were revised and new fees were introduced to allow for the implementation of recommendations arising from the Review. The fees are designed to reflect the amount of work effort and associated costs required to complete the relevant applications and evaluations, based on the complexity of documentation associated with them.

Types of assessed listed medicines pathway (L(A)1, L(A)2 and L(A)3)

L(A)1: Evaluation of a 'clone' of an existing product, where the only difference is the name and/or flavour, fragrance, printing ink or colour

L(A)2: Evaluation of a generic medicine or evaluation of efficacy based on reports from a comparable overseas regulator (COR)

L(A)3: Full de novo evaluation of efficacy for new products not covered by L(A)1 or L(A)2 or evaluation of an existing assessed listed medicine that is for a different active ingredient, indication, dosage form, strength or excipient.

New complementary medicine ingredients

A new fee structure was introduced in 2017-18 for making an application for a new ingredient. This replaced the inefficient and complex page-count structure for evaluation fees. The fees are based on the following application types:

- IN1: Evaluation of safety and quality based on evaluation reports from comparable international regulators which meet the minimum data requirements;
- IN2: Evaluation of safety based on evaluation reports from comparable international regulators which meet the minimum data requirements AND de novo evaluation of quality;
- IN3: Evaluation of quality based on evaluation reports from comparable international regulators which meet the minimum data requirements or an accepted monograph AND de novo evaluation of safety; and
- IN4: Full de novo evaluation of safety and quality.

Registered complementary medicines

In 2017-18, a new fee structure also replaced the previous page-count fee structure for registered complementary medicines.

RCM1: Evaluation of a 'clone' of an existing product, where the only difference is the name and/or flavour, fragrance, printing ink or colour

RCM2: Evaluation of safety, quality and efficacy based on evaluation reports from comparable international regulators

RCM3: Evaluation of a generic medicine for which bioequivalence data is not needed; or de novo evaluation of one of quality, safety or efficacy, with the remaining parameters evaluated based on evaluation reports from comparable international regulators

RCM4: Evaluation of a generic medicine for which bioequivalence data is needed; or de novo evaluation of one of two of safety, quality or efficacy, with the remaining parameter evaluated based on international evaluation reports from comparable international regulators; or evaluation of an existing registered medicine that is for an extension of indications, new directions for use or an increase in the target population of the medicine

RCM5: Full de novo evaluation of safety, quality and efficacy; or evaluation of an existing registered medicine that is for a new dosage form of the medicine, a new active ingredient in the medicine, an increase in strength of an active ingredient or addition of a new excipient in the medicine.

Variations to registered complementary medicines

The variation applications, and associated fees, are based on the level of risk associated with the variation. These are categorised as follows:

- RCMC1 (section 9D) request: variations specified in the changes table as an RCMC1 (section 9D) level change. These are changes classified as negligible risk that do not need safety, efficacy and/or quality data;
- RCMC2 (section 9D) request: variations specified in the changes table as an RCMC2 (section 9D) level change. These are low risk changes that require evaluation of quality data and do not need safety and/or efficacy data;
- RCMC3 (section 9D) request: variations specified in the changes table as an RCMC3 (section 9D) level change. These are low risk changes to the quality and non-quality aspects of a medicine and require evaluation of supporting safety and/or efficacy data;
- RCMC4 (section 9D) request: variations specified in the changes table as an RCMC2 (section 9D) level change. These are non-quality changes classified as 'moderate risk'. Applications require evaluation of safety and/or efficacy data (clinical and/or toxicological) to support the proposed changes;
- RCMC1 (section 23) application: variations specified in the changes table as an RCMC4 (section 23) level change. These are changes classified as negligible risk that do not need safety, efficacy and/or quality data;
- RCMC2 (section 23) application: variations specified in the changes table as an RCMC2 (section 23) level change. These are low risk changes that require evaluation of quality data and do not need safety and/or efficacy data;
- RCMC3 (section 23) application: variations specified in the changes table as an RCMC3 (section 23) level change. These are low risk changes to the quality and non-quality aspects of a medicine and require evaluation of supporting safety and/or efficacy data; and
- RCMC4 (section 23) application: variations specified in the changes table as an RCMC4 (section 23) level change. These are non-quality changes classified as 'moderate risk'. Applications require evaluation of safety and/or efficacy data (clinical and/or toxicological) to support the proposed changes.

Permitted indications for listed medicines

From 6 March 2018, indications available for use for listed medicines are contained in a 'list of permitted indications' which is contained in the Therapeutic Goods (Permissible Indications) Determination. The list of permitted indications is maintained by the TGA and provides a comprehensive list of indications currently accepted for listed medicines, provided appropriate evidence is held by the medicine sponsor. Sponsors who apply to list a new medicine will be required to select the indications for their medicine from the list of permitted indications.

Sponsors are able to apply to make additions to the list. Any applications for additions to the list will incur an application fee which is inclusive of the costs associated with maintaining the legislative instrument.

Accelerated assessments pathway for novel medical devices

As recommended by the Review, the TGA developed a new accelerated pathway for the conformity assessment and/or inclusion of novel medical devices in certain circumstances. The new pathways and associated fees commenced on 1 January 2018. This facilitates increased timeliness and access for Australian consumers and health professionals to new medical devices and assists industry through reducing regulatory delays.

