Australian Self-Medication Industry

Submission to Productivity Commission Inquiry into Cost Recovery Arrangements by Commonwealth Government regulatory, administrative and information agencies

November 2000

1. Executive Summary

The Australian Self-Medication Industry (ASMI) has a keen interest in cost recovery policy as its members pay 100% of the Therapeutic Goods Administration's costs for assessment and monitoring of non-prescription and consumer healthcare products, including compliance costs, administration charges and costs involved in policy advice and international representation.

ASMI believes that it is unreasonable, unsatisfactory and unfair to recover costs from industry that are incurred through activities which are clearly in the public interest. As a general principle, 100% cost recovery should only be applied to those costs incurred in providing direct support services to industry.

ASMI contends that the TGA – because of its central role in overseeing the safety, efficacy and quality of therapeutic goods – has legitimate community service obligations which should be recognised by the Government. There are grounds for making certain activities subject to either total funding by the Government, or at most partial funding by industry.

These activities include, but are not limited to, post-approval monitoring, general information and promotion, and 'whole of government' policy advice. However, the actual costs of market approval and at least some proportion of post-approval monitoring would be classified as 'private goods' and therefore subject to 100% cost recovery.

This delineation would also address perceptions that the TGA is "captured" by industry via the cost recovery process.

In addition, ASMI believes stakeholders in the TGA-Industry Consultative Committee (TICC) should be granted a greater degree of influence over the TGA's operations than at present and be given a greater input into the TGA's strategic planning process.

Financial and management information provided to industry through the TICC should be improved to provide better accountability and measurable results, with progress and performance monitored and reviewed on a quarterly basis.

In the spirit of openness and transparency, outcomes of TICC meetings should be routinely provided to the Parliamentary Secretary and the Departmental Secretary, and the issue of CPI indexation of TGA variable costs should be subject to further negotiation between the TGA and industry.

Cost blowouts and increases in approval times for non-prescription medicines by the TGA should be addressed as a matter of urgency.

2. Introduction

2.1 ASMI

ASMI is the peak industry body for the Australian self-care industry and represents companies involved in the manufacture and distribution of non-prescription and consumer healthcare products.

ASMI, until recently known as the Proprietary Medicines Association of Australia, also represents companies providing manufacturers with services, such as advertising, public relations, regulatory consultancy, recruitment agencies, cartage and industry statistics.

The mission of ASMI is to promote better health through responsible self-medication. This means ensuring that safe and effective self-care products are readily available to all Australians at a reasonable cost. ASMI works to encourage responsible use by consumers and an increasing role for cost-effective self-medication products as part of the overall Australian health strategy.

ASMI provides an authoritative voice for the consumer healthcare products industry as the acknowledged point of consultation for government, regulators, consumer organisations, professional organisations and other stakeholders. ASMI also serves as an information hub, providing the industry with the latest domestic and international developments affecting the self-care industry in technical, regulatory, social and legal arenas.

As a member of the World Self-Medication Industry (WSMI), a non-government organization with official links to the WHO, ASMI helps to promote the worldwide recognition of the role of non-prescription medicines in health care. This is an expanding role as self-care medicines go beyond their traditionally acknowledged role in treating the symptoms of self-limiting ailments. Around the world there is an increasing acceptance of the important role self-care can play in the treatment of previously diagnosed chronic conditions by increasing access to treatment and providing effective cost-containment. Self-care medicines also include complementary medicines which play a role in health maintenance and disease prevention.

2.2 Therapeutic Goods Administration

The Therapeutic Goods Administration is a Division of the Federal Department of Health and Aged Care and is responsible for administering the provisions of the Therapeutic Goods Act 1989 ("the Act").

The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard. At the same time, the TGA aims to ensure that the Australian community has access, within a reasonable time, to therapeutic advances.

Any product for which therapeutic claims are made must be entered in the Australian Register of Therapeutic Goods (ARTG) before the product can be supplied in Australia. The ARTG is a computer database of information about therapeutic goods for human use approved for supply in, or exported from, Australia.

The requirements for inclusion of therapeutic goods in the ARTG are set out in the Act and associated Regulations and Orders, including labelling, advertising, product appearance and appeal guidelines. The objective of the Act (which came into effect on 15 February 1991) is to provide a national framework for the regulation of therapeutic goods in Australia and ensure their quality, safety and efficacy.

