Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Administration

COST RECOVERY IMPACT STATEMENT

March 2009

ANNUAL REVIEW OF FEES AND CHARGES 2009-10
NON-PRESCRIPTION (REGISTERED) MEDICINES

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1 OVERVIEW

1.1 Purpose

The Therapeutic Goods Administration (TGA) is proposing to increase non-prescription (registered) medicines fees and charges by 13.3 per cent for 2009-10. 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 $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 2009-10 are $102m.

1.2 Background

The TGA is a business unit within the Department of Health and Ageing 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 Therapeutic Goods Administration (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 this country. The ARTG keeps a record of products that are approved for marketing, the ingredients contained in each product, and the therapeutic claims made for medicines and the intended use of medical devices. The TGA also regulates fresh blood, blood components and banked tissues. These products are not generally included on the ARTG, their regulation is through audit and licensing 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 and 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).

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. The Committee 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' (ABS) Consumer Price Index for the 12 months to September 2008 and the Wage-Cost Index. 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 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 a cost recovery impact statement (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 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 REVIEW – ANALYSIS OF TGA'S ACTIVITIES

This cost recovery impact statement deals with TGA's proposal for significant increases to fees in the non-prescription industry sector.

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 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 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 that are 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 being implemented in 1998.

Fees and charges are prescribed in regulations made under the Therapeutic Goods Act 1989 and the Therapeutic Goods (Charges) Act 1990.

3.3 Costs to be Included in Charges

For regulatory products or services, cost recovery 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.

a) Direct Costs
b) Corporate Costs
c) Support costs

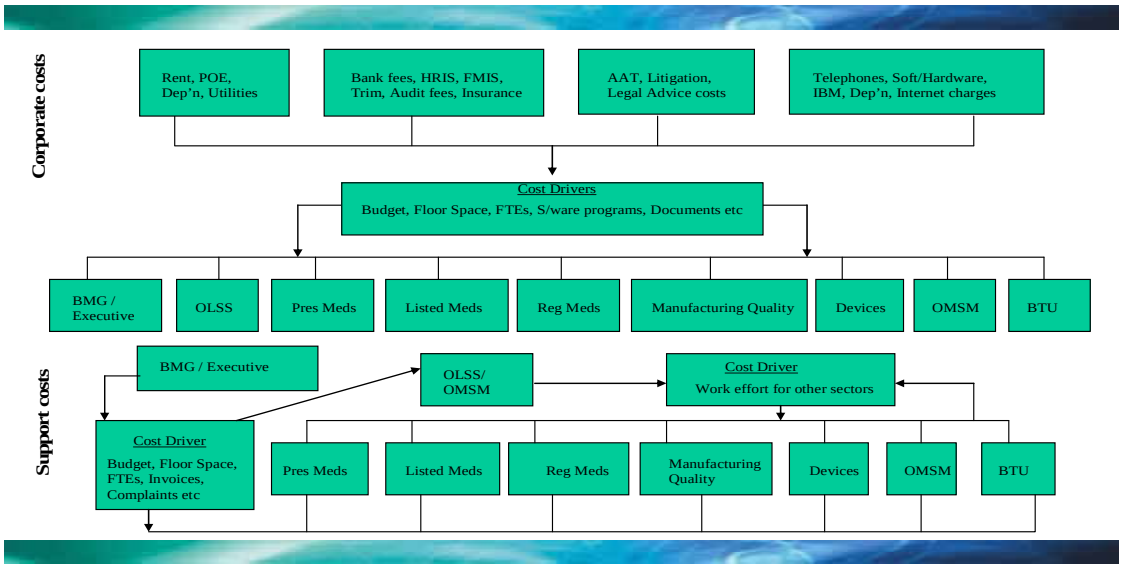
Direct Costs: These are expenses that are directly related in performing the regulatory activity and mainly include labour costs. Labour costs are based on the current Health and Ageing's Certified Agreement, plus appropriate allowances for on-costs.

Corporate Costs: Corporate costs, such as rent and information technology, are 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, HR and Finance. Business Units have very limited or no control over these expenses. Eg, 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 2008-09 and 2009-10 forecasts.

$(m)	2008-09 Forecast	2009-10 Forecast
Direct Cost (Employee and Supplier cost)	4.041	4.032
Corporate Cost (ABC allocation of rent, POE, computer, & depreciation cost)	1.085	1.005
Support Cost (ABC allocation of Executive, HR, Finance, Legal, Enforcements, Labs and other business areas cost)	2.456	2.346
Total Industry Cost	**7.583**	**7.383**

3.4 Reasons for fees and charges increase

The TGA have forecast an overall $1m net cost recovery deficit for 2009-10. The forecast deficit would require the TGA to call on its retained surpluses, which are expected to be $19m by 30 June 2009.

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 $3.2m in 2008-09, the TGA forecast reserves of $19m at 30 June 2009. This retained surplus will be used to offset the 2009-10 forecasted deficit of $1m.

The TGA is proposing to increase non-prescription (registered) medicines fees and charges by 13.3 per cent for 2009-10. The increases are planned to take effect from 1 July 2009.

The agreed indexation for 2009/10 is 4.3 percent being 50 percent of the 5 percent change in the Australian Bureau of Statistics' (ABS) Consumer Price Index (CPI) to September 2008 and 50 percent of the WCI rate of 3.6 percent.