Sponsors who can demonstrate that their medical device:

- will treat a serious condition; and
- addresses an unmet clinical need in Australian patients; and
- represents a breakthrough in technology, or a clinical advantage, or (in the case of *in vitro* diagnostic devices) provides a major public health benefit.

Sponsors can apply for a priority assessment designation. If approved, the designation places the application to the front-of-queue during the assessment procedures for conformity and ARTG inclusion.

It is estimated that the TGA will receive 5 applications annually under the new pathway which will bring additional revenue of \$48,300 to recover the additional TGA costs. This approach is consistent with CRGs.

Medical devices – conformity assessment bodies

In response to the Review the Government has developed a model where multiple bodies, designated by the TGA, are able to undertake conformity assessment certification in Australia (pre-market assessment) (MMDR Recommendation 15 (Pathway 2), 17 and 18).

Potential improvements are faster approval times and flexibility for the sponsors of medical devices.

The development of the Conformity Assessment Body (CAB) pathway requires establishment of technical, clinical competence and governance standards (including management of conflict of interest) which such bodies would need to meet in order to be designated. Designated Conformity Assessment Bodies will be subject to a complete re-assessment every five years.

The TGA will continue to make the final regulatory decisions to ensure that the Australian quality and safety standards are adhered to.

The application fee is an up-front, non-refundable fee to recover administrative costs associated with reviewing the initial application, including preparing a plan for assessment and a quote for the assessment fee. The assessment fee covers three phases of assessment - the document review (Stage 1), initial assessment (Stage 2), and witnessed audit (Stage 3), resulting in the designation of successful applicants as an Australian conformity assessment bodies. This fee may be abridged where appropriate, such as where the scope of designation sought is limited, or where assessment work of the conformity assessment body by other regulators is available and may be used by the TGA (such as reports on designation as an MDSAP Auditing Organisation, etc.).

Full designation

This involves designation for CABs performing full QMS audits and conformity assessments (including design examination) for a range of medical devices.

Partial designation

This entails designation for limited scope, which could be either only QMS or a combination of QMS and certain devices.

Partial designation fees have been set based on two different assumptions:

- Partial designation, Assumption 1: 100% QMS and 0% design to represent a CAB seeking designation to perform QMS certification only;
- Undertaking conformity assessment of QMS only, and not offering design examination services required for conformity assessment of high risk devices (Class II and AIMD);
- Partial designation, Assumption 2: 66.67% QMS and 50% design to represent a CAB seeking designation for a particular stream of devices only. This requires them to have 'product' type QMS as well as limited scope product certification; and

Undertaking conformity assessment of QMS and design examination services required for conformity assessment of high risk devices (Class II and AIMD), but for a limited range of products (such as specialising in IVDs, or orthopaedic devices).

Competitive neutrality

In implementing these reforms the TGA considered whether the competitive neutrality policy applies to the TGA's conformity assessment function. The applicability of competitive neutrality policy is assessed on three criteria:

- there must be user-charging for goods or services;
- there must be an actual or potential competitor i.e. users are not restricted by law or policy from choosing alternative sources of supply; and
- managers of the activity have a degree of independence in relation to the production or supply of the good or service and the price at which it is provided.

The TGA's conformity assessment function meets the first criterion, as all TGA activities are fully cost recovered through fees and charges from industry. With the introduction of a provision for Australian conformity assessment bodies to be designated by the TGA, the second 'competition' criterion is also potentially met.

However the third criterion does not appear to apply, particularly in relation to the independence of 'supply' of conformity assessment services. Under s.41EC of the Act the TGA must assess any valid application it receives, whereas commercial conformity assessment bodies are free to accept or reject clients as a business decision.

As the TGA's conformity assessment function does not meet all the criteria competitive neutrality does not apply to it.

The TGA consulted with the Productivity Commission, which administers the competitive neutrality complaints mechanism, who endorsed the interpretation that TGA does not meet all three test criteria for competitive neutrality. The Department of the Treasury also agreed to this view, on the additional ground that the current TGA conformity assessment activity results in user charges of around \$7 million per year, which is below the indicative threshold of \$10 million per year used by the Treasury to denote the size of a market above which competitive neutrality policy could be considered.

The Government has agreed not to apply competitive neutrality.

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.

A public consultation paper was published in September 2017 to seek comments from interested parties on the implementation of business process improvements supporting the complementary medicines assessment pathways. The consultation paper included draft application and evaluation fees for applications for new ingredients, assessed listed medicines and registered complementary medicines. Submissions received in response to the public consultation showed a majority of stakeholders support the proposed approach to implement these reforms.

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.

2018–19 Fees and Annual Charges – effective 1 July 2018

A. Changes to fees and charges for Good Manufacturing Practice

Background

There has been consistent under recovery in relation to the Good Manufacturing Practice (GMP) function. While the level of under recovery increased significantly last year, the average under recovery in the last 4 years was \$2.1 million.

	2013-14 \$m	2014-15 \$m	2015-16 \$m	2016-17 \$m	Average \$m
GMP Revenue	12.1	12.1	11.2	10	11.3
GMP Expenses	13.5	12.9	13.2	14.4	13.5
Under - Recovery	(1.4)	(0.7)	(2.0)	(4.4)	(2.1)

In order to address the significant under recovery, the TGA engaged Deloitte to review the fees and charges for the GMP function and to suggest options, consistent with the Government's Cost Recovery Guidelines (CRGs).

