

CRIS – Complementary Medicines



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

COMPLEMENTARY MEDICINES

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1 OVERVIEW

1.1 Purpose

The Therapeutic Goods Administration (TGA) is proposing to increase complementary medicines fees and charges by 14.3 per cent for 2009-2010. The increases are planned to take effect from 1 July 2009.

The Department of Finance and Deregulation new cost recovery guidelines stipulate that if an agency with gross cost recoveries over \$10 million 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 1990.

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 complementary medicines sector above the agreed rate of indexation.

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 cost recovery impact statement 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 fee 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 charges (a levy) are used to recover costs that cannot be reasonably assigned to individual firms.
- The fees and charges are set by regulation 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).
- Fees and charges will continue to be monitored by the TGA-Industry Consultative Committee to find the appropriate balance between fee predictability/stability and full cost recovery in the most cost-effective manner. The Committee meets twice annually and is supplemented with structured bilateral industry 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.

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 into the following three categories to ensure costs are 'materially' allocated correctly and to provide transparency:

- a) Direct Costs;
- b) Corporate Costs; and
- c) Support Costs

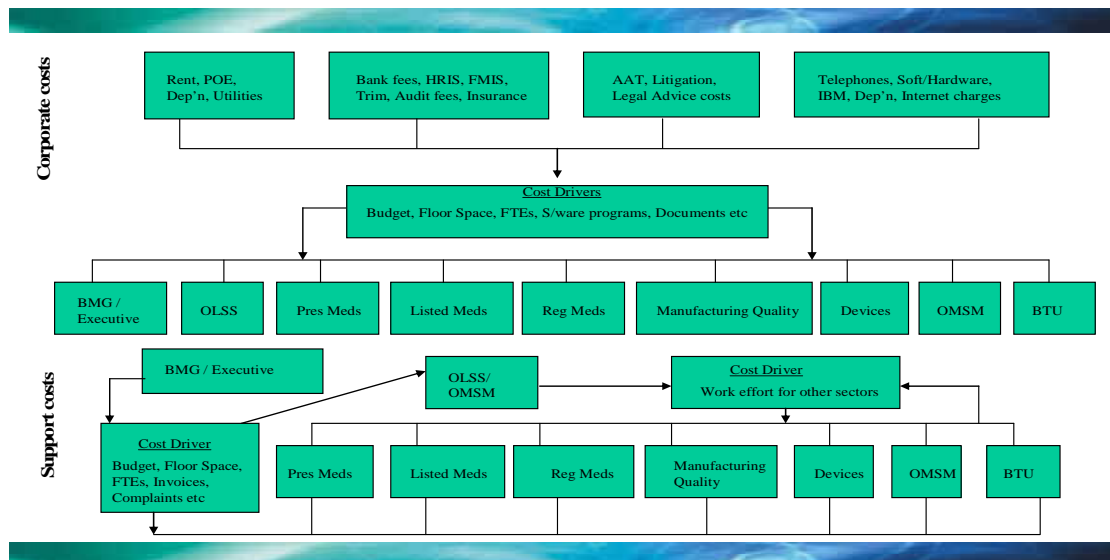
Direct Costs: These are expenses that are directly related in performing the regulatory activity and mainly include labour costs. Labour costs are based on the current DoHA Certified Agreement, plus appropriate allowances for on-costs.

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.

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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.

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)	3.489	4.038
Corporate Cost (ABC allocation of rent, POE, computer exp, depreciation)	0.958	0.752
Support Cost (ABC allocation of Executive, HR, Finance, Legal, Enforcements, Labs and other business areas cost)	4.771	5.290
Total Industry Cost	9.218	10.079

3.4 Reasons for fees and charges increase

The TGA has 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 the budget cycle, with detailed analysis of the expenditure budgets, the TGA has taken every effort to reduce costs where possible without significantly affecting the ability to deliver the TGA business plan.

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 complementary medicines fees and charges by 14.3 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) \$3.8m. Notwithstanding these forecasted increases, the TGA also expects to incur a further \$1.5m 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.

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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 consulted with the industry on these new initiatives as part of its business planning process in November 2008. Industry was generally supportive of the initiatives.

The forecasted cost increases for the complementary medicines sector in 2008-2009 and 2009-2010 are mainly due to an increased level of pre and post market safety and monitoring activities, including regulatory compliance and laboratory testing of complementary medicines products.

The increased focus on harmonisation of international regulatory controls and increased expectations from the public in terms of timely access to a range of therapeutic goods that are safe and appropriately promoted, have resulted in a refocussing of efforts to enhance regulation throughout the life cycle of product. The ongoing safety monitoring of medicinal safety of products is integral to the TGA's regulatory framework. This planned increase in work effort to continue monitoring product safety, throughout the product life cycle, should therefore remain. 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 regulatory compliance expenditure increase is due to the ever increasing number of products purporting to be complementary medicines, entering the Australian market that are not meeting the regulatory requirements. These include products that are not registered or listed on the Australian Register of Therapeutic Goods (ARTG), do not comply with required standards and/or do not conform to advertising requirements (the TGA allocates significant resources solely for the purpose of responding to and dealing with advertising complaints in relation to this sector).

