Australian Government
Department of Health
Therapeutic Goods Administration

Cost recovery impact statement

Over the counter medicines
1 July 2014 – 30 June 2015

Version 1.0, June 2014

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 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 2014

Contents

1. Introduction

1.1. Purpose of the Cost Recovery Impact Statement (CRIS)

The CRIS provides key information on how the TGA implements cost recovery of activities associated with the registration or listing of over the counter medicines (OTC) 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. It also reports on financial and non-financial performance of OTC activities and contains up-to-date financial forecasts. The TGA will maintain the CRIS until the activity or its cost recovery has been discontinued.

This CRIS will apply from July 2014 to June 2015.

1.2. Description of the activity

The TGA forms a part of the Department of Health, responsible for evaluating the safety, quality and efficacy of medicines, medical devices and biologicals 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 framework

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

1.4. Policy and statutory authority to cost recover

1.4.1. Government policy approval to cost recover the activity

In the 1997–98 Budget[1], the Government decided to cost recover 100 percent of all TGA's activities by 1998–99. This policy authority encompasses recovering expenses incurred by the TGA in regulating over the counter medicines.

[1] 1997–98 Budget Paper 2, Revenue Measures, Other Measures p 203.

1.4.2. Statutory authority to impose cost recovery charges

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 included in the Therapeutic Goods (Charges) Regulations 1990 and the Therapeutic Goods Regulations 1990 (the 'Regulations').

2. Cost recovery model

2.1. Outputs and business processes of the activity

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

- Pharmacy medicines;
- 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, antifungal 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.

Registered OTC medicines are considered to be of lower risk than prescription medicines, but they require an appropriate level of scrutiny.

Once a product has been registered, the sponsor can make further applications to change the details of registration. Examples of changes that may be sought include details related to:

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

2.2. Registration or listing on the ARTG

2.2.1. Listing an OTC 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 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 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.

2.2.2. Registering an OTC medicine on the ARTG

Registered 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 evaluated for quality, safety and efficacy prior to being accepted on the ARTG and able to be marketed.

The pre-market regulatory process for OTC medicines includes:

- Lodgement of application for product registration or listing on the ARTG;
- Administrative and technical screening
- scientific evaluation;
- Label assessment;
- Ensure appropriate GMP is in place;
- request advice from the Advisory Committee on Non-prescription Medicines; Advise the sponsor of the outcome of the application process; and
- Update the ARTG.

2.2.3. Risk management

TGA works with consumers, health professionals, industry, and its international counterparts in order to effectively regulate therapeutic products, many of which are increasingly complex as a result of rapid scientific developments.

The TGA applies a risk management approach 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).

2.3. Compliance monitoring and enforcement

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

2.3.1. Detection

- Undertaking laboratory testing of products (i.e. chemistry and microbiology)
- Investigating reported adverse events
- Reviewing the safety of products or classes of products

2.3.2. Compliance

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

2.3.3. Enforcement

- Investigating potential breaches
- Enforcing the regulations

2.4. Reform of business processes

The TGA is implementing reforms to the regulation of OTC medicines. These reforms provide a risk based approach to the categorisation of OTC medicine applications with the aim of providing more timely and predictable timelines for decisions on the basis of receiving and accepting higher quality applications though an electronic submission portal that facilitates efficient use by industry. Depending on the risk classification of a registered OTC medicine, evaluation effort is ranging from minimal for products with a long history of safe use, to full assessment of quality, safety and efficacy for new active combinations.

The reforms 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 online monitoring of application status by industry that is more transparent to the applicant
- Increase the predictability of the regulatory decisions
- Shorten evaluation timeframes

2.5. 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

	2013–14	2014–15
Registered over the counter medicines	3,185	3,212

2.6. Design of cost recovery charges

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

2.6.1. Fees and charges

Fees are used to recover the cost of the pre-market 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.

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, 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.

2.6.2. Reform program

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.

2.6.3. Indexation

For the 2014–15 financial year, fees and charges were indexed by 2.4% which is a 50:50 composite of the Australian Bureau of Statistics Consumer Price Index and the Wage Price Index.

2.7. Fees and charges

Registration of OTC medicines	2013–14 $	2014–15 $
Application fee	1,410	1,445
Additional /concurrent application fee	620	635
Processing fee (variation to an existing registration)	1,410	1,445
Annual charge	1,320	1,350

Listing of OTC medicines – including sunscreens	2013–14 $	2014–15 $
Application fee	740	760
Processing fee (variation to an existing listing)	370	380
Annual charge	940	965

Evaluation fees if the documentation does not contain Clinical or Toxicological data – per submission	2013–14 $	2014–15 $
New registered medicine	9,440	9,665
Variation	3,410	3,490
New substance: such as sunscreen excipients and complementary medicine substances	9,440	9,665

Evaluation fees based on total page count(s) of Clinical or Toxicological data per submission	Pages	2013–14 $	2014–15 $
New product	1 – 50	9,440	9,665
	51 – 250	12,100	12,400
	251 – 500	16,600	17,000
	501 – 1000	22,000	22,500
	1001 – 2000	33,000	33,800
	2001 – 3000	44,000	45,100

