Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Cost recovery impact statement

Good manufacturing practice
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 Manufacturing Quality	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 manufacture of medicines. TGA regulates manufacturers through application of Good Manufacturing Practice (GMP) principles.

This CRIS will apply from July 2013 to June 2014.

1.2. Background

The TGA is 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.

In Australia, manufacturers of therapeutic goods are required to hold a licence. To obtain the licence, a manufacturer must demonstrate that they have the ability to comply with manufacturing principles, which include relevant Codes of GMP and Quality Systems, and have appropriate facilities to manufacture safely. Overseas manufacturers of therapeutic goods suppled to Australia must provide evidence of compliance with equivalent GMP standards or otherwise undergo on-site inspections in the same manner as manufacturers based in Australia.

GMP is a generally accepted term internationally to describe a set of principles and procedures that, when followed by manufacturers of medicines, helps insure that the products manufactured will possess the required quality.

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 entities should set charges to recover all the costs of products or services 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 the regulation of therapeutic medicines manufacture.

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 the TG 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

The GMP related regulatory activities undertaken, are as follows:

[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>

Licencing

TGA usually undertakes on-site inspections of Australian manufacturers prior to the issue of a licence to ensure that the manufacturer can comply with the Manufacturing Principles set under the Act and has suitable premises to undertake the proposed manufacturing steps. The extent of the inspection depends on the size and complexity of the manufacturing processes.

The TGA communicates with overseas agencies to ensure that GMP requirements applied in Australia are world best practice.

Monitoring compliance

The TGA undertakes periodic planned and unplanned inspections of licensed manufacturers to assess the level of compliance with the GMP standards, both domestically and overseas. The level and frequency of inspections for a particular manufacturer is influenced by its size and complexity but also its previous compliance history. In particular, manufacturers with a history of lower levels of compliance are subject to a higher frequency of on-site inspections, compared with more compliant manufacturers, to ensure that those lower levels of compliance do not adversely affect the quality and safety of the products that they manufacture.

Investigation and enforcement

The TGA undertakes enforcement activities to promote compliance with the applicable GMP standards by manufacturers. Where a manufacturer breaches GMP, sanctions available range from (but are not limited to) revocation or suspension of the manufacturing licence to restriction of the type, kind or quantity of goods that can be manufactured for the Australian market at that site. Where required, sanctions are decided on a case-by-case basis after consideration of the circumstances involved and the best interests of the Australian consumer. Where the manufacturer is based outside Australia, limits are placed on the ability of sponsors to make the products available on the Australian market.

Information and education

The TGA promotes compliance with the GMP standards by producing guidelines and other informational materials primarily targeted at manufacturers whose products are supplied in Australia. These resources are made available through the TGA website. In addition, the TGA conducts seminars and information briefings to raise awareness of regulatory requirements, particularly when changes are proposed.

TGA contributes strongly to international programs to improve and harmonise manufacturing practices in developing regions through international meetings, seminars and training events.

Policy development and services to government

The TGA provides services to Government in relation to the regulation of manufacturers, including specific technical and policy advice that is considered to be integral to the regulation of manufacturers.

Broader policy advice is generally provided by DoHA as part of its tax payer funded activities and is not included in the fees and charges.

Reform of business processes

TGA has embarked on a series of reforms designed to improve its communication and engagement with the community. The reform program is detailed in the report *TGA reforms: a blueprint for TGA's future* which can be accessed from the TGA website.

Reform activities in the GMP sector aim to

- Provide more information on the regulatory framework so that stakeholders understand the regulatory processes and requirements
- Improve the usability, accuracy and consistency of supporting guidelines
- Consolidate trans-Tasman inspection processes
- Improve stakeholder understanding and confidence in the regulatory processes
- Make reliable and relevant information easily accessible to stakeholders
- Develop technology to support business processes
- Reform the charging structures for the GMP compliance program
- Develop closer relationships with international regulators
- Pursue administrative efficiencies in relationships with industry

3.2. 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 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, 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 it approximates 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 GMP sector, this is the Office of Manufacturing Quality.

