Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Cost recovery impact statement

Complementary medicines
1 July 2013 – 30 June 2014

Version 1.0, June 2013

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, 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 <http://www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	Original Publication	Office of Corporate Services/ Office of Complementary Medicines	1 July 2013

Contents

1. Overview

1.1. Purpose

The purpose of this Cost Recovery Impact Statement (CRIS) is to document cost recovery arrangements that the Therapeutic Goods Administration (TGA) will apply to activities 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.

This CRIS will apply from July 2013 to June 2014.

1.2. Background

The TGA forms a part of the Department of Health and Ageing (DoHA), responsible for evaluating the safety, quality and efficacy of medicines, medical devices and blood components available for supply in, or export from Australia. The TGA recovers the full costs of its regulatory activities through fees and charges imposed on sponsors and manufacturers of therapeutic products.

The Australian community has an expectation that therapeutic products in the marketplace are safe and of high quality, to a level equal to that of countries with comparable standards.

All complementary medicines imported into, supplied for use in, or exported from Australia must be registered or listed on the ARTG.

Australia has a risk based system where the level of regulatory control of a therapeutic product is based on the relative safety of the product and the seriousness of the condition for which it is intended to be used. Products are reviewed at a level consistent with the risk associated with their use in the community.

1.3. Australian Government cost recovery policy

In December 2002, the Australian Government adopted a formal cost recovery policy to improve the consistency, transparency and accountability of its cost recovery arrangements and promote the efficient allocation of resources. The underlying principle of the policy is that agencies set charges to recover all the costs of a product or service where it is efficient and effective to do so, where the beneficiaries are a narrow and identifiable group and where charging is consistent with the Australian Government policy objectives. Cost recovery policy is administered by the Department of Finance and Deregulation and outlined in the *Australian Government Cost Recovery Guidelines* (Cost Recovery Guidelines).

The policy applies to all *Financial Management and Accountability Act 1997* (FMA Act) agencies and to relevant *Commonwealth Authorities and Companies Act 1997* (CAC Act)

bodies that have been notified. In line with the policy, individual portfolio ministers are ultimately responsible for ensuring entities' implementation and compliance with the Cost Recovery Guidelines.

2. Policy and legal authority to cost recover

2.1. Policy authority

The TGA has been progressively increasing the level of cost recovery from industry since 1992-93. In the 1997-98 Budget, the Government agreed that the TGA would accelerate the rate of increase in the level of cost recovery from industry to 100 percent cost recovery of all its activities by 1998-99[1]. Government has not changed this decision in subsequent years. This policy authority encompasses recovering expenses incurred by the TGA in regulating complementary medicines.

As part of the 2012-13 Mid-Year Economic and Fiscal Outlook[2] the Government agreed that the cost of the TGA reform program, detailed in the report *TGA reforms: a blueprint for TGA's future*[3], should be recovered from the regulated industry through the existing arrangements. This measure has resulted in a small increase to the fees and charges over the period 2012-13 to 2015-16.

2.2. Legal authority

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 on a cost recovery basis. Applicable fees and charges are prescribed in regulations made under the Act and the *Therapeutic Goods (Charges) Act 1989* (the TG Charges Act). These regulations are Therapeutic Goods (Charges) Regulations 1990 and the Therapeutic Goods Regulations 1990.

3. Cost recovery model

3.1. Key activity components

Complementary medicines (also known as 'traditional' or 'alternative' medicines) include vitamin, mineral, herbal, aromatherapy and homoeopathic products.

[1] 1997-98 Budget Paper 2, Revenue Measures, Other Measures p 203.
[2] 2012-13 MYEFO, Appendix A: Policy decisions taken since the 2012-13 Budget p. 239 - 240.
[3] <http://www.tga.gov.au/about/tga-reforms-blueprint.htm>

Complementary medicines may be either listed or registered, depending on their substances and the claims made. Most complementary medicines are listed on the ARTG.

