Australian Government
Department of Health
Therapeutic Goods Administration

Cost recovery impact statement

Prescription 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 of prescription medicines onto the Australian Register of Therapeutic Goods (ARTG) and the ongoing monitoring and surveillance of prescription medicines included on the ARTG. The TGA will maintain the CRIS until the activity or its cost recovery has been discontinued. It also reports on financial and non-financial performance of prescription medicine 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 prescription medicines imported into, supplied for use in, or exported from Australia must undergo a registration process and be included 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 prescription medicines.

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.

2. Cost recovery model

2.1. Outputs and business processes of the activity

Australia has a two-tiered system for the regulation of medicines, higher risk medicines, such as prescription medicines, must be registered on the ARTG before they are made available for sale in Australia.

Prescription medicines are available from a pharmacist, supplied with a doctor's prescription. Otherwise, only authorised health care professionals can supply prescription medicines, such as in a hospital setting.

Examples include vaccines, blood pressure tablets, diabetes medications, contraceptive pills, antibiotics and strong pain killers.

There are some legal exemptions to the requirement for a prescription medicine to be registered on the ARTG. These are implemented through:

- The Special Access Scheme (SAS)
- The clinical trials systems (CTX and CTN)

2.2. Registration on the ARTG

Before being registered on the ARTG prescription medicines are assessed for quality, safety and efficacy.

2.2.1. Applications

All applications for registration of prescription medicines must be preceded by a pre-planning submission form (PPF). TGA assesses all PPFs to ensure that application dossiers for registration on the ARTG contain all the appropriate and required information.

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

The information provided in the PPF allows the TGA to effectively assign resources for the evaluation process. If the PPF is insufficient for planning purposes or indicates that mandatory requirements have not been met, the TGA may deem the PPF to be 'not effective' and the application will not proceed to the dossier submission stage.

2.2.2. Data evaluation

The data submitted with an application is divided into three types.

- Quality data evaluated by chemists, biochemists, microbiologists and other TGA officers includes:
  - The composition of the drug substance and the drug product
  - Batch consistency
  - Stability data
  - Sterility data (if applicable)
  - The impurity content
- Nonclinical data evaluated by toxicologists:
  - Pharmacology data
  - Toxicology data
- Clinical data evaluated by a medical doctor:
  - Mostly results of clinical trials

2.2.3. Applications to change details of registration

Once a product has been registered, the sponsor can make further applications to change the details of registration. Some examples of the types of change that might be applied for:

- A change in manufacturer
- An increase in shelf life
- A change in patient population (e.g. allowing children to use the medicine)
- Changing the intended use (usually adding an extra medical condition that can be treated)

2.2.4. Decision making

Before making a decision around the suitability of a prescription medicine for registration on the ARTG, the delegate may take into consideration independent expert advice provided by the Advisory Committee on Prescription Medicines.

Regulatory decisions in relation to new chemical entities or fixed dose combination products are published through the Australian Public Assessment Report (AusPAR).

Any person whose interests are affected by the decision may seek a reconsideration of the decision under section 60 of the Act.

2.2.5. 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. Regulatory framework

Regulatory decisions are made within a framework of guidelines. The guidelines must maintain currency with scientific and technical developments.

International regulators, or regulator groups such as International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), may publish guidelines that are reviewed and may be adopted by the TGA.

2.4. Export

Medicines for export from Australia must be of a similar quality and safety standard as those supplied domestically. However, they are not required to comply with the labelling standards or advertising standards in force in Australia. Export only products are required to be listed (not registered) on the ARTG before export.

2.5. Special Access Scheme

In the circumstances where patients need access to therapeutic goods that are not on the ARTG, access to the therapeutic good may be arranged through the Special Access Scheme (SAS).

TGA reviews each access under the SAS on a case by case basis.

2.6. Clinical trials

TGA reviews the use of unapproved medicines to be made available to patients participating in a clinical trial.