Based on the comprehensive activity-based cost data on the TGA's regulatory activities, Deloitte developed three options for consultation with stakeholders. These options were designed to address under recovery of up to \$2.1 million, rather than the \$4.4 million under recovery in the 2016-17 financial year. While the Deloitte consultation paper included 3 options, an additional option (option 3B) was developed after feedback from stakeholders at the consultation roadshows. Option 3B is a more transparent and fairer option for Australian sponsors who hold GMP clearances whereas the other options would continue to cross subsidise the under-recovery of compliance verification (CV) assessment.

Option 1

Under this option, all GMP fees and charges would increase by 17.4% to arrive at an additional \$2.1 million in revenue to address under recovery.

This option is administratively simple for the TGA and industry and proportionately spreads the additional cost. However, the proposed fees and charges under this option would not match with

regulatory effort which would further complicate the misalignment of costs associated with revenue. However, this option does not actively encourage a higher level of compliance by manufacturers and is not consistent with the Australian Government Cost Recovery Guidelines (CRGs), was not recommended by Deloitte and was not a TGA preferred option.

Option 2

This option includes minimal changes to rectify only the two most obvious issues associated with under-recovery which are 'free' inspection hours included in annual charges and under recovery in domestic inspection fees. Under this option, the TGA would only recover the cost of all inspection hours as there would be no implied 'free' inspection hours.

This option does not actively encourage a higher level of compliance by manufacturers and does not specifically address under-recovery in the GMP clearance and compliance verification fees which has become an increasing and significant part of the GMP function. This option is also not consistent with the CRGs, was not recommended by Deloitte and was not a TGA preferred option.

Option 3

This option builds on option 2 but also addresses under-recovery in the GMP clearance applications. This option also includes a reduction in the hourly fee for inspections when compared to option 2, as these improved cost recoveries against GMP clearances and licences results in a lower level of remaining regulatory cost to be recovered through the inspection fee. This option was the most consistent with the CRGs. This option was recommended by Deloitte and was presented during consultation as the TGA's preferred option.

Option 3B

At the roadshows a suggestion was made to slightly modify option 3 to address under recovery for the compliance verification (CV) assessment application separately from the other GMP clearance application. As a result of this feedback Deloitte and the TGA developed option 3B where the proposed GMP clearance application fee would increase to \$640 (rather than \$790) and the proposed CV assessment fee would increase to \$2,430 (rather than keeping it at \$2,030). Additionally, some of the respondents to the consultation proposed a modification to option 3 to avoid cross subsidisation whereby a smaller increase to the Clearance Application Fee is accompanied by an increase in the CV fee. This feedback aligned with option 3B.

While the overall impact of option 3 or 3B on the GMP cost recovery is the same, option 3B better aligns with CRGs as it more accurately reflects staff effort and is fairer for all sponsors who use overseas manufacturers for their products. The financial impact on manufacturers where on-site inspections are required will not change with the implementation of option 3 or option 3B. The impact on sponsors would vary marginally depending on whether they use overseas manufactures located in countries where we have a Mutual Recognition Agreement in place or not.

The below tables outline the final fees based on option 3B which were approved by the Government.

These charges are in the [Therapeutic Goods \(Charges\) Regulations 2018](#).

Annual charges for manufacturing licences	Charge	<i>Therapeutic Goods (Charges) Regulations 2018</i>
Manufacturing licence charge	\$4,590	Part 2 Item 7(5)(a-c, e)

These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*.

Fees related to Australian manufacturing licences	Fee	Item in Schedule 9 Part 2
Australian manufacturing sites – application fee for a manufacturing licence	\$770	Item 8(a)
Application for variation of licence	\$770	Item 8A
Australian manufacturing sites – inspection fee	\$970/hour/inspector	Item 9(a)

The impact of the changes on the top ten manufacturers/sponsors would be between \$42,000 and \$96,000 annually depending on the number of manufacturing licences held by them and/or the number of clearance applications they make in a year. In order to reduce the impact on industry, the increase in the GMP clearance application fee and compliance verification fee will be implemented from 1 July 2019 rather than 1 July 2018. This would result in under recovery of GMP clearance activities of \$1.4M during the 2018-19 financial year.

The impact is also lessened for Australian manufacturers as the existing 'free' inspection hours already accrued by manufacturer's paying the annual licence charges will be honoured by TGA until 30 June 2020 or exhausted by an on-site inspection, whichever occurs first.

Consultation

Given the magnitude of under recovery and the potential multiple options to address this, the TGA consulted with its stakeholders through multiple avenues. Deloitte's paper was published on the TGA's website on 9 February 2018 asking impacted stakeholders and other interested parties to submit feedback by 5 March 2018. The TGA also wrote to the 9 peak industry bodies requesting them to make submissions and bring this to the attention of their member companies. Additionally, a number of roadshows were held in Sydney, Brisbane and Melbourne between 14 and 19 February 2018.

The issue of under recovery was also foreshadowed in preliminary meetings held in December 2017. The proposed options for the GMP fees and charges were discussed at bilateral meetings with peak therapeutic industry bodies in February /March 2018. Several follow-up discussions were subsequently arranged with a number of peak bodies. In addition, these proposals were discussed at the TGA Industry Working Group on GMP (TIWGG) meeting on 15 March 2018.