Listed medicines:

- can only contain low risk substances in acceptable amounts that are permitted for use in listed medicines
- can carry indications (i.e. claims about the therapeutic use of the product) only for health maintenance and health enhancement or certain indications for non-serious, self-limiting conditions

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 requirements of section 26A of the Act.

3.2. Listing or Registering 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.

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. One of these mechanisms is that listed medicines may only contain substances that have been previously evaluated and approved as being of low risk. Additional substances may be evaluated and approved on application from the industry. On average, there are one or two such applications received each year.

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

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.

3.3. Compliance, monitoring and enforcement

The 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 coordinating and monitoring a recall action. There are three distinct recall actions - recall, recall for product correction and hazard alert.

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 1800 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.

3.4. Reform of business processes

In 2009-10, the Act was amended to include a new process for the submission, evaluation and approval of applications for new substances for use in listed medicines. Section 26BB was inserted into the Act to allow by legislative instrument, a determination specifying substances permissible for use in listed medicines.

Implementation of these arrangements is expected to occur during the 2013-14 financial year.

In 2011 a series of reforms to complementary medicines regulation were commenced that seek to improve community confidence in the safety and quality of these medicines.

This will be achieved by

- ensuring that the TGA effectively informs the community of its role in providing timely access to the therapeutic goods that Australians need, and that they meet appropriate standards of quality, safety and efficacy
- clarifying requirements for sponsors of complementary medicines

- improving the Australian community's understanding of the regulatory processes and decisions for complementary medicines
- strengthening the integrity and transparency of the regulatory framework for complementary medicines
- enhancing the complementary medicine regulatory framework to ensure that it remains adaptable to community and industry expectations

The reforms are part of the *TGA reforms: A blueprint for TGA's future*, including those stemming from the *Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines*.

The reforms will initially focus on the recommendations from the Auditor-General's report; the recommendations will be implemented through the following projects:

1. Key regulatory guidance materials
2. Standard indications
3. Publishing outcomes of listing compliance reviews
4. Using risk profiles in listing compliance reviews
5. Investigation processes for advertising breaches

There are additional recommendations included in the Blueprint that impact upon complementary medicines regulation and will lead to further projects in the future.

All changes to the regulatory processes will incorporate a review of the cost of underlying business processes and may include new or changed fees and charges.

3.5. Activity level assumptions

Listing or Registering on the ARTG

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.

Compliance monitoring and enforcement

Estimates for the number of products on the register incorporate expected cancellations and new additions.

A sponsor can seek exemption from the liability to pay an annual charge for an entry on the ARTG if the therapeutic good qualifies for low value turnover (LVT), which is a turnover of not more than 15 times the applicable annual charge for that therapeutic good.

Table 1 Volume estimates for complementary medicines on the ARTG

	2012-13	2013-14
Listed Complementary Medicines	13,159	13,311
Registered Complementary Medicines	208	190

3.6. Costs to be recovered

Fees and charges are established to cover the cost of all direct, corporate and support 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 services.

Total costs are categorised into the following groups for cost allocation and transparency purposes.

a. **direct costs**: are costs directly related to the regulatory activity, mainly labour. Labour costs are based on the current Enterprise Agreement applicable to all Department of Health and Ageing employees. Direct costs are incurred in the regulatory offices. Direct supplier costs include the use of contract staff, travel (where not otherwise recovered) and consumables.

b. **corporate costs:** include rent and information technology that regulatory offices can control consumption of but not the unit price. The allocation of corporate costs uses a range of cost drivers including floor space, full time equivalent staff (FTE) numbers, and budget size, chosen according to the nature of the costs to be allocated.

c. **support costs:** include costs for providing support services such as human resource management, finance, legal and information technology support. Regulatory offices have limited or no control over these costs. In allocating support costs, a cost driver is chosen from a range that includes FTE staff numbers, budget size and floor space, based on how closely these approximate use of the support service.

Cost allocation is undertaken in a three stage process.

In the first stage, the regulatory offices with significant contribution to the sector, as the source of direct costs, are identified. For the complementary medicines, these are the Office of Complementary Medicines and the Office of Product Review.

