



Australian Government

Department of Health

Therapeutic Goods Administration

Cost recovery implementation statement

Good manufacturing practice

Version 1.0, July 2015

TGA Health Safety
Regulation

Historical document

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <<https://www.tga.gov.au>>.

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Introduction

Purpose of the Cost Recovery Implementation Statement (CRIS)

This CRIS provides information on how the Therapeutic Goods Administration (TGA) implements cost recovery of activities associated with the manufacture of medicines. TGA regulates manufacturers through application of Good Manufacturing Practice (GMP) principles. This CRIS also reports financial and non-financial performance information and contains financial forecasts for 2015-16. The TGA will maintain the CRIS until the activity or cost recovery for the activity has been discontinued.

Description of the activity

The TGA forms a part of the Department of Health and is responsible for evaluating the safety, quality and efficacy of medicines, medical devices and biologicals available for supply in, or export from Australia.

The TGA approves and regulates products based on an assessment of risks against benefits. All therapeutic goods carry potential risks, some of which are minor, some potentially serious. The TGA applies scientific and clinical expertise to its decision-making to ensure that the benefits of a product outweigh any risk. The level of TGA regulatory control increases with the level of risk the medicine or 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.

In Australia, manufacturers of therapeutic goods are required to hold a licence, except for manufacturers of certain medical devices who have European conformity certification (CE Mark). To obtain the licence, a manufacturer must demonstrate that they have the ability to comply with manufacturing principles, which include relevant Codes of GMP and Quality Systems, and have appropriate facilities to manufacture safely. Overseas manufacturers of therapeutic goods supplied to Australia must provide evidence of compliance with equivalent GMP standards or otherwise undergo on-site inspections in the same manner as manufacturers based in Australia.

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

Outputs and business processes of the activity

The GMP related regulatory activities undertaken are as follows:

Licensing

TGA usually undertakes on-site inspections of Australian manufacturers prior to the issue of a licence to ensure that the manufacturer can comply with the manufacturing principles set under the *Therapeutic Goods Act 1989* (the Act) and has suitable premises to undertake the proposed manufacturing steps. The extent of the inspection depends on the size and complexity of the manufacturing processes.

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

Monitoring compliance

The TGA undertakes periodic planned and unplanned inspections of manufacturers to assess the level of compliance with the applicable manufacturing standards, both domestically and overseas. The level and frequency of inspections for a particular manufacturer is influenced by its size and complexity but also by its compliance history. In particular, manufacturers with a history of lower levels of compliance are subject to a higher frequency of on-site inspections, compared with more compliant manufacturers, to ensure that therapeutic goods supplied in Australia are of appropriate quality and to allow TGA to take appropriate regulatory action where safety concerns are identified.

Investigation and enforcement

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

Information and education

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

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

Policy development and services to government

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

Former policy advice is generally provided by the Department of Health as part of its taxpayer funded activities and is not included in the fees and charges.

Policy and statutory authority to cost recover

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 resources¹.

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

In the 1997-98 Budget, Budget Paper No.2, Part II: Revenue Measures it was stated that the TGA would fully recover all costs from industry from 1998-99. The TGA recovers the full costs of its regulatory activities through fees, charges and licences imposed on manufacturers of therapeutic goods.

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. Applicable fees and charges are prescribed in regulations made under the Act and the *Therapeutic Goods (Charges) Act 1989* (the Charges Act).

Cost recovery model

Design of cost recovery charges

Licence and inspection fees

The characteristics of a government activity determine the type of cost recovery charge used (<http://www.finance.gov.au/resource-management/cost-recover/>). There are two types of cost recovery charges:

- **Cost recovery fees:** fees charged when a good, service or regulation (in certain circumstances) is provided directly to a specific individual or organisation
- **Cost recovery levies:** charges imposed when a good, service or regulation is provided to a group of individuals or organisations (e.g. an industry sector) rather than to a specific individual or organisation. A cost recovery levy is a tax and is imposed via a separate taxation Act. It differs from general taxation as it is 'earmarked' to fund activities provided to the group that pays the levy.