Most stakeholders supported the TGA's need to fully cost recover its activities and to do so under a model which encourages increased manufacturer compliance. However, a number of respondents raised concerns regarding the level of increased fees and charges and the impact these changes may have on manufacturers and sponsors of medicines, in particular generic medicines. Concerns were also raised about the short notice for the implementation of these changes proposed for 1 July 2018. In addressing concerns about impact on industry, the implementation of increases to some fees has been delayed to 1 July 2019.

All stakeholder feedback was taken into account when calculating the final fee and implementation timeframes.

B. Application fee for the inclusion of Class I medical device \$530

From 1 July 2018, the Government approved the introduction of an application fee of \$530 for inclusion of Class I medical devices in the ARTG. Prior to this, the TGA had not been charging a fee for such inclusions. As a result, the costs of inclusions and review of Class I medical device

applications had been cross subsidised from other fees, such as those for prescription medicines or higher risk devices.

The fee of \$530 was set to recover the staff costs of managing the eligibility verification activities and administrative work³ (including the cost of IT systems) required in relation to new entries on the ARTG. The fee was determined according to the Australian Government Cost Recovery Guidelines, based on the administrative effort involved, which also included technical review of the correctness of the entry and maintenance cost of the relevant IT systems. To maintain the integrity of the regulatory framework for therapeutic goods, it is critical that the TGA ensures only appropriate entries are included in the ARTG. A recent review of Class I medical devices included in the ARTG has highlighted that such verification activities are required. It found that there were some products included as Class I devices that were of medium-high risk and thus should have been included as class II devices, and potentially require application audit by the TGA. In addition some products such as hospital furniture which are not medical devices were included on the ARTG.

The fee only applies to the new products included in the ARTG from 1 July 2018 and does not apply to any existing ARTG entries. Class I ARTG inclusions cover devices of the same kind (i.e. devices that have the same classification, manufacturer and sponsor are covered by the same GMDN code/term). The sponsor can supply all devices of the same kind under the same ARTG entry without any need for additional applications.

Based on average inclusions for the 1,288 sponsors that included new Class I medical devices during the three year period 2014-15 to 2016-17, the average number of inclusions per sponsor per year is 2.5, with a financial impact of up to \$1,590 if the fee had been in place in those years. While one large sponsor included an average of 414 entries, more than 70% of the sponsors, on average, had one new entry included over the three year period which means the financial impact on them would be \$530. Based on the previous trend, it is expected that the impact on 90% of sponsors would be up to \$2,650 which means, overall, the new fee is not likely to have a significant impact on a majority of sponsors of Class I medical devices. The TGA held information sessions for sponsors to assist them with optimising their new entries in order to minimise the potential financial impact of the new fee.

The TGA will continue to monitor the implementation of the new Class I medical device process from 1 July 2018 and recommend to government to make any appropriate adjustment to the fee in accordance with cost recovery obligations, if necessary.

Consultation

Consistent with long standing practice, every year the TGA undertakes comprehensive targeted consultation by engaging with peak therapeutic industry bodies regarding the fees and charges proposal for the forthcoming financial year. The introduction of a Class I application fee is neither a change in TGA policy nor a complex matter involving restructuring a set of fees. As such, the proposal to introduce this fee was raised at the industry bilateral meetings. In accordance with usual practice, the expectation is that the peak bodies disseminate information and advise businesses about the fees and charges proposals discussed during these meetings.

The TGA first raised the Class I fee proposal (with an indicative fee of \$600) at the February 2017 industry bilateral meetings when other fees and charges proposals for 2017-18 were discussed. At the December 2017 bilateral meeting the TGA advised that while the Class I fee, for implementation from 1 July 2018, was yet to be determined, it was expected to be comparable with other application fees (ranging from \$800 to \$1290). The final fee of \$530 was discussed at bilateral meetings held in late February/early March 2018 and is less than the indicative fees flagged on these previous occasions.

In response to concerns by a peak industry body representing a small segment of the medical device industry and to support transparency, the TGA provided explanatory information on how

³ Average effort of around 2 hours required by staff at various levels ranging from APS5 to EL1 for these new inclusion activities.

the fee was set. The TGA also conveyed to the peak industry body the reason why a targeted consultation was employed, instead of additional and formal public consultations.

C. Review of low risk products – impact on revenue

As part of the implementation of a number of recommendations of the Review, the TGA has undertaken a review of a range of low risk products currently on the ARTG. A public consultation was undertaken in 2018. The TGA will remove a range of low risk products from the ARTG by moving them to 'excluded' or exempted goods. A significant number of these products are currently included in the ARTG as Class I medical devices (around 8,500). When these products are removed from the ARTG they will not be required to pay the annual charges which will result in a reduction of revenue of up to \$0.7 million annually for medical devices alone.

D. Annual charges for provisional registration

Early in 2018 the TGA implemented a pathway for the provisional registration of certain prescription medicines as part of the Government's response to the Review. The pathway allows sponsors to apply for time-limited provisional registration (maximum of 6 years) on the ARTG on the basis of preliminary clinical data. It provides earlier access to certain promising new medicines where we assess that the benefit of early availability of the medicine outweighs the risk inherent in the fact that additional data are still required.