Control of the supply of therapeutic goods is exercised through three main avenues:

- *Pre-market assessment*

Products assessed as having a higher level of risk (prescription medicines, some non-prescription medicines and some medical devices) are evaluated for quality, safety and efficacy. Once approved for marketing in Australia, these products are included in the ARTG as 'registered' products and are identified by an AUST R number.

Products assessed as being lower risk (many Non-Prescription medicines including most complementary medicines and low risk medical devices) are assessed for quality and safety. Once approved for marketing in Australia, these products are included in the ARTG as 'listed' products and are identified by an AUST L number.

In assessing the level of risk, factors such as the strength of a product, side effects, potential harm through prolonged use, toxicity and the seriousness of the medical condition for which the product is intended to be used are all taken into account.

- *Licensing of manufacturers*

Australian manufacturers of therapeutic goods must be licensed. Their manufacturing processes must comply with principles of Good Manufacturing Practice (GMP). The aim of licensing and standards is to protect public health by ensuring that medicines and medical devices meet definable standards of quality assurance and are manufactured in conditions that are clean and free of contaminants.

- *Post marketing vigilance*

Post marketing activities include investigating reports of problems, laboratory testing of products on the market and monitoring to ensure compliance with the legislation.

3 Present cost recovery arrangements

3.1 Legislative basis

The TGA was created from a series of State and Territory-based regulatory environments. The development of cost recovery was part of this evolution, with 50% of the TGA's costs initially recovered from industry.

The Act and the Therapeutic Goods (Charges) Act and associated regulations dating from 1990 together form the principal legislative basis for TGA operations and charges. The Minister makes regulations to set fees and charges under the Act, although these are subject to disallowance by the Senate.

Cost-recovered revenue is accumulated in the TGA's Special Account (or Trust Account – in the original wording of the Act this was the Therapeutic Goods Reserve Account).

3.2 Cost recovery - history and structure

As part of the implementation of the Act in April 1991, the Federal Government decided the TGA would recover 50% of its operating costs through fees and charges collected from the therapeutic goods industry.

Subsequently, the TGA introduced fees and charges for applications, good manufacturing practice inspections and annual licensing. In 1992/93, fees and charges generated 28% of the total revenue requirement for the TGA and it was agreed with industry to move over the next three years to achieve the 50% target.

As part of its strategy to reduce the Federal Budget deficit after the 1996 election, the Government announced it would increase the level of cost recovery for TGA activities to 75% to be phased in over the following three financial years, starting in 1996/97.

The Government planned to introduce higher levels of cost recovery in several stages:

- 58% in 1996/97;
- 67% in 1997/98, and
- 75% in 1998/99.

However, in framing the 1997/98 Budget, the Government decided to accelerate the rate of increase in the level of cost recovery from industry, moving to 75% in 1997/98 and 100% cost recovery in 1998/99.

The cost recovery process now provides revenue of around $48 million to the TGA Special Account.

The decision to increase the level of cost recovery covered all activities falling within the scope of the Act, including regulation of the industry, the TGA's public health responsibilities, responsibilities to consumers for information on products and TGA's support for the industry generally (including the facilitation of exports and international harmonisation).

The TGA collects its revenue mostly through annual charges, evaluation fees and licence fees. These are set so as to fully recover the operating costs associated with regulating a particular product group and also reflect the TGA's risk-based approach to regulation.

For example, evaluation fees for a new prescription medicine can, depending on the quantity of data to be evaluated, be more than $150,000 whereas the cost for a low risk complementary medicine or sunscreen is presently $270.

The GST-exempt application based fees and charges administered by the TGA are paid in advance (with the exception of very complex applications, where the company may be invoiced after the application is lodged. In such cases, the company pays 75% of the fee on lodgement and 25% on finalisation).

These 'pre-market' fees and charges are reviewed on the basis of an assessment of the trends in the numbers of workload-generating applications and/or assessments expected in the forthcoming year. From these assessments, any changes in fee levels (to achieve full-cost recovery of these components of the TGA dealing with application/assessment based work) are calculated.

Evaluation fees are levied on a modular basis with separate fees being charged for each section of the required submission, based on the number of pages and the type of information contained in each part of the submission (for example, a 2000-page submission of 'clinical data' as part of an overall submission on a prescription medicine attracts a fee of $39,400, with other parts attracting equivalent fees).

