Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Cost recovery impact statement

Over the counter 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 Medicines Authorisation	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 over the counter medicines onto the Australian Register of Therapeutic Goods (ARTG) and the ongoing monitoring and surveillance of over the counter 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 over the counter 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 by the TGA 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 over the counter 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 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

Over-the-counter (OTC) medicines are defined in the Therapeutic Goods Regulations 1990 (the 'Regulations'). OTC medicines can be supplied as:

- Pharmacy medicines;

[1] 1997-98 Budget Paper 2, Revenue Measures, Other Measures p 203.
[2] <http://www.budget.gov.au/2012-13/content/myefo/html/09_appendix_a_expense-10.htm>
[3] <http://www.tga.gov.au/about/tga-reforms-blueprint.htm>

- Pharmacist only medicines; and
- General sales medicines

Medicines are grouped into schedules according to the appropriate level of regulatory control over their availability to consumers. 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. The distinction between registered and listed OTC medicines is made based on the sponsor's claims around the efficacy of the product.

Registered OTC medicines are considered to be of lower risk than prescription medicines, but they require an appropriate level of scrutiny. When making the decision to register an OTC medicine, the TGA takes into account all of the advice given by the scientific and medical experts and the advice given to it by the Advisory Committee on Non-prescription Medicines, along with the information provided by the sponsor.

Once a product has been registered, the sponsor can make further applications to change the conditions of registration. Changes may be sought for the following:

- Labels
- Shelf life
- Formulation
- Quality control
- Indications
- Directions for use

3.2. Registration or listing on the ARTG

The pre-market regulatory process for OTC medicines includes application processing, evaluation and listing or registration. Key steps in the process include:

- Lodgement of application for product registration or listing on the ARTG;
- Administrative and technical screening and evaluation of applications. This may include:
  - peer review;
  - scientific evaluation; and
  - referral to the Advisory Committee on Non-prescription Medicines;
- Advise the sponsor of the outcome of the application process; and
- Update the ARTG.

3.3. Compliance monitoring and enforcement

The OTC post market regulatory processes include detection, compliance and enforcement.

Detection

- Undertaking laboratory testing of products (ie chemistry and biochemistry)
- Investigating reported adverse events
- Reviewing products or classes of products

Compliance

- Monitoring compliance with regulations
- Maintaining product registers
- Ensuring compliance with advertising regulations
- Educating stakeholders
- Recalling products
- Issuing alerts to consumers
- Updating product information

Enforcement

- Investigating potential breaches
- Enforcing the regulations

3.4. Reform of business processes

The TGA has commenced work on a series of reforms to the regulation of OTC medicines. These reforms are based on tightening the risk based approach with more rigorous pre-application requirements and standardisation of response times. Depending on the risk classification of a registered OTC, evaluation effort would range from minimal (e.g. monographs) for products with a long history of safe use, to full assessment of quality, safety and efficacy for new active combinations.

The reforms are part of the *TGA reforms: a blueprint for TGA's future* and aim to:

- Achieve operational efficiencies
- Improve transparency and predictability of the regulatory process for sponsors
- Improve the quality of OTC applications
- Review cost recovery for OTC regulation
- Enable industry monitoring of application status
- Increase the predictability of the regulatory decisions
- Shorten evaluation timeframes

3.5. Activity level assumptions

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.

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 OTC medicines on the ARTG

	2012-13	2013-14
Registered over the counter medicines	3,301	3,404

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 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 (FTE) staff 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, laboratory services, finance, legal and information technology support. Regulatory offices have limited or no control over these costs. In allocating support costs, a cost driver is again chosen from a range that includes FTE staff numbers, budget size and floor space, based on how closely these approximate use of the support services.

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 OTC medicines sector, these are the Office of

Medicines Authorisation; the Office of Scientific Evaluation, the Office of Product Review and the Office of Laboratory and Scientific Services.

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 OTC medicines

	2012-13 Estimated outcome $m	2013-14 Forecast $m
Direct Costs	2.2	2.5
Corporate Costs	0.6	0.6
Support Costs	0.9	0.8
Total	**3.7**	**3.9**

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

	2012-13 Estimated outcome $m	2013-14 Forecast $m
Direct Costs	3.2	3.4
Corporate Costs	0.7	0.7
Support Costs	3.0	3.1
Total	**6.9**	**7.2**

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. The current fee structure in the Regulations is based on an application fee and evaluation fee. The evaluation fee differs for new registered medicines, variations and new substances. The total page numbers in the application document is the current basis for setting the evaluation fees. In the new fee structure that is expected to apply from July 2014 the use of page numbers as the basis for fees would be discontinued.

Charges

Annual charges are payable for OTCs that are registered or listed on the ARTG. Registered OTCs, that have a higher assessed risk, have a higher annual charge than listed OTCs.

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; or
- assigning costs to individual sponsors would deter sponsors from disclosing important public health information, such as reporting adverse events.

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).

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.

3.8. Fees and charges

Registration of OTC 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 OTC medicines - Including sunscreens	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. Revenues

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

	2012-13 Estimated outcome $m	2013-14 Forecast $m
Annual Charges	2.7	2.8
Application Fees	1.5	1.4
Evaluation Fees	2.7	2.0
Other[4]	0.2	0.4
Total	**7.1**	**6.6**

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.

5. Ongoing monitoring

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

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.

[4] Other revenue incorporates fee for service charges for review of advertising materials and appropriation in lieu of interest on cash holdings.

6. Periodic review

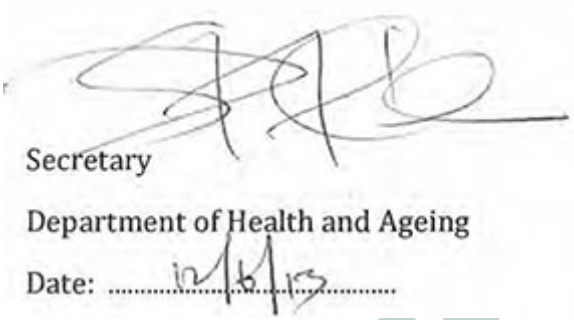
TGA is reviewing its ABC methodology to ensure that the fees and charges cover the costs of the services provided. Overall, fees and charges must cover the cost of the regulatory costs for the sector.

A business review of regulation of OTC medicines is being implemented, part of which includes evaluation processes based on the product risk. Higher risk products will attract greater scrutiny before registration on the ARTG, and evaluation fees will be set accordingly.

TGA aims to have updated OTC evaluation fees implemented by the end of the 2013-14 financial year. The updated fees and charges will be documented in a new CRIS.

7. 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