Fees are used to recover the cost of the pre-market services performed. For licensed domestic manufacturers, the fee structure is based on the licence and inspection fees. Prior to being granted an Australian licence, a domestic manufacturer is subject to an on-site inspection to ensure it can comply with the GMP code and standards and has suitable premises to conduct the manufacturing steps it proposes. The cost of the site inspection is based on the number of on-site hours, which reflects the size and complexity of the manufacturer's facilities. The inspection fee reflects the full cost of undertaking the inspection, including travel and preparation time.

Overseas manufacturers are not able to hold an Australian licence, but they must demonstrate that they operate to an acceptable good manufacturing standard before being granted access to the Australian market. Evidence relating to manufacturing standards is accepted from

¹ 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.

equivalent international regulators or may be achieved through an on-site inspection and a GMP clearance issued.

All domestic manufacturers of medicines are required to hold a licence with the level of annual charge reflecting the risk and complexity of the products manufactured. The annual charge depends on the level of complexity of the manufacturing steps. An allowance for the cost of periodically inspecting the manufacturer's facilities is included in the annual charge, based on an estimated typical inspection required to routinely ensure compliance with the GMP code and standards. Highly compliant manufacturers are inspected less frequently and thus an incentive for compliance is built into the charges.

Overseas manufacturers are not subject to an annual licence charge. Inspections to approve overseas manufacturers attract an hourly fee for time on-site, together with ancillary costs. Approval of an overseas manufacturer through the compliance verification process attracts one or more fixed fees per clearance application.

For the 2015-16 financial year, fees and charges were indexed by 2.12 percent in conjunction with other charges as outlined in this CRIS.

In past years, TGA fees and charges increases have been based on an indexation factor combining the Wage Price Index (50 percent) and the Consumer Price Index (50 percent). If we applied this formula to 2015-16 the increase would be 2.5 percent. However, based on an assessment of our budget outlook for the 2015-16 financial year of known direct cost increases an increase in fees and charges of 2.12 percent is required.

In addition to cost recovery, appropriation funding has been received on an annual basis since 2012-13 to fund activities outside of this CRIS. For example, the function of administering compliance frameworks for controlled drugs was transferred to the TGA group of the Department of Health in August 2014 and continues to be funded from the departmental appropriation. As a result, TGA now has multiple funding sources for its activities which all contribute to Outcome 7 'Health infrastructure, regulation, safety and quality'.

Annual charges exemption scheme (ACE)

The ACE scheme replaces the low value turnover (LVT) scheme.

A sponsor of an ARTG entry that has not commenced generating turnover will be exempt from the requirement to pay an annual charge in respect of that entry, up until the first year that turnover occurs. The annual charge would then apply to the entry until it was removed from the ARTG. The rationale for this option is that, as these products have not yet generated turnover, they require minimal post-market surveillance and monitoring by the TGA. For example, if a product has not commenced sales in Australia, the TGA is not required to undertake pharmacovigilance activities related to domestic recalls, product testing or adverse drug reactions for the vast majority of these products; however must retain the capacity to do so.

We recognise that pharmacovigilance requirements apply after a product is first supplied (which could feasibly be earlier than when the product starts generating turnover), our assessment is that most products would generate turnover at the same time as they commence supply. Accordingly, no significant issue would arise from a cost recovery perspective as there are minimal administrative costs in relation to maintaining the entry on the ARTG until the entry is generating turnover.

Consultation was conducted on the previous LVT scheme and proposed alternative models. Although several submissions to the public consultation did not explicitly support a single model among those proposed for discussion, most submissions supported amendments to the LVT scheme and/or a scheme wherein exemptions from TGA annual charges be granted to those therapeutic goods which had not been supplied to the Australian market.

Several submissions proposed that a self-declaration of sales turnover of a product seeking exemption (rather than a statement of turnover certified by a third party accountant) should be sufficient for confirming a products' eligibility for an exemption. The submissions acknowledged that a move to self-declaration would need to be complemented by an audit program to deter and identify any undesired behaviour.

