



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Administration

COST RECOVERY IMPACT STATEMENT

May 2009

ANNUAL REVIEW OF FEES AND CHARGES 2009-10

PRESCRIPTION MEDICINES

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1 OVERVIEW

1.1 Purpose

The Therapeutic Goods Administration (TGA) is proposing to increase prescription medicines fees and charges by 6.6 per cent for 2009-2010. The increases are planned to take effect from 1 July 2009.

The Department of Finance and Deregulation (DoFD) new cost recovery guidelines stipulate that if an agency with gross cost recoveries over \$5m were to increase fees by more than CPI, they are required to complete a cost recovery impact statement. TGA's budgeted gross cost recoveries for 2009-2010 are \$99.9 million.

1.2 Background

The TGA is a business unit within 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 Australia and their export. The TGA is a full cost recovery agency and derives its operating income from regulatory 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. The TGA is one of the world's front line regulators undertaking rigorous scientific and risk assessments of therapeutic products to ensure safety, quality and efficacy, without undue impact on the timely supply of essential products to consumers and patients.

Most products for which therapeutic claims are made must be assessed by the TGA and entered on the Australian Register of Therapeutic Goods (ARTG) before they can be marketed in Australia. The ARTG keeps a record of products that are approved for marketing, the ingredients contained in each product, the therapeutic claims made for medicines, and the intended use of medical devices. The TGA also regulates fresh blood, blood components and banked human tissues. These products are not generally included on the ARTG; their regulation is through audit and licencing of manufacturers and compliance with standards.

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. Subsequent entries on the ARTG are classified as either 'registered' or 'listed', or in the case of medical devices 'included'.

The TGA recovers the cost of all activities undertaken that are within the scope of the Therapeutic Goods Act 1989 (the Act).

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Fees and charges are prescribed in regulations made under the Therapeutic Goods Act 1989, and the Therapeutic Goods (Charges) Act 1989.

The TGA reviews its fees and charges each year in consultation with stakeholders through the TGA-Industry Consultative Committee (TICC). The TICC provides a forum to exchange information on industry trends and regulatory expectations, discuss the development of the TGA's corporate plan and annual business plans and budget, as well as consulting on fees and charges proposals.

TGA and Industry have an agreed indexation model based on the application of an index factor each year. The factor is a 50-50 composite comprising the Australian Bureau of Statistics' Consumer Price Index (CPI) and the Wage-Cost Index (WCI). The composite index for 2009-2010 was calculated based upon the CPI/WCI for the 12 months to September 2008. The model aimed to improve the predictability of fees and charges for industry budgetary planning as well as providing a guide to promote TGA's operational efficiency. Fee or charge increases above this level are subject to further consultation with industry.

In 2005 the TGA completed a comprehensive review of its fees and charges. The review was triggered by the promulgation of the Australian Government's cost recovery policy and found that the TGA's cost recovery arrangements complied with the Government's cost recovery guidelines. The TGA will undertake another "whole of agency" review of its fees and charges in the second half of 2009 which will include the completion of an agency CRIS.

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 Australian Government policy objectives. Cost recovery policy is administered by the DoFD 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 REVIEW – ANALYSIS OF TGA'S ACTIVITIES

This CRIS deals with the TGA's proposal to increase fees and annual product charges in the prescription medicines sector above the agreed rate of indexation.

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There has been no change to the policy underpinning the TGA's fees and charges arrangements, nor at this time there any proposals to alter the design of the fees and charges structure. These matters were discussed in detail in the 2005 CRIS for the regulation of therapeutic products, which were found to be compliant with the Government's cost recovery guidelines. The key attributes of the frame work are as follows:

- Companies (product sponsors and manufacturers) that give rise to the need for regulation should pay cost recovery charges, as it is not cost effective to impose fees on individuals. The cost of regulation is expected to be incorporated in pricing decisions for products;
- Fees and charges should be structured to ensure full cost recovery for the regulated sector - there is no inconsistency with other government policies, and there is no evidence that the proposed increases would result in a reduction in industry innovation or impact on competition;
- Fees are used for pre-market services performed. These should reflect as closely as possible the underlying cost of the activities performed. Annual product or licence charges (a levy) are used to recover costs that cannot be reasonably assigned to individual firms;
- The fees and charges are set by regulations pursuant to the Therapeutic Goods Act 1989 and the Therapeutic Goods (Charges) Act 1990;
- The administrative arrangements for cost recovery are simple and are cost-effective (online payment has improved efficiency); and
- Fees and charges will continue to be monitored by the TICC to find the appropriate balance between fee predictability/stability and full cost recovery in the most cost-effective manner. The TICC meets twice annually and is supplemented with structured sectoral (industry) bilateral meetings.