Each product included in the Australian Register of Therapeutic Goods (ARTG) - whether 'registered' or 'listed' – attracts an annual charge. Charges vary according to product group – for example, prescription medicines which are 'registered' attract an annual charge of $750 while 'listed' complementary medicines attract an annual charge of $270. The TGA also charges fees ranging from $3500 to $6800 for 'Good Manufacturing Practice' licence audits.

Surveillance and investigation of breaches is undertaken by the TGA. However, these activities are not subject to specific fees or charges, except where the costs are recoverable through the courts when an investigation leads to prosecution, but are absorbed across the overall revenue base of the TGA.

The TGA also undertakes a number of assessment and formal reporting tasks for other regulatory agencies, such as the National Registration Authority (NRA), which paid

$2.15 million in 1998/99 for assessments of agricultural and veterinary chemicals and their potential impact on human health.

The Government's introduction of 100% cost recovery for the TGA includes expenditure on its own administration and work related to 'government business' under the Therapeutic Goods Act. This area is subject to cost recovery on the grounds that all regulatory effort by the TGA is undertaken solely because the industry exists, and the community has a right to be sure that all therapeutic substances and appliances are safe to be used in accordance with the 'licences' granted by the TGA.

There are no other sources of funds for the work of the TGA under the TGA Act.

3.3 Industry response

The decision to move to 100% cost recovery was criticised by industry which believed that agreements with Government on fees dating from 1993 represented the maximum proportion of TGA costs that they would be asked to bear.

Subsequent discussions with industry regarding the trade-offs between process reforms and the higher proportion of costs recovered were crucial in achieving actual increases in fees and charges of only 34%, instead of the anticipated increase of 50% when the change in cost-recovery patterns occurred.

The TGA meets with representatives from the four major areas each year under the banner of the TGA-Industry Consultative Committee (TICC) to discuss and agree on the TGA's schedule of fees and charges for the forthcoming financial year. These meetings also discuss strategic issues and are designed to ensure that all stakeholders are aware of developments in both the regulatory and manufacturing environments.

3(a) TICC - role and functions

Under the TICC's terms of reference, its role is "to facilitate consultation between TGA and the industry in two broad areas:

- Input to forthcoming budgets;
- Open and transparent input to and accounting against the TGA Corporate Plan."

The TICC is described by TGA officials as a consultative forum, not a management or advisory committee. The TICC is the highest level forum for industry to provide direct feedback to TGA on broad policy, resource allocation and program performance issues.

Its objectives are to assist the TGA in identifying strategic directions, to ensure that the broad budget meets the identified strategic needs and to ensure that performance measures are in place to ensure accountability.

The TICC was established in late 1997 and comprises representatives from TGA and peak therapeutic goods industry groups as follows:

- Australian Pharmaceutical Manufacturers Association (APMA)
- Proprietary Medicines Association of Australia (PMAA) [now Australian Self-Medication Industry – ASMI]
- Nutritional Foods Association of Australia (NFAA) [now Complementary Healthcare Council]
- Medical Industry Association of Australia (MIAA)
- National Manager, TGA (Chairman)
- Director, Business and Services Branch, TGA
- Nominee of the Chairman to act as secretary

Other TGA managers, public health experts and other industry representatives are co-opted as required. All representatives must be able to attend meetings of TICC and be able to speak on behalf of their constituency.

The TICC meets twice a year in May and November.

Industry representatives are provided with information by TGA to enable TICC members to make informed comment on TGA policy, resource allocation and program performance.

TICC Terms of Reference

(i) To examine and comment on the TGA corporate strategic Plan developed within the context of government policies;
(ii) To examine and comment on TGA performance against the key performance indicators set out in the Corporate Plan and Budget Statements, and
(iii) To examine and comment on the TGA budget, including new initiatives and other budget measures, and on the proposed industry fees and charges.

3(b) TICC's access to financial and management information

In previous meetings of the TICC, industry representatives have stressed the importance of adequate information being made available to them which would then facilitate their making informed comment on TGA plans and the financial reports in particular. Under its terms of reference, members can provide input into TGA's planning processes. TICC also provides a vehicle for discussion and consultation on TGA's strategic directions.

The TGA has previously stated that it is committed to ensuring that TICC is provided with appropriate and adequate information to ensure transparency and accountability in the way it discharged its obligations.

However there are a number of areas where ASMI believes the quantity and quality of financial and management information provided to TICC could be improved.