The ACE scheme better aligns with the CRGs, as those who create the need for post-market activities bear the costs of such activities, whilst still providing some relief to sponsors who have products which are yet to generate turnover.

It is estimated that approximately 74 percent of the ARTG entries which are expected to be exempted under the LVT scheme in 2014-15 would continue to be exempted under ACE (until first turnover). A likely impact of the implementation of the scheme is the removal of some products with low turnover from the ARTG that would no longer be exempt from annual charges. To address the risk that a public health issue is presented where the sponsor of an essential product proposes to remove that product from the ARTG due to the cost of the annual charge, a new waiver provision has been added to the Regulations in conjunction with the ACE scheme.

The benefits of the ACE scheme are:

- Reduction in the rates of annual charges for non-biological prescription medicines and medical devices class IIa and above
- No application fee (saving around \$2.4m p.a. to industry)
- Automatic granting of exemption upon entry on the ARTG, until turnover first commences
- Administrative processes will be simpler as sponsors will only be required to provide a self-declaration of \$0 turnover to confirm their exemption. This will particularly assist sponsors (in particular small businesses) who may not have dedicated regulatory affairs officers and third-party accountants
- A reduction in regulatory burden to industry of an estimated \$30 million over the next ten years
- Relief from annual charges until the ARTG entry is generating turnover
- Annual charge invoices will only be issued for non-exempt entries
- A new waiver option will be introduced on public health/financial viability grounds.

For further information about the options considered to replace the LVT scheme please refer to the [Regulation impact statement - Review of the low value turnover annual charge exemption scheme](#). For further information on the new ACE scheme please refer to the TGA website.

Fees and charges

Attachment 1: schedule of fees and charges from 1 July 2015.

Risk assessment

A cost recovery risk assessment for this activity was undertaken in May 2015 resulting in a medium risk rating.

The cost recovery risk rating of medium is based on assessment of the criteria on the [Cost Recovery Risk Assessment](#) (CRRA) template. The key medium to high risks for the cost recovery

of this activity are that the amount to cost recover exceeds \$20.0 million, the recovery is sourced through fees and levies, they involve an Act of Parliament and many stakeholders will be affected.

The most likely risks identified 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 current best practice in activity based costing (ABC) methodology;
- Working closely with stakeholders and industry representatives to mitigate the cost impact to business; and
- Ensuring charging practices are aligned to our services and are transparent and defensible.

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

- Identifying, assessing, and evaluating the risks posed by therapeutic goods before they can be approved for use in Australia (pre-market assessment or evaluation);
- Identifying, assessing, and evaluating the risks posed by manufacturing processes before a manufacturer is issued with a licence to manufacture therapeutic goods (licensing of manufacturers); and
- Identifying, assessing, and evaluating the risks that may arise following approval of the product and licensing of the manufacturer (post-market surveillance).

Stakeholder engagement

The TGA external communication and education framework; Priorities and projects 2013-2015 describes the TGA's approach to providing:

- Better information that is easily understood by consumers
- Therapeutic goods information that can be received and shared by health professionals
- Information that will provide greater certainty on regulatory arrangements for the therapeutic goods industry

It also details specific communication and education projects that will target consumers, health professionals or industry.

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 implementation 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).

TGA has worked with industry stakeholders regarding the development of new fees for OTC medicines that would align the business process reforms to a new fee schedule and as a result

cease the use of the page count fee structure. In February 2015 TGA spoke with representatives from the Australian Self Medication Industry (ASMI) on the proposed new fee schedule where they raised concerns over the date of introduction resulting in an agreed start date of 1 January 2016.

In September and October 2014 meetings and teleconferences were held with key laboratory stakeholders to discuss the release of the IVD RIS and the proposed reforms for Class 4 in-house IVDs. The teleconferences were held with the National Association of Testing Authorities (NATA), the Public Health Laboratory Network (PHLN), the Royal College of Pathologists of Australasia (RCPA), the National Pathology Accreditation Advisory Council (NPAAC), the Australian Red Cross Blood Service (ARCBS) & the Biotherapeutics Association of Australia (BAA).