3 DESIGN AND IMPLEMENTATION

3.1 Basis of Charging – Fee or Levy

Fees are used for pre-market services performed. These reflect as closely as possible the underlying cost of the activities performed.

Annual product charges (a levy) are used to recover costs that cannot be reasonably assigned to individual firms. No change is being made to the current basis of charging.

3.2 Legal Requirements for the Imposition of Charges

The TGA recovers the full cost of all activities undertaken within the scope of the Therapeutic Goods Act 1989 (the Act). Partial cost recovery was introduced in 1991 following the commencement of the Act, with full cost recovery implemented in 1998.

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Fees and charges are prescribed in regulations made under the Therapeutic Goods Act 1989 and the Therapeutic Goods (Charges) Act 1990, specifically the *Therapeutic Goods Regulations 1990* (the TG Regulations); the *Therapeutic Goods (Medical Devices) Regulations 2002* (the TG (Medical Devices) Regulations); and the *Therapeutic Goods (Charges) Regulations 1990* (the TG (Charges) Regulations).

3.3 Costs to be Included in Charges

For regulatory products or services, cost recovery fees and charges ideally should reflect as closely as possible the costs of undertaking individual activities.

The TGA uses an activity based costing methodology for the assignment and allocation of all direct, indirect and overhead costs to activities undertaken. The methodology allows costs to be allocated to activities based on their consumption at each stage of the process through to the final product or service. Activity based costing facilitates product costing and pricing, cost analysis and management, resource planning and industry reporting.

A two-stage process is used to firstly attribute costs for corporate services, such as rent and information technology, to each business unit, including support services. Then a second step is used to assign these costs to regulatory activities.

The TGA's total expenses are broadly categorised in to the following three categories to ensure costs are 'materially' allocated correctly and to provide transparency:

- i. Direct Costs;
- ii. Corporate Costs; and
- iii. Support Costs.

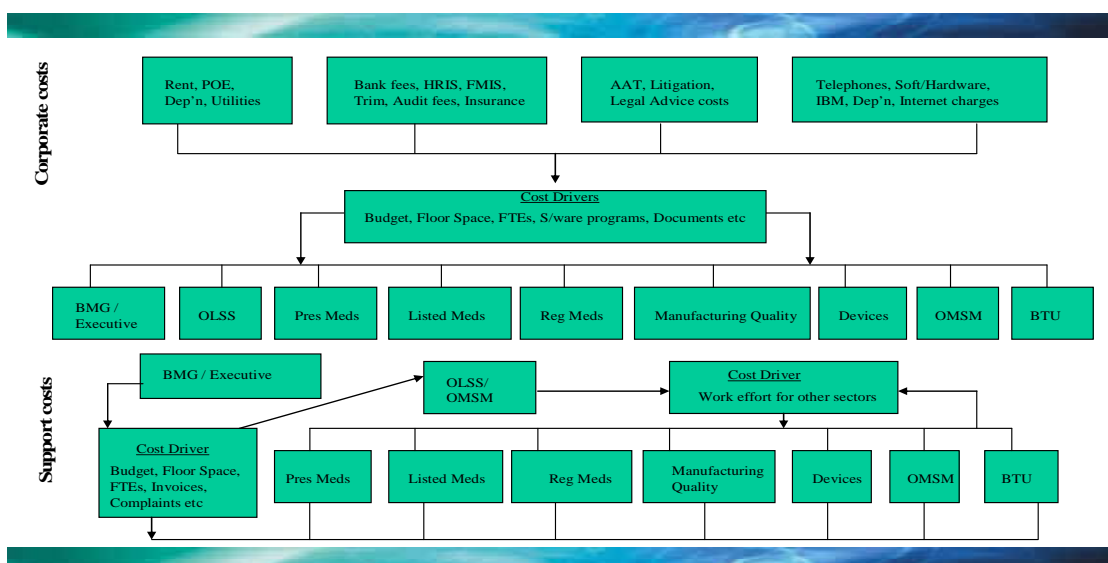
Direct Costs: These are expenses that are directly related in performing the regulatory activity and mainly include labour costs. Labour costs are based on the current DoHA Certified Agreement, plus appropriate allowances for on-costs.