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 1: Costs included in the GMP sector

	2012-13 Estimated outcome $m	2013-14 Forecast $m
Direct Costs	5.9	6.1
Corporate Costs	1.7	1.7
Support Costs	2.4	2.4
Total	**10.1**	**10.2**

3.3. Outline of charging structure

The cost of regulating therapeutics manufacturers is recovered through inspection fees and annual licence charges.

Licence and Inspection fees

Fees are used to recover the cost of the premarket services performed. For licensed domestic manufacturers, the fee structure is based on the licence and inspection fees. Prior to being granted an Australian licence, a domestic manufacturer is subject to an on-site inspection to ensure it could comply with the GMP code and standards and has suitable premises to conduct the manufacturing steps it proposes. The cost of the site inspection is based on the number of on-site hours, which reflects the size and complexity of the manufacturer's facilities. The inspection fee reflects the full cost of undertaking the inspection, including travel and preparation time.

Overseas manufacturers are not able to hold an Australian licence, but they must demonstrate that they operate to an acceptable manufacturing standard before being granted access to the Australian market. Evidence relating to manufacturing standards is accepted from other Government authorities or may be achieved through an on-site inspection.

Overseas manufacturers are not subject to an annual licence charge. Inspections to approve overseas manufacturers attract an hourly fee for time on site, together with ancillary costs. Approval of an overseas manufacturer through the compliance verification process attracts one or more fixed fees per application.

Annual licence charges

All domestic manufacturers of medicines are required to hold a licence with the level of annual charge reflecting the risk and complexity of the products manufactured. The TG Regulations prescribe a higher and lower annual charge for operations of higher and lower complexity. An allowance for the cost of periodically inspecting the manufacturer's facilities is included in the annual charge, based on an estimated typical inspection required to routinely ensure compliance with the GMP code and standards. Compliant manufacturers are inspected less frequently and thus an incentive for compliance is built into the charges.

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.

3.4. Fees and charges

The fees and charges for 2012-13 and 2013-14 are in the tables below. 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).

Table 2: GMP Fees

Good Manufacturing Practice Fees	2012-13	2013-14
Licence application fee (excluding Biologicals)	$890	$920
Australian Manufacturers – GMP Inspection Fee for all types of therapeutic goods	Hourly rate per Inspector $580	Hourly rate per Inspector $600
Overseas Manufacturers – GMP Inspection Fee for all types of therapeutic goods	Hourly rate per Inspector $1,190	Hourly rate per Inspector $1,220
Overseas manufacturers - Assessment of GMP evidence (per manufacturer, per site and per sponsor)	$340	$350
Overseas manufacturers - Obtaining evidence from overseas regulatory agency (per manufacturer, per site and per sponsor)	$600	$620

Good Manufacturing Practice Fees	2012-13	2013-14
Overseas manufacturers - Reinstatement of expired GMP clearance approval (per manufacturer, per site and per sponsor)	$1,020	$1,050
Overseas manufacturers - Compliance verification (in-lieu of an overseas GMP inspection)	$1,820	$1,870
Certificate of GMP Compliance	$140	$150
Quality Systems Certificate	$140	$150

Table 3 GMP Charges

Good Manufacturing Practice Annual Licence Charges	2012-13	2013-14
Low level GMP licence • Single step / single medicine / single type of therapeutic device • In-vitro diagnostic products • Ingredients or components • Herbal / Homeopathic medicinal products	$5,600	$5,760
High level GMP licence • Other types of therapeutic goods, including containers in which therapeutic goods are to be packed	$10,900	$11,200

An allowance for inspection hours is incorporated in the annual licence charge. For manufacturers with low level licence charges, a total of 16 inspection hours over 3 financial years are included. For manufacturers with high level licence charges, a total of 48 inspection hours over 3 financial years are included. Standard GMP inspection fees are payable once the available hours have been exceeded.