Evaluation fees based on total page count(s) of Clinical or Toxicological data per submission	Pages	2013–14 $	2014–15 $
	> 3000	66,000	67,600
Variations	1 – 50	3,410	3,490
	51 – 250	12,100	12,400
	251 – 500	16,600	17,000
	501 – 1000	22,000	22,500
	1001 – 2000	33,000	33,800
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New substance	1 – 50	9,440	9,665
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	501 – 1000	22,000	22,500
	1001 – 2000	33,000	33,800
	2001 – 3000	44,000	45,100
	> 3000	66,000	67,600
Multiple new excipients in listed or registered good for dermal use	1 – 50	9,440	9,665
	51 – 250	12,100	12,400
	251 – 500	16,600	17,000
	501 – 1000	22,000	22,500
	1001 – 2000	33,000	33,800
	2001 – 3000	44,000	45,100
	> 3000	66,000	67,600
Assessment of safety and efficacy	1 – 50	9,440	9,665
	51 – 250	12,100	12,400
	251 – 500	16,600	17,000
	501 – 1000	22,000	22,500

Evaluation fees based on total page count(s) of Clinical or Toxicological data per submission	Pages	2013–14 $	2014–15 $
	1001 – 2000	33,000	33,800
	2001 – 3000	44,000	45,100
	> 3000	66,000	67,600
New Listable medicine substance	1 – 50	9,440	9,665
	51 – 250	12,100	12,400
	251 – 500	16,600	17,000
	501 – 1000	22,000	22,500
	1001 – 2000	33,000	33,800
	2001 – 3000	44,000	45,100
	> 3000	66,000	67,600
Assessment of safety information or documents submitted pursuant to Section 31 of the *Therapeutic Goods Act 1989*		7,180	7,350

Listed medicines—Export only	2013–14 $	2014–15 $
Application fee	740	760
Processing fee (variation to an existing listing)	370	380

Listed medicines—Export certificates	2013–14 $	2014–15 $
Certificate of Pharmaceutical Product	150	155
Certificate of Listed Product	150	155
Certificate of Exempt Product	150	155

3. 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).

4. Financial estimates

4.1. Revenue

Table 2: Total revenues are a factor of the expected activity volume and the fee or charge

	2013–14 Estimated outcome $m	2014–15 Forecast $m
Annual charges	2.8	2.9
Application fees	1.6	1.4
Evaluation fees	3.0	2.8
Other[2]	0.4	0.4
Total	**7.8**	**7.5**

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

4.2. Costs of the activity

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 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 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 and information technology costs 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.

Table 3: Costs included in listing or registering OTC medicines

	2013–14 Estimated outcome $m	2014–15 Forecast $m
Direct costs	2.7	2.6
Corporate costs	0.6	0.5
Support costs	0.6	0.7
Total	**3.9**	**3.8**

Table 4: Costs included in compliance monitoring and enforcement of OTC medicines

	2013–14 Estimated outcome $m	2014–15 Forecast $m
Direct costs	2.2	2.3
Corporate costs	0.5	0.5
Support costs	2.5	2.0
Total	**5.2**	**4.8**

Table 5: Estimated revenue and expenses

	2013–14 Estimated outcome $m	2014–15 Forecast $m
Expenses	9.4	8.6
Revenue	7.8	7.5
Balance	**(1.3)**	**(1.1)**

5. Financial performance

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

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

Table 6: Financial results for the activity

	2011–12 $m	2012–13 $m	2013–14 Estimated outcome $m
Expenses	9.1	8.5	9.1
Revenue	7.5	7.2	7.8
Balance	**(1.6)**	**(1.3)**	**(1.3)**

6. Non-financial performance

The TGA reports to stakeholders at six monthly intervals on our progress in delivery against a set of agreed Key Performance Indicators (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 KPIs please visit <http://www.tga.gov.au/about/tga-kpi.htm>.

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.

7. Key forward events

During 2014–15 a review of fees and charges will be undertaken following development of a new activity based costing prepared in 2013–14. Consultation with industry representatives will be carried out to gather input on the framework of fees and charges and on proposed changes identified by the TGA, leading to revised fees and charges where appropriate.

Opportunities include alignment of over-the-counter (OTC) medicine fees to the new risk based categorisation of applications, and review of Good Manufacturing Practice (GMP) fees and charges. Annual charges, which primarily fund post-market regulatory activities such as the monitoring of product safety and of compliance with regulatory obligations, are subject to possible change with the review of the low value turnover (LVT) exemption scheme and the proposed introduction of clinical quality registers for implantable cardiac and breast devices.

The LVT scheme, introduced in 1990, allows sponsors to seek an exemption from payment of an annual charge where the annual turnover of the product is less than or equal to 15 times the annual charge for that product. The TGA has commenced a policy and operational review of the LVT scheme, the first stage of which was the release of the public consultation paper with submissions received in May 2014.

In 2014–15, the TGA will continue to identify opportunities for reducing regulatory burden on industry, consistent with the Government's deregulation and red tape reduction agenda, while continuing to meet the objectives of safeguarding and enhancing the health of the Australian community. Changes to the regulatory framework arising from this work may have a flow on impact on fees and charges.

8. Certification

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

Jane Halton

Secretary

Department of Health

Date: 26 June 2014

Therapeutic Goods Administration

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