Corporate Costs: Corporate costs, such as rent and information technology, are costs that Business Units can control the 'consumption' of, but not the unit price. For example, a Business Unit controls the total floor space occupied, but not the unit cost. The allocation of corporate costs (including amortisation and depreciation costs related to capital assets) use a range of drivers, including the number of transactions processed, staff numbers, workstations, or floor-space.

Support Costs: Support costs include costs for providing support services such as laboratory services, human resources, and financial services. Business Units have very limited or no control over these expenses. For example, accounts payable costs are allocated based on the number of invoices processed for the Business Unit as a percentage of the TGA total.

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TGA cost allocations



The TGA has advised industry of the following direct, corporate and support cost allocations for 2008-2009 and 2009-2010 forecasts.

\$(m)	2008-09 Forecast	2009-10 Forecast
Direct Cost (Employee and Supplier cost)	14.709	14.874
Corporate Cost (ABC allocation of rent, POE, computer exp, depreciation)	3.276	3.125
Support Cost (ABC allocation of Executive, HR, Finance, Legal, Enforcements, Labs and other business areas cost)	27.767	30.453
Total Industry Cost	45.752	48.452

3.4 Reasons for fees and charges increase

The TGA have forecast an overall \$0.4 million net cost recovery deficit for 2009-2010 after the proposed fees and charges increases. The forecast deficit would require the TGA to call on its retained surpluses, which are expected to be \$19 million by 30 June 2009.

The TGA has undertaken a detailed budgeting exercise for 2009-2010 after reviewing its business plan for the same period. Throughout this budget cycle, with detailed analysis of the TGA expenditure budgets, every effort was taken to reduce cost where possible without significantly affecting the ability to deliver the TGA business plan.

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The TGA's stakeholders are aware of the TGA aim of maintaining retained surpluses which are the equivalent of (up to) three months of operating expenses. Including the expected deficit of \$3.3 million in 2008-2009, the TGA forecast reserves of \$19 million at 30 June 2009. This retained surplus will be used to offset the 2009-2010 forecasted deficit of \$0.4 million.

The TGA is proposing to increase prescription medicines fees and charges by 6.6 per cent for 2009-2010. The increases are planned to take effect from 1 July 2009.

The TGA expects the 2009-2010 revenue volumes to remain (approximately) at 2008-2009 forecast levels.

The TGA 2009-2010 budget forecast is a net cost recovery deficit of \$0.4 million; with revenue forecast to increase by \$8.6 million; whilst expenditure is forecast to increase by \$5.9 million.

The industry and TGA has agreed that a CRIS should be prepared if the proposed price increases are above the agreed composite indexation rate. The agreed indexation rate for 2009-2010 is 4.3 per cent.

If the TGA applies a 4.1 per cent increase to 2008-2009 forecasted employee expenses (*in accordance with the DOHA Certified Agreement*); and a 3.6 per cent increase to non employee expenses; the resulting cost increases for 2009-2010 will be (approximately) \$3.8 million. Notwithstanding these forecasted increases, the TGA also expects to incur a further \$1.5 million increase in expenditure in 2009-2010 [above 2008-2009 forecast levels] resulting directly from the implementation of the following range of initiatives:

- transparency initiatives to increase publicly available information about regulatory decision making, improved monitoring of product safety;
- simplification and/or deregulation of many existing requirements (such as the fit and proper person test, default pharmacopoeial requirements, suspension of registration, civil infringements regimen);
- additional resources will be recruited into the manufacturing quality and assessment program to meet the growing demand from industry for domestic and international on-site audits and inspections; and
- enhancing the robustness of administrative decision-making within the TGA.

Prescription Medicines Business Process Redesign

From 2009, the TGA began a business process redesign project which is aimed at delivering real efficiencies in the prescription medicines sector and its corporate support areas.

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The key objectives of the Prescription Medicines Business Process Review (BPR) include:

- accelerated application entry processes, specifically, the business process review will examine options to reduce the timeframes to market by replacing the current 40 day application entry process with an improved pre-submission process;
- improved application coordination to reduce timeframes to market through better application coordination. This is likely require the TGA to move to a single set of questions to industry sponsors; and implementation of a more coordinated approach for the receipt of medicines applications through (for example) regular, pre-set submission dates; and
- increased transparency of the prescription medicine regulatory process through the publication of an Australian Public Assessment Report on the TGA Website.