It is reasonable to assume that if industry is providing 100% of the TGA's funding, it should be able to access sufficient information via the TICC to ensure that the TGA is operating with maximum efficiency, that costs are rigorously controlled and that accountability to industry is and remains a high priority for the TGA.

ASMI acknowledges that TICC is intended as a consultative mechanism. However, it also needs to deliver measurable results and accountability.

PriceWaterhouseCoopers was commissioned by the TGA in June 2000 to review the TICC's future reporting needs. A number of requests and suggestions for future management information reporting needs were made by TICC members and subsequently incorporated into the Interim Report.

The Interim Report listed the responsibilities of industry representatives as being to review and provide comment on issues such as:

- The strategic direction of the TGA;
- The TGA's performance against key performance indicators;
- Costs that are passed onto Industry sectors and thus ensuring that an efficient and effective regulatory system exists.

ASMI believes a number of refinements to the TICC financial reporting structure are necessary if industry is to gain maximum value from its input into the consultative process.

In light of the responsibilities listed above, ASMI contends that these refinements are crucial if industry is to continue its support of the TICC process and make the TGA accountable to industry.

TICC's stakeholders reasonably expect to have an appropriate level of influence and advice in planning, monitoring and assessing performance and results. The companies represented on the TICC provide consumers with safe products produced to a high standard and therefore have a legitimate role in helping reduce the costs and complexity of regulation to benefit both industry and the community.

This should occur in an open and transparent way, based on agreement of all parties as to the breadth and depth of information requirements between parties, which may require adjustment over time as experience and knowledge is gained.

The outcomes of TICC meetings should be routinely provided to the Parliamentary Secretary and the Departmental Secretary.

If the members of TICC are to be able to provide useful and constructive input which leads to agreed and attainable outcomes, TICC must be allowed a degree of involvement greater than merely making 'informed comment.'

Overall, ASMI contends that a number of key issues should determine TICC's performance and accountability measures:

- The approach to planning revenue and expenditure, including identification of overheads and how they impact on the budget
- How these are charged back
- How they are controlled
- Steps to reduce costs, and
- Accurate activity forecasts.

- Reporting mechanisms, including
- Productivity initiatives;
- Accountability criteria and measures (Key Performance Indicators), and
- Understandable and relevant reporting formats.

Specific suggested improvements mainly relate to the format of the financial information provided by the TICC for industry review, including:

- Identification of fixed vs. variable costs in the accounts and the remuneration budget;
- Expenditure should be split in the same way as revenue;
- Better separation of business units such as advertising and surveillance and legal costs;
- Reporting periods should be consistent each year;
- Improved identification of purpose of expenditure apart from remuneration;
- Improved separation of sources of revenue including prescription, non-prescription (including registered complementary and other goods and listed complementary and other goods) and exports;
- Detailing of the steps taken by the TGA during the reporting period to reduce costs;
- Detailing of how overhead costs are charged back, and
- Introduction of concrete measures of accountability.

ASMI believes the introduction of these refinements would lead to increased transparency and openness in industry's oversight of the TGA's revenue and expenditure reporting through the TICC process.

Given the size of the TGA budget and the policy of 100% cost recovery, TICC should be required to monitor and review progress and performance quarterly.

Industry also wants the opportunity to make a greater input into the TGA's strategic planning process.

In relation to the PriceWaterhouseCoopers Interim Report, the proposed financial reporting format is an improvement on the existing structure but should also incorporate elements of the TGA's current quarterly performance reports.

In addition, there is a need for the provision of both sectoral and overall financial strategic management information and a requirement that TICC provide reports against performance measures that had previously been discussed with industry (for example, those included in Memorandums of Understanding with each industry sector).

ASMI contends there are serious deficiencies in relation to recent moves by the TGA to introduce CPI-based indexing of TGA fees and charges.

While ASMI accepts that CPI indexing could be introduced in relation to agreed fixed costs, indexing on variable costs should be subject to negotiation without the assumption that service and resource levels are static.

In ASMI's view, the TGA is passing on the CPI increases as a matter of course with inadequate examination of how the TGA may have looked for increased efficiencies to manage this increase.

In addition, the introduction of the GST has brought about an abnormal inflation of the CPI and industry should not bear the brunt of this abnormality. There are negligible opportunities for industry to increase prices to compensate for CPI-based indexing of fees and charges, at the same time that the GST is forcing up prices.

4 Impacts - benefits/costs

4.1 Benefits

4.1.1 Benefits to industry

Although industry benefits from an increased level of consultation regarding TGA policy and greater access to financial and management information through the TICC, it has limited input on the actual fees and charges with the final decision being made by the Minister via the TGA.