The food-medicine interface is highly dynamic with new products emerging almost daily that challenge the effectiveness of the existing regulatory framework. An equally dynamic regulatory response is therefore needed, particularly in circumstances where new and emerging products, for example "sport foods", are found to be making unsubstantiated therapeutic claims or contain contamination by prescription only substances.

Equally challenging to maintaining the regulatory framework is the ease of access to certain products from overseas which are obtained via the Internet, for example, products that are classified as dietary supplements in the United States but are regarded as complementary medicines in Australia. Some other products claim to be herbal or natural products, but are adulterated with prescription pharmaceuticals.

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The products that are detected are analysed by the TGA laboratories (incurring additional cost) and in most cases are found to be contaminated with prescription only substances or counterfeit products, both of which are considered a potential public health risk.

In addition to increased costs and efforts associated with illegally supplied therapeutic goods, there has been increased workload related to the conduct of post market reviews of listed medicines. The majority of products reviewed are found to have deficiencies. These include deficiencies relating to unacceptable claims or advertising, packaging and labelling, manufacture, and/or evidence. Post market activities may also include laboratory analysis that may be difficult and costly to conduct as products often contain multiple ingredients. For example one recent laboratory testing regime to verify potential issues around a range of products was estimated to have cost the TGA in excess of \$85,000 dollars.

The revenue and expenditure for 2008-2009 and 2009-2010 forecasts, including a nil increase in fees and charges, 4.3 per cent increase and a 14.3 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 14.3% price increase
Revenue	8.348	8.822	9.100	9.518
Expense	9.218	10.079	10.079	10.079
Net Operating Result	(0.870)	(1.258)	(0.979)	(0.562)

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)
Complementary Medicines	(0.868)	(1.144)	0.218	0.010

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.

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In 2009-2010, the TGA expects to issue annual charges invoices for (approximately) 15,343 complementary medicine products on the ARTG. The revenue from these invoices will however be offset by 7,671 complementary medicines products which are likely to either qualify for LVLV exemption *and therefore only be subject to the \$130 LVLV application fee, not the \$810 annual product charge*; or be cancelled by the manufacturer off the ARTG.

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	Current Fee \$	Proposed Fee \$	Forecasted volumes for 2009-10	Forecasted revenue for 2009-10
Application Fees	\$560	\$640	2200	\$1,407,909
Processing Fees	\$280	\$320	200	\$64,000
New product not involving clinical or toxicological evaluation	\$7,230	\$8,260	2	\$16,520
New OCM substance not involving clinical or toxicological evaluation	\$7,230	\$8,260	2	\$16,520
Variation not involving clinical or toxicological evaluation	\$2,610	\$2,980	13	\$38,740
Evaluation fees (1-50 pages)	\$7,230	\$8,260	6	\$49,560
Evaluation fees (51-250 pages)	\$9,260	\$10,600	2	\$21,200
Evaluation fees (251-500 pages)	\$12,700	\$14,500	3	\$43,500
Evaluation fees (501-1000 pages)	\$16,900	\$19,300	1	\$19,300
Evaluation fees (1001-2000 pages)	\$25,300	\$28,900	1	\$28,900
Evaluation fees (2001-3000 pages)	\$33,800	\$38,600	1	\$38,600
Evaluation fees (> 3001 pages)	\$50,600	\$57,800	1	\$57,800
Annual Charge	\$710	\$810	7671	\$6,213,890
Other Revenue (Exports, LVLV, interest and other minor revenue)				\$1,501,360
Total Complementary Medicines Revenue				\$9,517,799

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3.6 Listed Non Prescription Medicines Fees - Sponsor Impacts

The 14.3 per cent increase in listed non prescription medicines application and processing fees will represent between \$40 and \$80 per application.

- 99 per cent of listed non prescription medicines forecasted to be listed in 2009-2010 are subject to the \$40 to \$80 increases. These increases reflect the cost of listing non prescription medicines on the Australian Register of Therapeutic Goods - *Table 1 refers.*