The TGA expects that the Prescription Medicines BPR will be completed during the second quarter of the 2009-2010 financial year. The flow on effect of efficiencies will be delivered to industry sponsors soon thereafter. The costs for the BPR are recognised in the 6.6 per cent increases which have been proposed for prescription medicines fees and annual charges in 2009-2010.

The TGA consulted with industry associations on the new initiatives (including the BPR) as part of its business planning process in November 2008. Industry were generally supportive of the initiatives, particularly the BPR for which industry have previously expressed high expectations.

In addition to the above mentioned cost pressures, the TGA expects to incur additional legal costs related to an increase in case work related to Freedom of Information requests (FOI); the Administrative Appeals Tribunal (AAT); and other Federal Court actions. These increases will be partially off-set by a reduction in information technology (IT) business as usual costs because the TGA was required to reduce these costs by 2.5 per cent [or \$0.2 million] in 2009-2010 as part of the Gershon savings. The TGA has complied with this requirement.

The TGA is planning to further increase activities in medicines safety monitoring due to this refocusing to ensure consistent regulation throughout the life-cycle of products. This increase in activity will contribute to the prescription medicines sector's forecast cost increases during the 2009-2010.

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The TGA considers the ongoing monitoring of medicines safety to be an integral part of the TGA's regulatory framework. The planned increase in work efforts to continue monitoring product safety should therefore remain. The TGA believes that reducing or limiting the effort would only serve to increase health and safety risks to the Australian public and a possible cost to public and the government which is disproportionate to the increase in regulatory costs.

The revenue and expenditure for 2008-2009 and 2009-2010 forecasts including a nil increase, 4.3 per cent increase and a 6.6 per cent increase in fees and charges are set out below:

\$(m)	2008-09 Forecast	2009-10 Forecast with nil increase in fees and charges	2009-10 Forecast with 4.3% increase in fees and charges	2009-10 Forecast with 6.6% increase in fees and charges
Revenue	45.704	45.763	47.730	48.783
Expense	45.752	48.452	48.452	48.452
Net Operating Result	(0.048)	(2.689)	(0.722)	0.331

The TGA believes that its current revenue volume forecast for prescription medicines sector is slightly optimistic given the current global financial crisis. As such TGA believes the proposed fees and charges increase by 6.6 percent should remain despite the forecasted minor surplus for the sector. As the forecast surplus is less than the value of two evaluations for new chemical entities, a reduction in volume of less than 0.7 per cent will result in a deficit for the sector.

The actual results for 2004-2005 to 2007-2008 are set out below:

\$(m)	2004-05 Actual Surplus/(Deficit)	2005-06 Actual Surplus/(Deficit)	2006-07 Actual Surplus/(Deficit)	2007-08 Actual Surplus/(Deficit)
Prescription Medicines	3.522	(1.495)	0.948	5.546

Low volume turnover declaration application fees

Low volume turnover application fees apply to any therapeutic product (including registered) where the product annual charge exceeds 6.8 per cent of the estimated or actual value of wholesale sales turnover of a product. The exemption aims to reduce the regulatory cost for products with very low circulation.

In 2009-2010, the TGA expects to issue annual charges invoices for (approximately) 6,120 prescription medicine products which are registered on the ARTG. The revenue from these invoices will however be offset by 1,810 prescription medicines products which are likely to qualify for LVLV exemption *and therefore only be subject to the \$130 LVLV application fee, not the applicable \$5,600 or \$3,350 (biological or non biological respectively) annual product charge.*

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For 2009-2010, the low value low volume (LVLV) application processing fee will be increased by 4.3 per cent (up from \$120 to \$130 rounded), *as the fee is common across all sectors.*

3.5 Proposed Fees and Charges

The current and proposed fees and charges are shown in the table below:

Fees and Charges	Basis of Charge	Current Fee	Proposed Fee	Forecasted Volumes for 2009-10	Forecasted Revenue for 2009-10
New Chemical Entity Evaluation	Per application	\$176,300	\$188,000	36	\$6,768,000
Extension of Indicators Evaluation	Per application	\$104,800	\$112,000	47	\$5,264,000
Major Variation Evaluation	Per application	\$68,300	\$72,800	48	\$3,494,400
New Generic Product Evaluation	Per application	\$67,300	\$71,700	109	\$7,815,300
Additional Trade Name Evaluation	Per application	\$11,100	\$11,800	66	\$776,794
Variation involving only chemical, quality control & manufacturing information	Per application	\$4,020	\$4,290	1001	\$4,292,488
Changes to Product Information Involving Data Evaluation	Per application	\$4,020	\$4,290	30	\$128,700
Changes to Product Information Involving No Evaluation	Per application	\$1,240	\$1,320	51	\$67,320
Self Assessable Charges & Safety Related Notification	Per notification	\$1,240	\$1,320	1740	\$2,296,800
Biologics Annual Charge	Per registration	\$5,250	\$5,600	377	\$2,111,200
Non Biologics Annual Charge	Per registration	\$3,140	\$3,350	3933	\$13,175,550
Other Revenue (Clinical Trials, LVLV, interest and other minor revenue)					\$2,591,995
Total Prescription (Registered) Medicines Revenue					\$48,782,547