As the medicines are made available earlier in their clinical development there is a need to monitor these medicines more closely in the post-market period. The need for increased monitoring is greatest in the period of provisional registration while confirmatory efficacy and safety trials are ongoing.

Post-market monitoring of provisionally registered products will include regular review of adverse drug reaction reports submitted to the TGA, Periodic Safety Update Reports (PSUR) review, monitoring of risk management plan (RMP) compliance and consideration of RMP updates. In addition, more frequent safety updates are expected as the product's safety profile evolves through monitoring of post-market safety and ongoing clinical trials. It is estimated that there will be eight new provisionally registered products per year, which will remain provisionally registered for an average of five years. These products are expected to include approximately two ARTG entries per product. Therefore, the number of provisionally registered products will accumulate over five years to approximately 40 products being monitored each year. The actual number of provisional registrations will be reviewed annually to compare against the estimated workload.

The additional staff cost in year 1 is estimated around \$0.147 million which will increase every year proportionally with increase in the number of provisional registrations on a 5 year cycle basis. In order to recover the post market and pharmacovigilance costs, annual charges were introduced for provisionally registered prescription medicines from 1 July 2018. These charges are higher by \$9,160 per entry than the annual charges for other registered biological and non-biological prescription medicines.

The annual charges for 2018-19 can be found in the [Therapeutic Goods \(Charges\) Regulations 2018](#) Schedule 9.

Type of prescription medicine	Charge	Regulation
Provisionally registered biological medicine	\$16,100	9(1)(a)
Provisionally registered non-biological medicine	\$13,100	9(1)(b)

Consultation

Extensive public and targeted consultation with consumers, industry and health professionals on various regulatory reforms, including the new provisional registration pathway for prescription medicines, has been conducted since late 2016. The proposal to levy an annual charge for the provisionally registered prescription medicines was raised at a number of meetings with industry. The final annual charge was discussed at the bilateral meetings held in late February/early March 2018 and no concerns were raised by stakeholders.

E. Changes to Annual charges for listed medicines

The Review reforms envisaged a greater number of listed medicine compliance reviews. Since 2018 the TGA has been progressively implementing an enhanced compliance framework for listed medicines and costs have been absorbed within current annual charges. It was anticipated that the number of reviewers will need to increase progressively in future, especially after fully implementing complementary and other listed medicines reforms, in order to further strengthen the compliance framework for listed medicines. This will require more resources which must be cost recovered through annual charges. Based on the estimated increase in compliance costs, an increase of \$80 per entry (in addition to the indexation increase) was approved in annual charge for listed medicines from 1 July 2018.

These charges can be found in the [Therapeutic Goods \(Charges\) Regulations 2018](#) Section 7(1)(c).

Consultation

During the December 2017 bilateral meetings with industry, TGA had flagged that the annual charges for listed medicines would go up because of the increased compliance costs. The final annual charge of \$1,120 was discussed at bilateral meetings held in late February/early March 2018 and no concerns were raised by stakeholders.

F. Other fees and charges changes for 2018-19

A general increase of 1.9% was also approved to fees and charges from 1 July 2018 to meet estimated cost increases, mainly in employee expenses as a result of salary increases under the Department of Health Enterprise Agreement as well as salary increments and increases in facility rental costs. 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 1.9%.

In applying the indexation factor, fees and charges were rounded to the nearest \$10 for items less than \$10,000 and to the nearest \$100 for items \$10,000 and above, subject to a minimum increase of \$10. Due to the rounding policy and low indexation increases, a number of low level fees had not changed for the last number of years. For example, the annual charge for Class I medical devices remained unchanged at \$80 since 2013-14. The compound impact of approved indexation increases to TGA fees and charges, other than the low level fees, since 2013-14 is 8.7%. Therefore, the low level fees (less than \$200) are to increase by \$10.

The Office of Best Practice Regulation advised that a Regulatory Impact Statement was not required for the above changes to fees and charges.

The amendment regulations were approved by the Executive Council at their meeting of 7 June 2018 to effect the above changes.

Consultation

At the February/March 2018 bilateral meetings, held with the nine key industry representative bodies, the TGA discussed the fees and charges proposals for 2018-19. The representatives acknowledged that the proposed fee of 1.9% increase is consistent with past practice and would

be reasonable. A link to the fees and charges applicable from 1 July 2018 is provided in [Appendix 2](#).

G. Further changes – lowering the application fee for export only medical devices

Following the approval of the [Therapeutic Goods Legislation Amendment \(2018 Measures No. 2\) Regulations 2018](#), the new application fee of \$530 for applications to include Class I medical devices took effect from 1 July 2018. Previously, no fee was payable for such applications, meaning the cost of verification of applications was not being recovered directly from the sponsors of these devices.

While export only medical devices are included in the ARTG as Class I medical devices, the assessment process for inclusion of export only medical device is not the same as for other Class I medical devices. This is because the TGA principally focusses on verifying the correctness of the information provided by the sponsor of export only medical devices.