Table 1. Listed Non Prescription Medicines Fees

Fees	Current Fee	Proposed Fee	Variance	Forecasted Volumes 2009-2010	%
Application Fees	\$560	\$640	\$80	2200	91%
Processing Fees	\$280	\$320	\$40	200	8%
New product not involving clinical or toxicological evaluation	\$7,230	\$8,260	\$1,030	2	<1%
New OCM substance not involving clinical or toxicological evaluation	\$7,230	\$8,260	\$1,030	2	<1%
Variation not involving clinical or toxicological evaluation	\$2,610	\$2,980	\$370	13	<1%
Evaluation fees (1-50 pages)	\$7,230	\$8,190	\$960	6	
Evaluation fees (51-250 pages)	\$9,260	\$10,500	\$1,240	2	
Evaluation fees (251-500 pages)	\$12,700	\$14,400	\$1,700	3	
Evaluation fees (501-1000 pages)	\$16,900	\$19,100	\$2,200	1	
Evaluation fees (1001-2000 pages)	\$25,300	\$28,700	\$3,400	1	
Evaluation fees (2001-3000 pages)	\$33,800	\$38,300	\$4,500	1	
Evaluation fees (> 3001 pages)	\$50,600	\$57,300	\$6,700	1	
Note. The increased cost for most listed non prescription medicines varies between \$40 and \$80 (only)					

The TGA has forecasted 32 listed non prescription medicine applications (only) which will be subject to any evaluation fees. The increase to the evaluation fees for that minimal percentage of applications varies between \$370 and \$6,700.

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

3.7 Listed Non Prescription Medicines Charges – Sponsor Impacts

The 14.3 per cent increase in annual charges for listed non 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, the availability of the low turnover exemption from annual charges limits the impact of the annual charges increase to no more than 0.8 per cent of the product shelf price per unit.

Table 2. Listed Non Prescription Medicines Charges

	Annual Charge	Low Turnover Threshold	Units (\$5ea)	Units (\$10ea)	Units (\$15ea)	Units (\$20ea)
Current	\$710	\$10,441	2088	1044	696	522
Proposed	\$810	\$11,912	2382	1191	794	596
Fee increase per unit			\$0.04	\$0.08	\$0.13	\$0.17
Percent of price			0.8%	0.8%	0.8%	0.8%

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 the table 3, the maximum increase for the price of each product is 1.0 per cent. The increase falls sharply when the sales volume per product rises above 5,000 units (to as little as 0.05 per cent based on a \$20 unit price per product).

Table 3. Impact per Product – Sales Volume

Sales volume	Charge increase	Charge per Unit	Units (\$5ea)	Units (\$10ea)	Units (\$15ea)	Units (\$20ea)
2000 units	\$100	\$0.05	1.00%	0.50%	0.33%	0.25%
5000 units	\$100	\$0.02	0.40%	0.20%	0.13%	0.10%
10000 units	\$100	\$0.01	0.20%	0.10%	0.07%	0.05%

Note. The increase for the price of each product varies between 0.05 per cent and 1.0 per cent (maximum)

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 and the Complementary Healthcare Council of Australia (CHC) on the 17 March, the CHC was advised of the TGA proposal to increase fees and charges by 14.3 per cent.

The TGA is very aware that in these economic times caused by the Global Financial Crisis, increases in regulatory costs are undesirable.

If the TGA is to both meet its obligations for cost recovery, and at the same time avoid additional costs for CHC members in future years, it believes that a fundamental examination of the resources and processes applied to regulation of complementary medicines is required to determine if this regulatory framework can be offered at lower cost. To that end, the TGA will engage with CHC members during the 2009-2010 periods to discuss options for regulatory reform within the regulation of complementary medicines.

Industry Submissions

The TGA received one response from the CHC to the complementary medicines draft CRIS published on the TGA web site.

Submission 1

On 8 April 2009, an industry body wrote to the TGA to express their concerns in relation to the proposed 14.3 per cent increases to fees and charges for the complementary medicines sector.

The industry body submitted a counter-proposal to increase fees and charges by 5.3 per cent (comprising the 4.3 per cent composite index plus an additional 1 per cent).

TGA Reply

The TGA declines the industry counter-proposal because:

- a. if the 5.3 per cent industry counter-proposal was accepted it would only exacerbate the cost recovery issues that the TGA proposals are intended to address.

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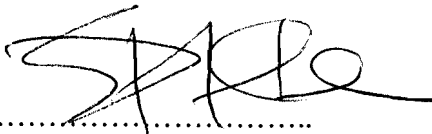
- i. the complementary medicines sector would under recover its costs by approximately \$1.2m in 2009-2010.
 - ii. industry has been informed that any under-recovery in 2009-2010 will be in addition to the \$2.28 million deficit already incurred by the sector between 2003-2004 and 2008-2009.
- b. the TGA proposal to increase fees and charges by 14.3 per cent already defers proposals for full cost recovery in the sector.
- i. industry has previously been informed that increases of 21 per cent (not 14.3 per cent) are required in 2009-2010 to achieve full cost recovery in the complementary medicines sector.
 - ii. the TGA's 14.3 per cent proposal is intended to reflect the uncertainty of the current global economic climate and limit the immediate impact on industry and consumers.
- c. the TGA has agreed to actively engage with industry associations (i.e. CHC) during the 2009-2010 periods to discuss options for regulatory reform for the regulation of complementary medicines.
- i. the industry engagement will include a review of the current schedule of TGA fees and charges for complementary medicines.

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: 10/6/09
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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.