In the second stage, corporate costs are allocated to all offices, both regulatory and support, based on the driver that best reflects the use of the corporate service. For example, rent and other property operating costs are allocated using floor space; information technology and communications are allocated by FTE.

In the third stage, support costs are assigned to regulatory offices based on a driver that is related to the services provided by the support team. For example, the property team costs are allocated by the floor space driver, the human resources team are allocated by FTE.

Table 2: Costs included in listing or registering complementary medicines

	2012-13 Estimated outcome $m	2013-14 Forecast $m
Direct Costs	2.1	2.2
Corporate Costs	0.5	0.5
Support Costs	1.1	1.1
Total	**3.7**	**3.8**

Table 3: Costs included in compliance, monitoring and enforcement of complementary medicines

	2012-13 Estimated outcome $m	2013-14 Forecast $m
Direct Costs	2.9	3.3
Corporate Costs	0.7	0.7
Support Costs	4.5	4.7
Total	**8.1**	**8.7**

3.7. Outline of charging structure

TGA recovers the full cost of its regulatory activities through fees and charges for services provided to product manufacturers and sponsors.

Fees

Fees are used to recover the cost of the premarket 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 processes.

Listing of a complementary medicine requires the payment of an application fee only.

Charges

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 complimentary medicines.

Annual charges are used to recover cost of activities, usually post market, where:

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

TGA recovers the full costs of its regulatory services from industry. Fees and charges were historically established through an Activity Based Costing (ABC) methodology and indexed to maintain currency. Fees and charges for the regulation of complementary medicines were established to reflect as closely as possible the costs of undertaking the individual activities.

Reform program

All fees and charges include a component for the cost of the reform program, which was introduced through a 2% increase in fees and charges from 2012-13. The implementation of the reform program is scheduled to continue through to mid 2015-16. As changes in regulatory activities are implemented, fees and charges will be adjusted to ensure that they continue to accurately reflect the costs of underlying activities.

Indexation

For the 2013-14 financial year, fees and charges were indexed by 2.9% which is a 50:50 composite of the Australian Bureau of Statistics Consumer Price Index and the Wage Price Index (for the September Quarter 2011 to September Quarter 2012).

3.8. Fees and charges

Registration of Complementary Medicines	2012-13 $	2013-14 $
Application fee	1,370	1,410
Additional /concurrent application fee	600	620
Processing fee (variation to an existing registration)	1,370	1,410
Annual Charge	1,280	1,320

Listing of Complementary medicines	2012-13 $	2013-14 $
Application fee	720	740
Processing fee (variation to an existing listing)	360	370
Annual Charge	910	940

Evaluation Fees if the documentation does not contain Clinical or Toxicological data - per submission	2012-13 $	2013-14 $
New registered medicine	9,170	9,440
Variation	3,310	3,410
New substance: such as sunscreen excipients and complementary medicine substances	9,170	9,440

Evaluation Fees based on total page count(s) of Clinical or Toxicological data per submission		2012-13 $	2013-14 $
New Product	1 - 50	9,170	9,440
	51 - 250	11,800	12,100
	251 - 500	16,100	16,600
	501 - 1000	21,400	22,000
	1001 - 2000	32,100	33,000
	2001 - 3000	42,800	44,000
	> 3000	64,100	66,000
Variations	1 - 50	3,310	3,410
	51 - 250	11,800	12,100
	251 - 500	16,100	16,600
	501 - 1000	21,400	22,000
	1001 - 2000	32,100	33,000
	2001 - 3000	42,800	44,000
	> 3000	64,100	66,000
New Substance	1 - 50	9,170	9,440
	51 - 250	11,800	12,100
	251 - 500	16,100	16,600
	501 - 1000	21,400	22,000
	1001 - 2000	32,100	33,000
	2001 - 3000	42,800	44,000
	> 3000	64,100	66,000
Multiple New Excipients in listed or registered good for dermal use	1 - 50	9,170	9,440
	51 - 250	11,800	12,100
	251 - 500	16,100	16,600
	501 - 1000	21,400	22,000
	1001 - 2000	32,100	33,000
	2001 - 3000	42,800	44,000
	> 3000	64,100	66,000