An opportunity was also identified to further streamline the processing of applications for export only medical devices by modifying existing software to automatically include such devices in the ARTG. Reflecting the automation of the approval process but allowing for the cost of maintaining the software, and consistent with the CRGs, a separate application fee of \$90 was approved by the Government for applications to include export only medical devices (other than in-vitro diagnostic medical devices). The lower fee was set to cover the direct staff effort required for managing new export only medical device applications as well as a component of IT costs required to make a small modification to the TGA business system for such applications.

The amendment regulation to give effect to the new fee was approved by the Federal Executive Committee on 11 October 2018 which applied retrospectively from 1 July 2018. A small number of sponsors of affected products had already paid the higher application fee of \$530 for the inclusion of the export only medical devices in the ARTG since 1 July 2018, which was \$440 more than the new fee of \$90. The excess amounts have been refunded to the affected sponsors.

On average, the TGA receives around 400 applications for inclusion of export only medical devices each year. The lower fee of \$90 results in an overall reduction of approximately \$0.172 million each year in the TGA's revenue. This reduction is unlikely to have a significant impact on the TGA's cost recovery.

Financial and non-financial performance

a) Financial performance

	2015-16 Actual \$'m	2016-17 Actual \$'m	2017-18 Actual \$'m	2018-19 Budget \$'m	2019-20 Estimate \$'m
A: Revenue					
Revenue from Government	3.177	2.574	2.439	2.253	2.253
Sale of goods and services	141.539	139.037	152.905	161.063	165.292
Other revenue and gains	0.148	0.012	0.001	0.000	0.000
Total A	144.864	141.623	155.345	163.316	167.545
B: Expenses					
Employee expenses	66.158	73.781	75.802	103.170	105.238
Suppliers	57.849	61.686	62.837	52.967	53.628
Depreciation and amortisation	4.672	4.286	6.846	7.179	8.679
Write-down and impairment of assets	0.105	1.961	2.895	0.000	0.000
Total B	128.784	146.715	148.380	163.316	167.545
Surplus (deficit)	16.080	(5.092)	6.965	0.000	0.000

TGA's activities are primarily cost recovered from industry except for the cost of the medicines and chemicals scheduling function for which an appropriation is provided by the Government. In addition, the TGA 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 2017-18 was \$10.31 million above the approved budget. Revenue ended up above budget by \$6.36 million following increased volumes in evaluation applications received towards the end of the financial year. Expenses were below budget by \$3.96 million primarily due to employee expenses being below budget by \$4.18 million, resulting from delays in recruitments and staff turnover.

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 25% of operating budget. 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.

The surplus in 2017-18 allowed the TGA to repay earlier than planned a part of the \$20.4 million drawn from its reserves.

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: Regulators do not unnecessarily impede the efficient operation of regulated entities;
- Communication with regulated entities is clear, targeted and effective;
- Actions undertaken by regulators are proportionate to the regulatory risk being managed;
- Compliance and monitoring approaches are streamlined and coordinated;
- Regulators are open and transparent in their dealings with regulated entities; and
- 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 annually⁴ 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. More information on the TGA’s KPIs is available at: [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, 2, 3, 4, and 6 with 'strong performance' against these measures and through substantially meeting KPI 5. The [2017-18 report](#) is published on TGA’s website, a brief summary is provided below.

⁴ 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>We held regular formal stakeholder forums and participated in industry events as well as senior executive meetings with peak bodies.</p> <p>We hosted a workshop for small to medium businesses 'Meeting Your Obligations' at the Good Manufacturing Practice (GMP) Forum, and implemented a number of initiatives through the Business Improvement Program.</p>
KPI 2. Communication with regulated entities is clear, targeted and effective	Met	<p>We communicated through webinars and other forums, delivery of changes to the therapeutic goods advertising framework through extensive targeted and public consultations, and changes to the regulation of autologous human cell and tissue products.</p>
KPI 3. Actions undertaken by regulators are proportionate to the regulatory risk being managed	Met	<p>We took a risk-based approach which was proportionate to the therapeutic products we regulate.</p> <p>We continued to monitor signals of non-compliance and considered compliance history when undertaking intervention.</p> <p>We continued to triage and prioritise advertising complaints based on the risk that the advertising could pose to public health and safety.</p>
KPI 4. Compliance and monitoring approaches are streamlined and coordinated	Met	<p>We have built a Case Categorisation and Prioritisation Model to ensure consistent triaging and risk based responses to alleged breaches of the <i>Therapeutic Goods Act 1989</i>.</p> <p>A new notifications process for very low risk variations to biologicals and to the registered medicines was introduced, allowing the use of a single electronic form to request certain types of changes to a medicine.</p>

KPI	Performance rating	Comments
KPI 5. Regulators are open and transparent in their dealings with regulated entities	Substantially met	<p>We continued to raise awareness of our regulatory framework through our various interactions with industry and other stakeholders through workshops, publication of educational material, engaging with the TGA Industry Forum, and maintaining our telephone and email enquiry lines.</p> <p>In addition, we published monthly and annual performance reports on our website.</p> <p>We have rated ourselves as 'substantially met' against this KPI because we did not meet the TGA Customer Service Standards in all cases when responding to email and telephone enquiries. This was partly due to the transition to a new enquiry management system, which resulted in some enquiry data being lost during the July-September 2017 period.</p>
KPI 6. Regulators actively contribute to the continuous improvement of regulatory frameworks	Met	<p>We maintained high levels of stakeholder engagement through market research, continued business improvements as well as interactions with other Government Departments and comparable regulators.</p> <p>We have implemented a number of reforms, including streamlining the advertising framework.</p> <p>A new electronic notifications process for very low risk variations to prescription medicines was introduced in late 2017. This followed the earlier introduction of a similar process for non-prescription registered medicines. TGA approval for these variations is made automatically, if the application passes electronic validation and payment is received, reducing compliance costs and approval times.</p> <p>We implemented an improved streamlined and coordinated approach to the implementation of the new provisional approval pathway for the registration of prescription medicines, providing earlier access to certain new medicines.</p>