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3.6 Registered Prescription Medicines Fees - Sponsor Impacts

The 6.6 per cent increase in registered prescription medicines evaluation fees will represent:

- between an additional \$80 and \$270 per application for a *low or nil level* evaluation, (e.g.) Safety Related Notification to Change to Product Information Evaluation;
 - 64 per cent of low level evaluations forecasted to be performed in 2009-2010 will be subject to the \$80 increase (only)
- an additional \$700 per application for a *medium level* (e.g.) Additional Trade Name Evaluation; and
- between an additional \$4,400 and \$11,700 per application for a *high level* evaluation, (e.g.) New Generic Product Evaluation to New Chemical Entity Evaluation.
 - 65 per cent of high level evaluations forecasted to be performed in 2009-2010 will be subject to modest increases of no greater than \$4,500.

Table 1. Registered Prescription Medicines Fees

Fees	Current Fee	Proposed Fee	Variance	Forecasted Volumes 2009-2010	%
High					
New Chemical Entity Evaluation	\$176,300	\$188,000	\$11,700	36	15%
Extension of Indicators Evaluation	\$104,800	\$112,000	\$7,200	47	20%
Major Variation Evaluation	\$68,300	\$72,800	\$4,500	48	20%
New Generic Product Evaluation	\$67,300	\$71,700	\$4,400	109	45%
Medium					
Additional Trade Name Evaluation	\$11,100	\$11,800	\$700	66	100%
Low or Nil					
Variation involving only chem., qual control & manufacturing info	\$4,020	\$4,290	\$270	1001	35%
Changes to Product Information Involving Data Evaluation	\$4,020	\$4,290	\$270	30	1%
Changes to Product Information Involving No Evaluation	\$1,240	\$1,320	\$80	51	2%
Self Assessable Charges & Safety Related Notification	\$1,240	\$1,320	\$80	1740	62%
Note. The maximum increase of \$11,700 affects only 15 per cent of high level evaluations (or less than 1.2 per cent of all registered prescription medicine evaluations forecasted for 2009-2010)					

The increased evaluation fees are likely to represent only a small fraction of the cost of bringing a registered prescription medicine product to market and are not expected to impact on the development of products introduced into Australia.

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3.7 Registered Prescription Medicines Charges – Sponsor Impacts

The 6.6 per cent increase in annual charges for biological and non biological registered prescription medicines is not expected to make any significant impacts on the number of products entered on the ARTG, nor on product pricing. As shown in the Table 2.1 and 2.2, the availability of the low turnover exemption from annual charges limits the impact of the annual charges increase to 0.4 per cent of the product shelf price per unit.

Table 2.1 Registered Prescription Medicines (Biological) Charges

	Annual Charge	Low Turnover Threshold	Units (\$30ea)
Current	\$5,250	\$77,206	2,574
Proposed	\$5,600	\$82,353	2,745
Fee increase per unit			\$0.13
Percent of price			0.4%

Table 2.2 Registered Prescription Medicines (Non Biological) Charges

	Annual Charge	Low Turnover Threshold	Units (\$30ea)
Current	\$3,140	\$46,176	1539
Proposed	\$3,350	\$49,265	1642
Fee increase per unit			\$0.13
Percent of price			0.4%

Note. There is no impact on price where sales volume is less than the low turnover threshold.

The impact per product reduces based on the total sales volume (as many products sell well above the low-turnover threshold) as well as the price of each product. As shown in table 3.1 and 3.2, the maximum increase for the price of each product is 0.58 per cent. The increase in each category falls sharply when the sales volume per product rises above 5,000 units (to as little as 0.07 per cent based on a \$30 unit price per product).

