



Australian Government

Department of Health

Therapeutic Goods Administration

Cost recovery implementation statement

Complementary medicines

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Historical document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>>.

Copyright

© Commonwealth of Australia 2015

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au>.

Contents

Introduction	4
Purpose of the Cost Recovery Implementation Statement (CRIS)	4
Description of the activity	4
Outputs and business processes of the activity	4
Policy and statutory authority to cost recover	6
Cost recovery model	6
Design of cost recovery charges	6
Risk assessment	9
Stakeholder engagement	9
Financial estimates	10
Volumes	10
Costs of the activity	11
Financial performance	11
Non-financial performance	12
Reform of business processes	12
Performance reporting	13
Key forward events	13
CRIS approval and change register	14
Attachments	15
1. Schedule of fees and charges from 1 July 2015	15

Introduction

Purpose of the Cost Recovery Implementation Statement (CRIS)

This CRIS provides information on how the Therapeutic Goods Administration (TGA) implements cost recovery associated with the registration or listing of complementary medicines onto the Australian Register of Therapeutic Goods (ARTG) and the ongoing monitoring and surveillance of complementary medicines registered or listed on the ARTG. It also reports financial and non-financial performance information for complementary medicines regulation 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.

Outputs and business processes of the activity

In Australia, medicinal products containing such ingredients as herbs, vitamins, minerals, nutritional supplements, homeopathic and certain aromatherapy preparations are referred to as 'complementary medicines' and are regulated as medicines under the *Therapeutic Goods Act 1989* (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 included on the ARTG via a streamlined electronic listing facility. This process for listing products allows for early market access for low risk complementary medicines. At the time of submitting a listed medicine application, the sponsor must certify that the goods that are the subject of the application meet all of the regulatory requirements.

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

- They may only contain substances that have been previously evaluated and approved as being of low risk, and

- They can only make indications (for therapeutic use) for health maintenance and health enhancement or certain indications for non-serious, self-limiting conditions.

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

Additional substances or ingredients to be used in listed medicines may be evaluated and approved by the TGA on application from the industry. On average, there are twelve such applications received each year.

Registering a complementary medicine on the ARTG

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

Compliance monitoring and enforcement

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

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

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

- The evidence that a sponsor holds to support the indications
- The presentation of the medicine
- The advertising of the medicine

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

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

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

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

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

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. All complementary medicines imported into, supplied for use in, or exported from Australia must be registered or listed on the ARTG. The TGA recovers the full costs of its regulatory activities through fees and charges imposed on sponsors and manufacturers of therapeutic products.

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

Fees and charges

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:

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.

- **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 registered complementary medicines, the fee structure is based on an application and evaluation fee. The evaluation fee is separated into new registered medicines, variations and new substances. The total page numbers in the application document is the current basis for setting the evaluation fees. The appropriateness of this basis as a proxy for risk is being reviewed as part of the reform process. Listing of a complementary medicine requires the payment of an application fee only.

Annual charges are payable for complementary medicines that are registered or listed on the ARTG. Registered complementary medicines, that have a higher assessed risk, have a higher annual charge than listed complementary medicines. Annual charges are used to recover the cost of activities, usually post-market, where they cannot reasonably be assigned to individual sponsors, where they maintain the integrity of the regulated industry to the benefit of all sponsors or where assigning costs to individual sponsors would deter sponsors from disclosing important public health information, such as reporting adverse events.

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 the 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 \$7.4m 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](#) (CRRRA) 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

The 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.

Estimates for the number of products on the register incorporate expected cancellations and new additions. Due to changes in the LVT scheme it is expected that there will be a reduction in ARTG entries in 2015-16 as opposed to 2014-15.

Volumes for complementary medicines on the ARTG

	2014-15	2015-16
Listed Complementary Medicines	11,829	10,023
Registered Complementary Medicines	171	139

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.

Costs included in listing or registering complementary medicines

	2014-15 Estimated outcome \$m	2015-16 Forecast \$m	2016-17 Forward estimate \$m	2017-18 Forward estimate \$m
Direct Costs	13.2	11.4	10.8	10.3
Indirect Costs	8.6	7.5	7.1	6.8
Total	21.8	18.9	18.0	17.1

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 complementary medicines sector is forecast to be \$11.2 million. The total costs associated in generating that revenue are forecast to be \$18.9 million. The under-recovery of costs forecast is comparable to prior years. 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 will also look at the underlying costs of complementary medicines regulatory functions in conjunction with a review of fees and 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	21.8	18.9	18.0	17.1
Revenue	11.4	11.2	11.4	11.5
Balance	(10.4)	(7.7)	(6.6)	(5.5)

Non-financial performance

Reform of business processes

During 2014 the TGA continued to improve its business processes by:

- Clarifying requirements for sponsors of complementary medicines
- Improving the electronic listing facility to increase useability and provide additional information to applicants

We continue to work on improvements to:

- Further develop risk profiles to more efficiently manage compliance reviews of listed complementary medicines
- Improve the market authorisation processes for registered complementary medicines and new substances (ingredients)
- Improve stakeholders' understanding of the regulatory framework for complementary medicines, particularly through engagement with industry.

Reforms including those stemming from the Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines have now been achieved, for example, the TGA has published its updated Australian Regulatory Guidelines for Complementary Medicines and the revised Guidelines on the evidence required to support indications for listed complementary medicines and publishes cancellations of listed complementary medicines following compliance review.

The TGA will continue to progress improvements to business processes including streamlining of applications for registered complementary medicines and new substances for use in listed medicines.

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 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. For more information on the TGA's KPI's please visit [TGA key performance indicators](#).

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 charging 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

Registration of complementary medicines	Fee \$
Application fee	1,475
Additional / concurrent application fee	650
Processing fee (variation to an existing registration)	1,475
Annual charge	1,380

Listing of complementary medicines	Fee \$
Application fee	775
Processing fee (variation to an existing listing)	390
Annual Charge	985

Evaluation fees if the documentation does not contain Clinical or Toxicological data – per submission	Fee \$
New registered medicine	9,870
Variation	3,565
New substance: such as sunscreen excipients and complementary medicine substances	9,870

Evaluation Fees based on total page count(s) of Clinical or Toxicological data per submission	Pages	Fee \$
New Listable Medicine Substance	1 – 50	9,870
New Listable Medicine Substance	51 - 250	12,700

Evaluation Fees based on total page count(s) of Clinical or Toxicological data per submission	Pages	Fee \$
New Listable Medicine Substance	251 - 500	17,400
New Listable Medicine Substance	501 - 1000	23,000
New Listable Medicine Substance	1001 - 2000	34,500
New Listable Medicine Substance	2001 - 3000	46,100
New Listable Medicine Substance	> 3000	69,000
Assessment of safety information or documents submitted pursuant to Section 31 of the <i>Therapeutic Goods Act 1989</i>	n/a	7,505

Evaluation Fees based on total page count(s) of Clinical or Toxicological data per submission	Pages	Fee \$
Variations	1 - 50	3,565
Variations	51 - 250	12,700
Variations	251 - 500	17,400
Variations	501 - 1000	23,000
Variations	1001 - 2000	34,500
Variations	2001 - 3000	46,100
Variations	> 3000	69,000

Listed medicines—Export only	Fee \$
Application fee	775
Processing fee (variation to an existing listing)	390

Listed medicines—Export certificates	Fee \$
Certificate of Pharmaceutical Product	160
Certificate of Listed Product	160
Certificate of Exempt Product	160

Historical document

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605
<http://www.tga.gov.au>

Reference/Publication #