The TGA met with industry representative bodies in October and November 2014, and with consumer health advocacy groups in December 2014, to discuss proposed changes to annual charges exemption arrangements, and follow-up communications were done in writing. Subsequent sectoral meetings were held with these groups to discuss the proposed changes and a targeted industry information session was held in late March 2015.

Consultation also occurred at meetings with industry representative bodies in March 2015 for the proposed general increase to fees and charges from 1 July 2015, along with all other changes to fees and charges to take effect in 2015-16. At the meetings it was proposed that fees and charges would be increased from 1 July 2015 at a rate less than the relevant CPI/WPI rate (2.5 percent). Following the meetings, TGA wrote to industry representative bodies with the final rate proposed for a general increase to fees and charges of 2.12 percent.

Financial estimates

Volumes

TGA estimates demand for its services based on prior years' volumes which are adjusted for forecast changes in the industry operations and changes in the regulatory framework and/or service delivery models.

Estimated volumes for GMF

	2014-15	2015-16
Low level GMF licence	103	107
High level GMF licence	171	165

Costs of the activity

Fees and charges are established to cover the cost of all direct and indirect costs for the sector. The costing methodology allows costs to be allocated to activities based on their resource consumption at each stage of the process through to the final product or service.

In line with the Australian Government's CRGs total costs are categorised into the following groups for cost allocation and transparency purposes.

- **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 if the entity's financial

system is able to generate relevant information. The most common direct costs are staff salaries (including oncosts, such as training, superannuation and leave) and supplier costs (e.g. office supplies and workers compensation premiums).

- **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 should be apportioned to a cost object using the entity's documented internal costing methodology. Common indirect costs include overhead costs such as salaries of staff in corporate (e.g. finance, human resources) and technical support (e.g. legal) areas, or accommodation costs (e.g. rent, maintenance, utilities).

A new software solution is being installed to improve TGA's ABC capability. Staff work effort surveys will be undertaken periodically and they will identify the time regulatory staff spend on our activities. A review of the results against current fees and charges will be carried out in 2015-16.

Direct and indirect costs of the activity

	2014-15 Estimated outcome \$m	2015-16 Forecast \$m	2016-17 Forward estimate \$m	2017-18 Forward estimate \$m
Direct Costs	10.3	9.4	9.2	9.0
Indirect Costs	4.0	3.6	3.5	3.5
Total	14.3	13.0	12.7	12.5

Financial performance

Cost recovery revenue will be reported in the Department of Health's Annual Report in accordance with the Public Governance, Performance and Accountability (Financial Reporting) Rule 2015.

In 2015-16 total revenue for the GMP sector is forecast to be \$11.4 million. The total costs associated in generating that revenue are forecast to be \$13.0 million. Increasing fees and charges is one option to address the under-recovery; however, this is not the only option. The TGA is committed to ensuring regulatory functions are performed efficiently and so we are seeking ways to reduce our costs before we look to increase fees or charges. In 2013-14 TGA began an extensive review of its activities and cost drivers using current ABC best practice methodology. This project involves each of the six sectors that TGA regulates. In 2014-15 TGA began the implementation of an advanced ABC software tool. This tool will provide improved transparency of costs and the associated revenue. This information will be used to inform management and external stakeholders of where improved alignment of revenue and costs needs to occur. The initial results of this work are expected to be available in 2015-16. The forward estimates below are estimates only and are based on the anticipated results of the ABC project and will be reviewed and adjusted through consultation with industry.

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 (recall, product tampering). Depreciation is also accumulated for the replacement of assets. The Government expects the TGA group to manage within its cost recovery resources and therefore investment, such as the Business Improvement Programme, must also come from the

responsible management of these reserves. The target for the reserve balance is set to be at least one quarter of operating expenses. During 2015-16 we expect our reserves to remain above that target.