The TICC is not a management committee, but a consultative forum. Its ability to influence the direction of TGA policy is therefore marginal, and the limitations on the information that is discussed by the TICC (as outlined in 2(b) above) severely restrict industry's ability to participate in a meaningful dialogue with TGA officials.

The benefits to industry from cost recovery of TGA fees and charges are therefore extremely limited.

4.1.2 Benefits to government

The Federal Government benefits through shifting increases in approval and testing costs to industry by not having to fund these costs through the Budget.

Resources which would otherwise be devoted to funding the TGA can therefore be diverted to other uses, both within and outside the Health and Aged Care field.

The Government gets the 'best of both worlds' under the cost recovery arrangements – it has virtually complete control over TGA policy, but does not have to fund the TGA's activities.

Industry, however, is in the position of having almost no control over the TGA's policy while being obliged to fund 100% of its costs.

Such a situation is clearly unsatisfactory.

4.1.3 Benefits for consumers

Consumers would benefit under the cost recovery arrangements if there was substantial and ongoing pressure to reduce fees and charges paid by industry as this would mean they would pay less for therapeutic goods.

However, in the current environment – and particularly in the context of recent moves by the TGA to introduce unjustified CPI-linked adjustment of fees and charges – it is

unlikely that consumers would receive any benefit in the form of lower costs for therapeutic goods.

4.2 Cost impacts

4.2.1 Impacts on industry

The imposition of 100% cost recovery on industry will oblige industry to increase prices charged for therapeutic goods as a result of fee increases to cover increases in costs.

These price increases are difficult to justify in a low-inflation environment and while the industry is also dealing with the impact of the GST and other business taxation changes.

It should not be assumed that industry can automatically absorb the impact of increased fees and charges.

In addition, Australia's market is relatively small (19 million) in comparison to markets in the European Union (374 million), the US (273 million) and Canada (31 million). Yet industry is expected to cover fees and charges which are substantially higher than those applying in these much larger markets.

ASMI and other industry groups work closely with the Department of Health and Aged Care to reduce the costs of healthcare delivery – which are under increasing pressure from higher fees and charges.

4.2.2 Impacts on consumers

Consumer groups have previously expressed concern that full cost recovery of TGA fees and charges from industry could lead to perceptions that the TGA had been "captured" by industry.

When the Consumers Health Forum sought representation on the TICC in May 1998, the TGA advised that the Forum "believes it was important that with effective funding provided through industry contributions that this industry funding of the TGA is not interpreted as industry 'ownership' which could lead to a downgrading of its vital public interest functions."

Subsequently, a TICC meeting discussed the issue and agreed "that there are potential benefits for both the TGA and industry in ensuring transparency and in dispelling some possible misconceptions amongst consumers and others that have arisen with the introduction of full cost recovery."

In a letter to the then Parliamentary Secretary to the Minister for Health and Family Services, Trish Worth MP, in June 1998, the Australian Pharmaceutical Manufacturers Association said that "the Government and TGA have already been subject to public criticism of the possibility that the TGA will be unduly influenced by industry under the

new proposal" and that "we understand that ADEC (Australian Drug Evaluation Committee) members have also expressed concern that their activities will now be funded by industry and therefore their independence may be perceived to be compromised."

ASMI contends that a clear and generally agreed delineation between public and industry-related activities, and a subsequent division of funding between government and industry depending on that delineation, would substantially dispel negative consumer sentiment regarding the TGA being 'captured' by industry through 100% cost recovery.

5 Application of 100% cost recovery

ASMI believes that cost recovery of 100% should only apply to those costs incurred in providing direct support services to industry, as required under the relevant Therapeutic Goods Acts.

When only 50% of TGA's costs were recovered from industry, there was clearer delineation between industry-related activities and public interest-related activities.

Under that agreement, industry fully funded the activities which were primarily industry-related; government fully funded the activities which were undertaken primarily in the public interest, and those activities with a perceived benefit to both industry and the public would be jointly funded in the agreed proportions by both industry and the government.

However, the 100% cost recovery policy has greatly enlarged the range of TGA activities that industry pays for – beyond 'industry service' activities into the realm of government and public-interest activities.

ASMI believes that the Government should re-examine its policy of not funding identified public-interest activities. The TGA, because of its central role in overseeing the safety, efficacy and quality of therapeutic goods, has legitimate community service obligations which should be recognised by the Government.