Evaluation Fees based on total page count(s) of Clinical or Toxicological data per submission		2012-13 $	2013-14 $
Assessment of Safety and Efficacy	1 - 50	9,170	9,440
	51 - 250	11,800	12,100
	251 - 500	16,100	16,600
	501 - 1000	21,400	22,000
	1001 - 2000	32,100	33,000
	2001 - 3000	42,800	44,000
	> 3000	64,100	66,000

Evaluation Fees based on total page count(s) of Clinical or Toxicological data per submission		2012-13 $	2013-14 $
New Listable Medicine Substance	1 – 50	9,170	9,440
	51 – 250	11,800	12,100
	251 – 500	16,100	16,600
	501 – 1000	21,400	22,000
	1001 – 2000	32,100	33,000
	2001 – 3000	42,800	44,000
	> 3000	64,100	66,000
Assessment of safety information or documents submitted pursuant to Section 31 of the *Therapeutic Goods Act 1989*		6,980	7,180

Listed medicines—Export only	2012-13 $	2013-14 $
Application fee	720	740
Processing fee (variation to an existing listing)	360	370

Listed medicines—Export certificates	2012-13 $	2013-14 $
Certificate of Pharmaceutical Product	140	150
Certificate of Listed Product	140	150
Certificate of Exempt Product	140	150

3.9. Revenue

Total revenues are a factor of the expected activity volume and the fee or charge[4].

Table 4: Complementary medicines revenue estimates

	2012-13 Estimated outcome $m	2013-14 Forecast $m
Annual Charges	7.7	8.1
Application Fees	2.3	2.3
Evaluation Fees	0.4	0.4
Other[5]	0.8	0.8
Total	**11.2**	**11.6**

4. Stakeholder engagement

A regular mechanism used by industry stakeholders to monitor the TGA's activities and performance is the TGA Industry Consultative Committee (TICC). The TICC meets twice yearly to examine progress against key projects, agreed targets and financial performance. TGA also 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.

4.1. Ongoing monitoring

Cost recovery revenue will be reported in the Department of Health and Ageing's Annual Report in accordance with the Finance Minister's Orders.

[4] The costs of the reform program are being recovered over a number of years from the whole therapeutic goods industry.
[5] Other revenue incorporates fee for service charges for review of advertising materials and appropriation in lieu of interest on cash holdings.

The TGA executive is provided with monthly financial reports showing progress against the monthly budgets and an analysis of financial performance and position undertaken by the TGA Chief Financial Officer.

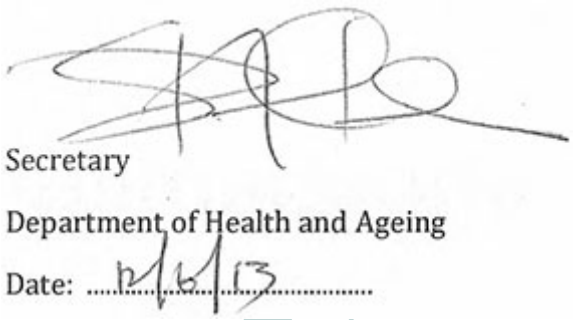
TGA prepares a half yearly performance report detailing statistical information on regulatory workflows. The report is distributed to the TICC members.

5. Periodic review

TGA is currently reviewing its ABC methodology to ensure that the fees and charges cover the costs of the services provided for the sector in an effective and efficient manner that is consistent with the Cost Recovery Guidelines. The current ABC methodology indicates presence of an under recovery in the complementary medicines sector. Following the review of the methodology, TGA will consult with the complementary medicines sector on the options available to address the under recovery, with the implementation of any changes expected to occur for the 2014-15 financial year.

6. Certification

I certify that this CRIS complies with the Australian Government Cost Recovery Guidelines



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