Estimated revenue and expenses

	2014-15 Estimated outcome \$m	2015-16 Forecast \$m	2016-17 Forward estimate \$m	2017-18 Forward estimate \$m
Expenses	14.3	13.0	12.7	12.5
Revenue	10.9	11.4	11.6	11.7
Balance	(3.4)	(1.6)	(1.2)	(0.7)

Non-financial performance

Reform of business processes

TGA has embarked on a series of reforms designed to improve its communication and engagement with the community. Reform activities in the GMP sector aim to:

- Provide more information on the regulatory framework so that stakeholders understand the regulatory processes and requirements
- Improve the usability, accuracy and consistency of supporting guidelines
- Consolidate Trans-Tasman collaboration on GMP
- Improve stakeholder understanding and confidence in the regulatory processes
- Make reliable and relevant information easily accessible to stakeholders
- Develop technology to support business processes
- Reform the charging structures for the GMP compliance program
- Develop closer relationships with international regulators
- Pursue administrative efficiencies in relationships with industry

Performance reporting

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

The KPIs are high-level indicators for the TGA's overall performance against our broad strategic intent. Within that matrix of KPIs is a requirement for measuring whether 'business operations

are consistent and meet agreed service and timeliness standards'. Measures of specific business activities will continue to be documented in our half-yearly performance reports.

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

Key forward events

An independent Review of Medicines and Medical Devices Regulation (Expert Review) was announced on 24 October 2014. The aim of the Expert Review was to examine the TGA's regulatory framework and processes with a view to identifying:

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

During 2015-16 implementation of Government agreed recommendations from the Expert Review will begin. The Government has committed to boost productivity and reduce regulation through its deregulation agenda. The deregulation agenda is guided by the principle that regulation should only be imposed where absolutely necessary, and should not be the default position for dealing with public policy issues.

Key forward events schedule	Next scheduled update
Forward (financial) estimates	30 June 2016
Update of actual (financial) results	Reported in the Department of Health's Annual Report
Stakeholder engagement round	Second quarter 2015-16
Scheduled portfolio changing review	2017-18

CRIS approval and change register

Date of CRIS change	Approver	CRIS change
01/07/2014	Secretary Department of Health	CRIS for 1 July 2014
01/07/2014	Assistant Minister for Health	CRIS for 1 July 2014
01/07/2015	Secretary Department of Health (noted by Assistant Minister for Health)	CRIS updated for 1 July 2015

Attachments

1. Schedule of fees and charges from 1 July 2015

Good manufacturing practice fees	Fee \$
Licence application fee (excluding Biologicals)	960
Australian manufacturers - GMP inspection fee for all types of therapeutic goods	Hourly rate per Inspector \$630
Overseas manufacturers - GMP inspection fee for all types of therapeutic goods	Hourly rate per Inspector \$1,275
Overseas manufacturers - Assessment of GMP evidence (per manufacturer, per site and per sponsor)	370
Overseas manufacturers - Obtaining evidence from overseas regulatory agency (per manufacturer, per site and per sponsor)	650
Overseas manufacturers - Reinstatement of expired GMP clearance approval (per manufacturer, per site and per sponsor)	1,100
Overseas manufacturers - Compliance verification (in-lieu of an overseas GMP inspection)	1,955
Certificate of GMP Compliance	160
Quality Systems Certificate	160
Mutual Recognition Agreement Certificate	310
Notarised copy of original GMP licence / certificate of GMP compliance / quality systems certificate	60

Good manufacturing practice annual licence charges	Fee \$
Low level GMP licence <ul style="list-style-type: none"> • Single step / single medicine / single type of therapeutic device • In-vitro diagnostic products • Ingredients or components • Herbal / homeopathic medicinal products 	6,025

Good manufacturing practice annual licence charges	Fee \$
<p>High level GMP licence</p> <ul style="list-style-type: none">• Other types of therapeutic goods, including containers in which therapeutic goods are to be packed	11,700

Historical document

Historical document

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