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 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 2018-19 was undertaken at bilateral meetings with the following industry representative groups in February/March 2018:

- Medicines Australia
- Generic and Biosimilar Medicines Association
- AusBiotech
- Medical Technology Association of Australia
- IVD Australia
- Australian Dental Industry Association
- Australian Self Medication Industry
- Complementary Medicines Australia

- Accord Australasia.

Key forward events

Key forward events schedule	Next scheduled update
Revised fees and charges for 2019-20	June 2019
Portfolio Charging Review	2021

CRIS approval and change register

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

Appendix 1 - Financial performance by industry sector group

1. Prescription medicines

Volumes ⁵	2015-16 Actual	2016-17 Actual	2017-18 Actual	2018-19 Budget	2019-20 Estimate
Biological prescription medicines	580	501	764	702	702
Non-biological prescription medicines – higher charge	522	522	628	480	480
Non-biological prescription medicines – lower charge	6,536	5,888	6,523	6,250	6,250

Revenue and expenses	2015-16 Actual \$'m	2016-17 Actual \$'m	2017-18 Actual \$'m	2018-19 Budget \$'m	2019-20 Estimate \$'m
A: Revenue					
Cost recovery revenue	71.7	68.5	72.9	77.7	79.7
Total A	71.7	68.5	72.9	77.7	79.7
B: Expenses⁶					
Direct	36.9	40.0	39.4	47.7	48.9
Indirect	26.3	28.3	28.8	28.7	29.4
Total B	63.2	68.4	68.2	76.4	78.4
Surplus (deficit)	8.5	0.1	4.7	1.3	1.3

⁵ Number of entries on the ARTG subject to the annual charge.

⁶ A new activity based costing model was developed in 2016-17 based on a staff effort survey methodology which takes into account updates in organisational structure and regulatory activities undertaken. The model has been recently updated based on a staff effort survey undertaken in July 2018. The total estimated expenses for 2019-20 have been split into direct and indirect expenses in the same proportion as in 2018-19. The TGA will continue to review the costing model and apply changes when necessary.

2. Over the counter medicines

Volumes ⁷	2015-16 Actual	2016-17 Actual	2017-18 Actual	2018-19 Budget	2019-20 Estimate
Over the counter medicines	2,667	2,441	2,687	2,587	2,587

Revenue and expenses	2015-16 Actual \$'m	2016-17 Actual \$'m	2017-18 Actual \$'m	2018-19 Budget \$'m	2019-20 Estimate \$'m
A: Revenue					
Cost recovery revenue	6.7	7.8	9.0	9.8	10.0
Total A	6.7	7.8	9.0	9.8	10.0
B: Expenses⁸					
Direct	2.8	3.0	2.9	4.2	4.3
Indirect	2.3	2.6	2.4	2.7	2.8
Total B	5.1	5.7	5.3	6.9	7.1
Surplus (deficit)	1.6	2.2	3.7	2.9	3.0

⁷ Number of entries on the ARTG subject to the annual charge.

⁸ A new activity based costing model was developed in 2016-17 based on a staff effort survey methodology which takes into account updates in organisational structure and regulatory activities undertaken. The model has been recently updated based on a staff effort survey undertaken in July 2018. The total estimated expenses for 2019-20 have been split into direct and indirect expenses in the same proportion as in 2018-19. The TGA will continue to review the costing model and apply changes when necessary.

3. Complementary medicines

Volumes ⁹	2015-16 Actual	2016-17 Actual	2017-18 Actual	2018-19 Budget	2019-20 Estimate
Registered complementary medicines	132	131	128	124	124
Listed complementary medicines	11,003	10,052	10,801	11,132	11,132

Revenue and expenses	2015-16 Actual \$'m	2016-17 Actual \$'m	2017-18 Actual \$'m	2018-19 Budget \$'m	2019-20 Estimate \$'m
A: Revenue					
Cost recovery revenue	15.7	13.8	14.5	17.4	17.8
Total A	15.7	13.8	14.5	17.4	17.8
B: Expenses¹⁰					
Direct	7.2	7.3	6.9	10.4	10.7
Indirect	5.2	5.6	5.3	7.4	7.6
Total B	12.4	12.9	12.1	17.9	18.3
Surplus (deficit)	3.3	0.9	2.4	(0.5)	(0.4)

⁹ Number of entries on the ARTG subject to the annual charge.

¹⁰ A new activity based costing model was developed in 2016-17 based on a staff effort survey methodology which takes into account updates in organisational structure and regulatory activities undertaken. The model has been recently updated based on a staff effort survey undertaken in July 2018. The total estimated expenses for 2019-20 have been split into direct and indirect expenses in the same proportion as in 2018-19. The TGA will continue to review the costing model and apply changes when necessary.