The under-recovery was highlighted ahead of the 2005-06 budget, however due to the TGA's overall fiscal position and the development of the joint regulatory scheme, action was not taken to address the shortfalls and the deficits were off-set against TGA's retained surpluses.

The TGA advised industry that the 2008-09 budgeted under recovery before price increases were 19 percent. The industry agreed to increase fees and charges by 10 percent in 2008-09 to partially address the shortfall in the sector.

The TGA 2009-10 forecast is a deficit of $1m. The revenue is $102.2m compared to 2008-09 forecast of $92.3m, an increase of $9.9m. The expenditure is $103.2m compared to 2008-09 forecast of $95.5m, an increase of $7.7m.

The TGA expect the 2009-10 revenue volumes to remain at 2008-09 forecast levels with the exception of prescription medicines volumes increasing by approximately 1 percent, and conformity assessments increasing by approximately 5 percent.

Key assumptions used by the TGA in setting its budget are that all of its non labour costs will increase by a minimum of the CPI rate, a 4.1 percent increase in employment costs in accordance with the Department of Health and Aging Certified Agreement and a range of new initiatives which include:

- 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),
- business process redesign aimed at delivering efficiencies in the Prescription

Medicines sector and its Corporate Support areas and
- enhancing the robustness of the administrative decision-making within the TGA.

In addition to above mentioned cost pressures, the TGA expects to incur additional legal cost related to increase in case work related to FOI, AAT and Federal court actions. However reduction in IT business as usual cost has partially offset the increases. The TGA, in relation to Gershon savings was required to reduce IT business as usual cost by 2.5 percent or $0.2m in 2009-10. The TGA has complied with this requirement.

However TGA believes an increase of 21 percent in 2009-10 in the current global financial environment may be too high and proposes a 13.3 per cent increase (inline with the proposal to industry in 2008-09 – 9 percent catch-up increase plus indexation of 4.3 percent) to all non prescription (registered) medicines application, processing and evaluation fees; and annual product charges.

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 ASMI members in future years, it believes that a fundamental examination of the resources and processes applied to regulation of non-prescription medicines is required to determine if this regulatory framework can be offered at lower cost. To that end, the TGA will engage with ASMI members during the 2009-10 period to discuss options for regulatory reform within the regulation of non prescription medicines.

The revenue and expenditure for 2008-09 and 2009-10 forecasts including a nil increase in fees and charges, 4.3 percent increase in fees and charges and a 13.3 percent 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 13.3% increase in fees and charges
Revenue	**6.133**	**6.133**	**6.396**	**6.948**
Expense	**7.583**	**7.383**	**7.383**	**7.383**
Net Operating Result	**(1.450)**	**(1.250)**	**(0.987)**	**(0.435)**

The actual results for 2004-05 to 2007-08 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)
Non-Prescription (Registered) Medicines	**(1.600)**	**(2.308)**	**(0.489)**	**(1.367)**

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 percent 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.

For 2009-10, the low value low volume application processing fee will be increased by 4.3 percent (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
New registered medicine application	$1,090	$1,230	279	$343,170
Concurrent registered medicine application	$480	$540	36	$19,440
Processing fee for a variation to an existing registered medicine	$1,090	$1,230	740	$910,200
New product not involving clinical or toxicological evaluation	$7,230	$8,190	88.5	$724,897
Variation not involving clinical or toxicological evaluation	$2,610	$2,960	48.0	$142,110
Evaluation fees (1-50 pages)	$7,230	$8,190	71.0	$581,490
Evaluation fees (51-250 pages)	$9,260	$10,500	13.0	$136,500
Evaluation fees (251-500 pages)	$12,700	$14,400	11.0	$158,400
Evaluation fees (501-1000 pages)	$16,900	$19,100	4.0	$76,400
Evaluation fees (1001-2000 pages)	$25,300	$28,700	6.0	$172,200
Evaluation fees (2001-3000 pages)	$33,800	$38,300	2.0	$76,600
Evaluation fees (> 3001 pages)	$50,600	$57,300	1.0	$57,300
Annual Charge – registered medicine	$1,010	$1,140	2,763	$3,149,980
Other Revenue (LVLV, interest and other minor revenue)				$399,534
Total Non Prescription (Registered) Medicines Revenue				**$6,948,220**

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 2008-09 and 2009-10 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 TGA and ASMI on the 16 March, ASMI were advised of the TGA proposal to increase fees and charges by 13.3 percent.

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 ASMI members in future years, it believes that a fundamental examination of the resources and processes applied to regulation of non-prescription medicines is required to determine if this regulatory framework can be offered at lower cost. To that end, the TGA will engage with ASMI members during the 2009-10 period to discuss options for regulatory reform within the regulation of non prescription medicines.

4.2 Periodic Review

The Cost Recovery Guidelines require that all cost recovery arrangements be subject to periodic review no less frequently than every five years. A TGA wide review of cost recoveries for all products will be conducted in 2009-10.

5 CERTIFICATION

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

……..
Secretary
Department of Health and Ageing

Date: …….

6 COST RECOVERY LINKS

- The Australian Government Cost Recovery Guidelines and the accompanying Finance Circular can be found at;

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

- For proposals that involve regulation or amendment to regulation that affects business, a Regulation Impact Statement is required. Contact the Office of Best Practice Regulation for further information below

http://www.finance.gov.au/obpr/index.html