Table 3.1 Impact per Biological Product – Sales Volume

Sales volume	Charge increase	Charge per Unit	Units (\$30ea)
2000 units	\$350	\$0.18	0.58%
5000 units	\$350	\$0.07	0.23%
10000 units	\$350	\$0.04	0.12%

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Table 3.2 Impact per Non Biological Product – Sales Volume

Sales volume	Charge increase	Charge per Unit	Units (\$30ea)
2000 units	\$210	\$0.11	0.35%
5000 units	\$210	\$0.04	0.14%
10000 units	\$210	\$0.02	0.07%

Note. The increase for the price of each product is less than 1 per cent.

4 ONGOING MONITORING

4.1 Monitoring and Consultation

The primary mechanism used to monitor TGA activities, performance and costs is the TGA-Industry Consultative Committee (TICC). The TICC meets twice each year to examine the budget and progress on the business plan, with industry associations consulted separately on regulatory matters and cost impacts relating to specific sectors. Industry associations are also consulted in the process of regulatory development and reform, which are taken into account in regulatory impact statements, and in developing cost recovery arrangements.

Due to the uncertainty surrounding the estimated revenue for 2008-2009 and 2009-2010 caused by the Global Financial Crisis the TGA met with individual industry sectors twice (late 2008 and mid March 2009) to discuss its draft business plans and budgets. At the meeting between the TGA, Medicines Australia (MA), and the Generic Medicines Industry Association (GMIA) on the 17 March, MA and GMIA were advised of the TGA proposal to increase fees and charges by 6.6 per cent.

Industry Submissions

The TGA received three submissions (from MA, GMIA and the Royal College of Physicians (RACP) respectively) responding to the prescription medicines draft CRIS published on the TGA web site.

Submission 1

On 9 April 2009, an industry body wrote to the TGA and in general did not oppose the proposed 6.6 per cent increase to prescription medicines.

TGA Reply

The TGA noted the industry body support.

Submission 2

On 9 April 2009, a second industry body wrote to the TGA and in general did not oppose the proposed 6.6 per cent increase to prescription medicines, however did note that the proposed increases were significantly higher than the current rate of inflation. The

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industry body emphasised the importance [to its members] that the TGA's Business Process Review (BPR) of the prescription medicines sector is not jeopardised and that regulatory and business reforms are implemented as soon as is practicable.

TGA Reply

The TGA is aware of the high expectations from industry for the timely completion of the prescription medicines BPR. The TGA will maintain its commitment to completing and then implementing BPR outcomes for the benefit of the TGA and industry.

Submission 3

On 9 April 2009, a third body wrote to the TGA to discuss Quality Use of Medicines initiatives out of TGA funding [independent from industry funding], expressing concerns that changes to Product Information (PI) and Consumer Medicines Information (CMI) will limit the affordability of products which are already being used for long standing accepted 'off label' use.

TGA Reply

The TGA has calculated that the impact of the proposed increases on product sponsors [as detailed in 3.6 "Sponsor Impacts Fees" and 3.7 "Sponsor Impacts Charges"] only represents a very marginal increase of between 0.07 per cent and 0.35 per cent to the price of each product.

Separately, the TGA does not mandate policy for off-label use of prescription medicine products as the *Therapeutic Goods Act 1989* neither prohibits nor sanctions off-label use of prescription medicines.

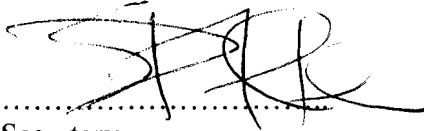
- a. the prescription and administration of medicines is subject to State or Territory legislation. The responsibility is on the prescriber to adhere to relevant State or Territory legislation for such use.

4.2 Periodic Review

The Cost Recovery Guidelines require that all cost recovery arrangements are subject to periodic review no less frequently than every five (5) years. A TGA wide review of cost recoveries for all products will be conducted in 2009-2010. The TGA believes the review will move industry sectors towards full cost recovery in future years.

5 CERTIFICATION

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



Secretary
Department of Health and Ageing

Date: 15/10/07

6 REFERENCE

6.1 Cost Recovery Links

The Australian Government Cost Recovery Guidelines and the accompanying Finance Circular are available on the Department of Finance and Deregulation Website.

- <http://www.finance.gov.au/financial-framework/financial-management-policy-guidance/cost-recovery.html> refers.

For proposals that involve regulations or amendments to regulations that affect business, a Regulation Impact Statement (RIS) is required. Further information regarding RIS is available from the Office of Best Practice Regulation.

- <http://www.finance.gov.au/obpr/index.html> refers.