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

Volumes ¹¹	2015-16 Actual	2016-17 Actual	2017-18 Actual	2018-19 Budget	2019-20 Estimate
Included medical devices	44,878	45,267	49,311	41,925	41,925
IVD medical devices	N/A	N/A	2,452	2,377	2,377
Other therapeutic goods	359	294	293	116	116

Revenue and expenses	2015-16 Actual \$'m	2016-17 Actual \$'m	2017-18 Actual \$'m	2018-19 Budget \$'m	2019-20 Estimate \$'m
A: Revenue					
Cost recovery revenue	34.3	37.2	40.6	42.0	43.1
Total A	34.3	37.2	40.6	42.0	43.1
B: Expenses¹²					
Direct	17.1	19.6	20.6	25.0	25.6
Indirect	12.2	13.8	16.9	16.5	16.9
Total B	29.4	33.3	37.6	41.5	42.6
Surplus (deficit)	4.9	3.9	3.0	0.5	0.5

¹¹ Number of entries on the ARTG subject to the annual charge.

¹² A new activity based costing model was developed in 2016-17 based on a staff effort survey methodology which takes into account updates in organisational structure and regulatory activities undertaken. The model has been recently updated based on a staff effort survey undertaken in July 2018. The total estimated expenses for 2019-20 have been split into direct and indirect expenses in the same proportion as in 2018-19. The TGA will continue to review the costing model and apply changes when necessary.

5. Good manufacturing practices

Volumes ¹³	2015-16 Actual	2016-17 Actual	2017-18 Actual	2018-19 Budget	2019-20 Estimate
Low level GMP licence	105	112	111	283*	283*
High level GMP licence	163	163	179	-	-

*From 1 July 2018, the low level and high level fees have replaced with single annual licence fee, GMP Annual Licence.

Revenue and expenses	2015-16 Actual \$'m	2016-17 Actual \$'m	2017-18 Actual \$'m	2018-19 Budget \$'m	2019-20 Estimate \$'m
A: Revenue					
Cost recovery revenue	11.2	9.9	13.2	11.4	11.7
Total A	11.2	9.9	13.2	11.4	11.7
B: Expenses¹⁴					
Direct	7.8	8.7	8.8	8.8	9.0
Indirect	5.4	5.7	6.2	5.4	5.5
Total B	13.2	14.4	14.9	14.2	14.6
Surplus (deficit)	(2.0)	(4.4)	(1.7)	(2.8)	(2.9)

¹³ Number of entries on the ARTG subject to the annual charge.

¹⁴ A new activity based costing model was developed in 2016-17 based on a staff effort survey methodology which takes into account updates in organisational structure and regulatory activities undertaken. The model has been recently updated based on a staff effort survey undertaken in July 2018. The total estimated expenses for 2019-20 have been split into direct and indirect expenses in the same proportion as in 2018-19. The TGA will continue to review the costing model and apply changes when necessary.

6. Blood, blood components and biologicals

Volumes ¹⁵	2015-16 Actual	2016-17 Actual	2017-18 Actual	2018-19 Budget	2019-20 Estimate
Blood primary site	5	5	5	5	5
Blood secondary site	79	81	78	76	76
Single step manufacturer of human tissue	24	18	17	16	16
Class 2 biological products	20	20	20	20	20
Class 3 biological products	5	6	6	6	6

Revenue and expenses	2015-16 Actual \$'m	2016-17 Actual \$'m	2017-18 Actual \$'m	2018-19 Budget \$'m	2019-20 Estimate \$'m
A: Revenue					
Cost recovery revenue	2.2	2.6	2.4	3.1	3.2
Total A	2.2	2.6	2.4	3.1	3.2
B: Expenses¹⁶					
Direct	1.6	2.0	2.0	2.6	2.7
Indirect	1.3	1.6	1.7	1.6	1.6
Total B	2.9	3.6	3.6	4.2	4.3
Surplus (deficit)	(0.6)	(0.9)	(1.3)	(1.1)	(1.1)

¹⁵ Number of entries on the ARTG subject to the annual charge.

¹⁶ A new activity based costing model was developed in 2016-17 based on a staff effort survey methodology which takes into account updates in organisational structure and regulatory activities undertaken. The model has been recently updated based on a staff effort survey undertaken in July 2018. The total estimated expenses for 2019-20 have been split into direct and indirect expenses in the same proportion as in 2018-19. The TGA will continue to review the costing model and apply changes when necessary.

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

Revenue and expenses	2015-16 Actual \$'m	2016-17 Actual \$'m	2017-18 Actual \$'m	2018-19 Budget \$'m	2019-20 Estimate \$'m
A: Revenue					
Revenue	2.0	1.7	2.7	2.0	2.1
Total A	2.0	1.7	2.7	2.0	2.1
B: Expenses					
Other Expense	2.0	2.7	2.6	2.3	2.4
MMDR Expense	N/A	6.9	4.1	N/A	N/A
Total B	2.0	8.6	6.7	2.3	2.4
Surplus (deficit)	0.0	(6.9)	(4.0)	(0.3)	(0.3)

Appendix 2 - Schedule of fees and charges

The current 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 Phone: 1800 020 653 Fax: 02 6203 1605
<https://www.tga.gov.au>

Reference/Publication #