3.5. Revenues

Total revenues are a factor of the expected activity volume and the fee or charge. In addition, reasonable travel expenses are recovered at cost.

Estimated revenues are as follows:

Item	Estimated Volume[4] 2012-13	Estimated Revenue 2012-13	Forecast Volume 2013-14	Forecast Revenue 2013-14
Licence application fee (excluding Biologicals)	37.2	$33,108	35	$32,200
Australian Manufacturers – GMP Inspection Fee for all types of therapeutic goods	1,064.2	$617,236	1,065	$639,000
Overseas Manufacturers – GMP Inspection Fee for all types of therapeutic goods	3,891	$4,630,290	4,228.5	$5,158,770
Overseas manufacturers - Assessment of GMP evidence (per manufacturer, per site and per sponsor)	3,212.4	$1,092,216	3,200	$1,120,000
Overseas manufacturers - Obtaining evidence from overseas regulatory agency (per manufacturer, per site and per sponsor)	661.2	$396,720	645	$399,900
Overseas manufacturers - Reinstatement of expired GMP clearance approval (per manufacturer, per site and per sponsor)	-	$0	-	$0
Overseas manufacturers - Compliance verification (in-lieu of an overseas GMP inspection)	310.8	$565,656	325	$607,750
Certificate of GMP Compliance	129.6	$18,144	0	$0
Quality Systems Certificate	26	$3,640	0	0
Low level GMP licence • Single step / single medicine / single type of therapeutic device • In-vitro diagnostic products • Ingredients or components • Herbal / Homeopathic medicinal products	103	$576,800	101.5	$584,640

[4] Volumes are based on work completed and thus revenue earned.

Item	Estimated Volume[4] 2012-13	Estimated Revenue 2012-13	Forecast Volume 2013-14	Forecast Revenue 2013-14
High level GMP licence • Other types of therapeutic goods, including containers in which therapeutic goods are to be packed	167	$1,820,300	171.5	$1,920,800
Total cost recovery revenue		$9,754,110		$10,463,060
Other Revenues • interest • recovery of travel costs	n/a	$1,321,000		$1,112,000
Total Revenue		**$11,075,110**		**$11575,060**

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 recovers the full costs of its regulatory services from industry. Fees and charges were historically established through an Activity Based Costing (ABC) methodology and indexed to maintain currency.

Fees and charges for GMP assurance are established to reflect as closely as possible the costs of undertaking the individual activities.

In 2012, TGA commenced a review of its ABC model, including undertaking an effort collection exercise. Analysis of the effort data and the review of the impact of the fees and charges have indicated presence of an over-recovery and that a structural review of the fees and charges for the GMP sector is warranted.

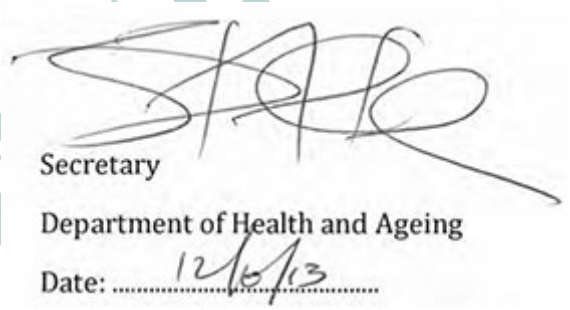
In reviewing the underlying structures of the fees and charges, TGA will take into consideration any changes in business processes, such as a move to greater reliance on compliance verifications over on-site inspections; ensuring that the charging regimen is consistent with compliance with good manufacturing practices; and minimising administrative effort in managing inspections. A key objective will also be to tighten the nexus between activities for which fees are charged and the scheduled fee.

The review may result in the establishment of a new suite of fees and charges. Rather than implementing significant changes arising from the ABC review to the current fees and charges for 2013-14 and then implementing additional changes following the structural review, TGA has opted to combine the processes and update fees and charges once.

TGA aims to have the changes implemented for the 2015-16 financial year and these will be documented in a new CRIS.

7. Certification

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



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