2.7. Compliance monitoring and enforcement

Post-market activities undertaken in relation to prescription medicines include:

- Providing access to a comprehensive source of up to date consumer medicine information and product information
- Review Periodic Safety Update Reports to ensure the ongoing suitability of products for registration on the ARTG
- Monitoring risk management plans that detail how safety concerns will be identified and mitigated post-registration
- Ensuring that regular post-market reports are received from sponsors
- Monitoring any international concerns about a product's safety or efficacy
- Laboratory testing program on selected medicines
- Publishing a Medicines Safety Update in each edition of the Australian Prescriber
- Managing the problem reporting system for:
  - Medicine deficiency or defect
  - Adverse reaction to a medicine
- Undertaking random and targeted sampling of approved products
- Undertaking appropriate regulatory action for identified problems. Actions include:
  - informing health care professionals and consumers about the risks of using the product
  - re-assessing the benefit-risk profile
  - requiring product labelling changes
  - requiring design or manufacturing change
  - requesting post-marketing studies
  - restricting access
  - recalling products
  - removing the product from the ARTG

2.8. Reform of business processes

The TGA has continued to work on a series of reforms to improve understanding of regulatory processes by its stakeholders; significantly enhance post market and surveillance capability and enhance public trust in the safety and quality of therapeutic goods. For the prescription medicines sector these reforms aim to:

- Upgrade the content of the *Australian Regulatory Guidelines for Prescription Medicines* (ARGPM) to improve the usability, accuracy and consistency of business processes and requirements to external user groups of prescription medicines
- Provide more information on the regulatory framework so that stakeholders understand regulatory processes and requirements

- Revise labelling and packaging requirements to improve consumer safety and quality use of medicines
- Align ingredient names used in Australia to international standards
- Improve the management of adverse event reporting in support of consumer safety
- Promote the distribution of therapeutic goods safety information so that consumers are alert to warning signals
- Align recall procedures including communication of alerts to the public and health professionals
- Ongoing review of registration processes to provide for predictable timeframes for applicants and the efficient use of resources
- Enhance the receipt, processing, review and lifecycle management of applications, minimise paper use during the exchange of information between applicants and agency and facilitate business processes through the adoption of the electronic Common Technical Document (eCTD) – a set of rules and requirements for the structured submission of electronic files developed under the auspices of International Conference on Harmonisation (ICH)
- Provide guidance on how to organize application information for electronic submission to the Agency using the eCTD specifications and harmonise the organization and formatting of electronic submissions for various application types
- Support the evaluation process through the adoption of international guidelines concerning data requirements
- Assess and report on the feasibility of an online tracking system for submissions or applications
- Streamlining processes for minor variations to the entry of the medicine on the ARTG. The minor variations that are being considered include:
  - corrections to the entry
  - safety-related variations
  - 'self-assessable' variations
  - Category 3 quality related changes

2.9. Activity level assumptions

2.9.1. 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.

2.9.2. 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: Estimated volumes for prescription medicines on the ARTG

	2013–14	2014–15
Prescription medicines – biologics	992	998
Prescription medicines – non-biologics	13,110	14,556

2.10. Design of cost recovery charges

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

2.10.1. Fees

Fees are used to recover the cost of the premarket services performed. For registered prescription medicines, the fee structure is based on an application and evaluation fee. Fees are scaled to account for the effort undertaken with the highest fees applicable for evaluating a new chemical entity.

Fees are also charged when a sponsor requires a change to the information contained in the ARTG.

2.10.2. Charges

Annual charges are payable for prescription medicines that are registered on the ARTG.

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

2.10.3. 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.

2.10.4. 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.

2.11.Fees and charges

Fees and charges for the prescription medicine sector for 2014–15 are outlined below. Fees and charges that applied for the sector for 2013–14 are at Attachment A.

Registration fees	2014–15 Application Fee $	2014–15 Evaluation Fee $
New Chemical Entity	44,200	177,200
New Chemical Entity of a medicine used as an ancillary medical component of a device (item 4(aa)(i) and 4(aa)(ii))	14,700	59,100
New Chemical Entity of a medicine used as an ancillary medical component of a device (item 4(aa)(iii))	29,500	118,000
Extension of indications	26,300	105,300
Extension of indicators of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing or pre-clinical studies	8,775	35,100
Extension of indicators of a medicine used as an ancillary medical component of a device – documentation mentioned in subparagraphs (i) and (ii)	17,600	70,100
Major variations	17,200	68,500
Major variation of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing or pre-clinical studies	5,725	22,700
Major variation of a medicine used as an ancillary medical component of a device – documentation mentioned in subparagraphs (i) and (ii)	11,500	45,800
New generic product	17,000	67,600
Additional trade name	2,785	11,200
Minor variations (Change in formulation, composition, design specifications, type of container or change of trade name).	1,015	4,035