ASMI contends that there are legitimate grounds for making a certain number of activities subject to either total funding by the Government, or at most partial funding by industry. These activities, which could be seen as "public goods," include:

- 'Whole of government' policy advice;
- TGA services promotion overseas;
- Trans-Tasman harmonisation costs;
- Regulatory policy;
- Post-approval monitoring;
- Product recall (not arising from sponsor negligence or non-observance of rules, but from extortion);
- General information and promotion.

However, the actual costs of market approval and at least some proportion of post-approval monitoring would be classified as "private goods" and therefore subject to 100% cost recovery.

5.1 Issues of parliamentary scrutiny

The Minister for Health and Aged Care (or the Parliamentary Secretary) administers the Act and is responsible to Parliament under the Constitution for the administration of the TGA. If the TGA was funded by the Government, its forward Budget estimates would be subject to scrutiny by the Senate Estimates Committee process.

However, as its costs are recovered from industry, parliamentary scrutiny of the operations of the TGA is substantially reduced.

Industry is supposedly one of the constituencies represented by the Parliament, but in reality lacks representation because of the absence of scrutiny of the TGA's Budget through the Estimates Committees.

It is unreasonable to expect industry to pay 100% of the TGA's cost if the TGA can never be held fully accountable.

5.2 Industry's expectations

As industry is the sole source of funding for the TGA, ASMI contends that industry has both a right and a responsibility to ensure that the TGA's costs (both fixed and variable) are kept under constant review.

In this way, Australians will have access to low-cost non-prescription medicines and the costs of regulation to industry will be minimised.

The TGA's Draft Corporate Plan 1997/2000 stated that "it was important (for the TGA to be) in the position to…achieve a regulatory system which…is transparent and straight-forward…(and) is accountable and increasingly cost-efficient."

This year, the TGA has stated that "it is very conscious of the costs associated with its regulatory responsibilities and is continually seeking to contain those costs through improvements in both efficiency and effectiveness."

"Substantial reforms benefiting industry were implemented following the 1996/97 Government Review of TGA, and further reform has been introduced through work initiated since," according to an Explanatory Note on TGA Fees and Charges issued in March 2000.

However, ASMI contends that industry still holds significant concerns regarding unforeseen cost blowouts within the TGA and the lengthy delays for approval of non-prescription medicines.

For example, projected waiting times (defined as the amount of time before an application is first opened by an evaluator) were 40 working days as of 1 June 1999 and were projected to be as much as 100 working days by December 2000 without a

significant increase in TGA resources (the TGA estimated an increase in revenue of $1 million would be required to address the shortfall as well as recruit five additional evaluators and a medical officer).

Data on registration of non-prescription medicines as at 30 June 2000 showed the largest category in Stage of Processing was 'more than 16 weeks,' with 186 applications falling into that category in the final quarter of 1999/2000. However, this had fallen since the second quarter when the number of applications which had been in the processing stage for more than 16 weeks was 206.

The total number of applications in progress (with 'time in progress' ranging from less than 10 weeks to more than 16 weeks) had also been reduced from 327 to 286 between the third and fourth quarters.

ASMI submits that although the TGA has been working hard to resolve industry concerns regarding increases in approval times, these have only recently been brought under control.

6 Recommendations

ASMI recommends:

- That a joint industry/TGA working group be set up as part of the TICC structure to decide annually on the areas of TGA activity that should be subject to full or partial cost recovery;

- As a general principle, 100% cost recovery should only be applied to those costs incurred in providing direct support services to industry;

- TGA financial and management information provided to industry through the TICC be improved to provide better accountability and measurable results, including accountability criteria and measures, understandable and relevant reporting formats and productivity initiatives;

- TICC stakeholders be granted a greater degree of influence than at present;

- Outcomes of TICC meetings should be routinely provided to the Parliamentary Secretary and the Departmental Secretary;

- TICC should be required to monitor and review progress and performance on a quarterly basis;

- Industry be given a greater input into the TGA's strategic planning process;

- The issue of CPI indexation of TGA variable costs be subject to further negotiation between the TGA and industry;

- Perceptions that the TGA is "captured" by industry via the cost recovery process be addressed through a clear and generally agreed delineation between public and industry-related activities;

- Cost blowouts and increases in approval times for non-prescription medicines be addressed as a matter of urgency.