Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Cost recovery impact statement

Prescription 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 of prescription medicines onto the Australian Register of Therapeutic Goods (ARTG) and the ongoing monitoring and surveillance of prescription medicines included 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 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 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 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 prescription 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. Analysis of activities

3.1. Key activity components

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 contraceptive pills, antibiotics and strong pain killers.

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[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>

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)

3.2. Registration on the ARTG

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

Applications

All applications for registration of prescription medicines must be preceded by a pre-planning submission form (PPF). TGA will assess all PPFs and provide advice to sponsors to ensure that application dossiers for registration on the ARTG are well-planned, high quality and complete.

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.

Data evaluation

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

- Quality data evaluated by chemists, biochemists, microbiologists, toxicologists 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

Applications to change conditions of registration

Once a product has been registered, the sponsor can make further applications to change the conditions 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)

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.

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.

Export

Medicines for export from Australia must be of a similar quality and safety standard as those supplied domestically.

Export only products are required to be listed (not registered) on the ARTG before export. Broadly, they are expected to meet the same requirements as products listed for supply in Australia. They are assessed using the same criteria as listed products that are intended for supply in Australia. However, they are not required to comply with the labelling standards or advertising standards in force in Australia.

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.

Clinical trials

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

3.3. 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
- Undertaking 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
- 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.

3.4. Reform of business processes

The TGA has started 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
- Reform processes for the evaluation of registration applications
- Develop technology to support business processes
- 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

3.5. Activity level assumptions

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. Estimates of new additions are based on the outcomes of work on assessing products for registering on the ARTG.

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 product with a turnover of not more than 15 times the applicable annual charge.

Table 1 Volume estimates for prescription medicines on the ARTG

	2012-13	2013-14
Prescription medicines – biologics	1,001	1,069
Prescription medicines – non-biologics	12,207	13,028

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, finance, laboratory, legal and information technology support. Regulatory offices have limited or no control over these costs. In allocating support costs, a cost driver was chosen from a range that includes FTE staff numbers, budget size and floor space, based on how closely they 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; 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 the registering of prescription medicines on the ARTG

	2012-13 Estimated outcome $m	2013-14 Forecast $m
Direct Costs	23.6	25.0
Corporate Costs	5.8	5.7
Support Costs	16.0	16.6
Total	**45.4**	**47.3**

Table 3: Costs included in compliance monitoring and enforcement for prescription medicines

	2012-13 Estimated outcome $m	2013-14 Forecast $m
Direct Costs	3.6	4.2
Corporate Costs	0.8	0.8
Support Costs	11.7	12.3
Total	**16.1**	**17.3**

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 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.

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

For the 2013-14 financial year, fees and charges for prescription medicines 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 - 2013-14

Fees and charges for the prescription medicine sector for 2013-14 are outlined below. Fees and charges that applied for the sector for 2012-13 are at Attachment A.

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

Registration Fees	2013-14 Application Fee $	2013-14 Evaluation Fee $
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
Minor 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

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	2014-15 Estimate $m
Annual Charges	19.3	21.8	22.5
Application Fees	10.9	11.0	11.3
Evaluation Fees	32.2	32.7	33.7
Other[4]	2.3	2.4	2.5
Total	**64.7**	**67.9**	**70.0**

[4] Includes fees for services provided for clinical trials and revenues from government in lieu of interest on cash holdings.

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 will be 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.

6. 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 over recovery in the prescription medicines sector. Following the review of the methodology, TGA will consult with the prescription medicines sector on the options to address the over-recovery with the implementation of any changes expected to occur in the 2014-15 financial year.

7. Certification

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

8. Fees and charges 2012–13

Registration Fees	2012-13 Application Fee $	2012-13 Evaluation Fee $
New Chemical Entity	42,000	168,100
New Chemical Entity of a medicine used as an ancillary medical component of a device (item 4(aa)(i) and 4(aa)(ii))	14,000	56,100
New Chemical Entity of a medicine used as an ancillary medical component of a device (item 4(aa)(iii))	28,000	112,000
Extension of indications	25,000	99,900
Extension of indicators of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing or pre-clinical studies	8,330	33,300
Extension of indicators of a medicine used as an ancillary medical component of a device – documentation mentioned in subparagraphs (i) and (ii)	16,700	66,600
Major variations	16,300	65,000
Major variation of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing or pre-clinical studies	5,430	21,600
Major variation of a medicine used as an ancillary medical component of a device – documentation mentioned in subparagraphs (i) and (ii)	10,900	43,400
New generic product	16,100	64,100
Additional trade name	2,640	10,600
Minor variations (Change in formulation, composition, design specifications, type of container or change of trade name)	960	3,830

Registration Fees	2012-13 Application Fee $	2012-13 Evaluation Fee $
Fees for the evaluation of the quality and/or the non-clinical data of a new chemical entity incorporated as an ancillary component of a medical device of therapeutic device.	various	various

Variation Fees	2012-13 Application Fee $	2012-13 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.	960	3,830
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.		4,790
Variations to a Register entry (requiring changes to Product Information) with no evaluation of data 'minor editorial changes'		1,480
Testing and provision of advice, requested from Pharmaceutical Benefits Program, prior to listing on Pharmaceutical Benefits Listing Program (*this item is inclusive of GST)		1,930 (2,123*)

Administrative Charges	2012-13 Fee $
Correction of a Register entry	1,480

Annual Charges	2012-13 Charge $
Biological Medicines (Biologics)	6,250
Non-Biologics	3,750

Clinical Trials	2012-13 Fee $
CTX 30 Days	1,520
CTX 50 Days	18,900
CTN	310
CTN – more than one trialing body	310

Therapeutic Goods Administration

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