Variation fees	2014–15 Application Fee $	2014–15 Evaluation Fee $
Variations to a Register entry involving the evaluation of clinical, pre-clinical or bio-equivalence data, but not included in another fee category. Includes applications for changes to Product Information involving the evaluation of clinical, pre-clinical or bio-equivalence data.	1,015	4,035
Variations to a Register entry involving the evaluation of only chemistry, quality control or manufacturing data. Includes applications for changes to Product Information involving the evaluation of only chemistry, quality control or manufacturing information.		5,050
Variations to a Register entry (requiring changes to Product Information) with no evaluation of data 'minor editorial changes'		1,555
Testing and provision of advice, requested from Pharmaceutical Benefits Program, prior to listing on Pharmaceutical Benefits Listing Program (*this item is inclusive of GST)		2,040 (2,244*)

Administrative fees	2014–15 Fee $
Correction of a Register entry	1,555

Annual charges	2014–15 Charge $
Biological Medicines (Biologics)	6,585
Non-Biologics	3,955

Clinical trials	2014–15 Fee $
CTX 30 Days	1,595
CTX 50 Days	19,900
CTN	330
CTN – more than one trialing body	330

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

Total revenues are a factor of the expected activity volume and the fee or charge[2].

Table 2: Prescription medicines revenue estimate

	2013–14 Estimated outcome $m	2014–15 Forecast $m
Annual charges	21.2	23.0
Application fees	10.5	10.3
Evaluation fees	28.7	29.9
Other[3]	2.1	1.8
Total	**62.5**	**65.0**

[2] The costs of the reform program are being recovered over a number of years from the whole therapeutic goods industry.
[3] 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 prescription medicines sector, these are the Office of Medicines Authorisation, Office of Scientific Evaluation, Office of Laboratory and Scientific Services 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 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 registering prescription medicines on the ARTG

	2013–14 Estimated outcome $m	2014–15 Forecast $m
Direct costs	24.5	25.4
Corporate costs	5.3	5.4
Support costs	16.1	15.5
Total	**45.9**	**46.3**

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

	2013–14 Estimated outcome $m	2014–15 Forecast $m
Direct costs	3.3	3.5
Corporate costs	0.7	0.7
Support costs	11.1	11.9
Total	**15.1**	**16.1**

Table 5: Estimated revenue and expenses

	2013–14 Estimated outcome $m	2014–15 Forecast $m
Expenses	61.0	62.4
Revenue	62.5	65.0
Balance	**1.5**	**2.6**

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	55.9	59.4	61.0
Revenue	58.6	64.0	62.5
Balance	**2.7**	**4.6**	**1.5**

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

Attachment A: Fees and charges 2013–14

Fees and charges for the prescription medicine sector for 2013–14 are outlined below.

Registration fees	2013–14 Application Fee $	2013–14 Evaluation Fee $
New Chemical Entity	43,200	173,000
New Chemical Entity of a medicine used as an ancillary medical component of a device (item 4(aa)(i) and 4(aa)(ii))	14,400	57,700
New Chemical Entity of a medicine used as an ancillary medical component of a device (item 4(aa)(iii))	28,800	115,200
Extension of indications	25,700	102,800
Extension of indicators of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing or pre-clinical studies	8,570	34,300
Extension of indicators of a medicine used as an ancillary medical component of a device – documentation mentioned in subparagraphs (i) and (ii)	17,200	68,500
Major variations	16,800	66,900
Major variation of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing or pre-clinical studies	5,590	22,200
Major variation of a medicine used as an ancillary medical component of a device – documentation mentioned in subparagraphs (i) and (ii)	11,200	44,700
New generic product	16,600	66,000
Additional trade name	2,720	10,900
Major variations (Change in formulation, composition, design specifications, type of container or change of trade name)	990	3,940

Variation fees	2013–14 Application Fee $	2013–14 Evaluation Fee $
Variations to a Register entry involving the evaluation of clinical, pre-clinical or bio-equivalence data, but not included in another fee category. Includes applications for changes to Product Information involving the evaluation of clinical, pre-clinical or bio-equivalence data.	990	3,940
Variations to a Register entry involving the evaluation of only chemistry, quality control or manufacturing data. Includes applications for changes to Product Information involving the evaluation of only chemistry, quality control or manufacturing information.		4,930
Variations to a Register entry (requiring changes to Product Information) with no evaluation of data 'minor editorial changes'		1,520
Testing and provision of advice, requested from Pharmaceutical Benefits Program, prior to listing on Pharmaceutical Benefits Listing Program (*this item is inclusive of GST)		1,990 (2,189*)

Administrative charges	2013–14 Fee $
Correction of a Register entry	1,520

Annual charges	2013–14 Charge $
Biological Medicines (Biologics)	6,430
Non-Biologics	3,860

Clinical trials	2013–14 Fee $
CTX 30 Days	1,560
CTX 50 Days	19,400
CTN	320
CTN – more than one trialing body	320

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