13th November 2000

Ms. Helen Owens
Presiding Commissioner
Cost Recovery Inquiry
Productivity Commission
Locked Bag 2
Collins Street East
Melbourne VIC 8003

# Submission to the Productivity Commission re Federal Government Cost Recovery

In accordance with your call for submissions on cost recovery by Commonwealth Government regulatory (and other) agencies, the Medical Industry Association of Australia Inc (MIAA) is pleased to address the following key issues:

***Current 100% cost recovery practices within the Therapeutic Goods Administration (TGA) are a matter of key concern, in contravention of competition principles and a disincentive to healthcare delivery and industry development.***

***Cost recovery arrangements and conditions attached to Commonwealth Scientific and Industrial Research Organisation (CSIRO) support, have the effect of driving offshore, essential research and development activities for our industry.***

## What is MIAA

MIAA is an incorporated Association whose members are companies that manufacture, import, design, package, test, sterilize or distribute medical devices or medical diagnostic products in Australia, or that are engaged in associated research or industry development activities. The Association was formed in 1980, and currently has over 90 member companies. While there are more than 500 companies active in the manufacture or supply of medical devices and diagnostics, MIAA member companies account for 85% of the value of medical devices and diagnostics sold in Australia each year, with a value of $1.5 billion. A list of member companies is attached to this submission as Attachment 1.

The range of products supplied by MIAA members is vast - from syringes and needles to highly specific diagnostic kits, from disposable surgical gloves to defibrillators, from bandages and dressings to cardiac catheters. Some 250,000 different catalogue items are covered.

As the peak industry body for our industry, MIAA's charter includes representation of member interests to Governments, both State and Federal, on issues of concern.

## Organisations that Cost Recover from our Industry

MIAA member companies currently pay fees or charges to the following:

***Therapeutic Goods Administration***

- product evaluation
- annual charges for all products entered onto the Australian Register of Therapeutic Goods
- auditing of manufacturing facilities both in Australia and overseas
- fees for changes to products including changes in labelling, changes in manufacturing sites, or variations to products

Except for the costs of auditing manufacturing facilities, which are charged on the basis of fee-for-service (calculated at an hourly rate), all other fees and charges levied by the TGA are unrelated to fee-for-service.

***Australian Quarantine Inspection Service (AQIS)***

- evaluation of products of human and animal origin for permit to import

The cost structure is based on the average time taken to evaluate applications and issue permits according to the categorisation of the application type. Categories are based on the assessed risk of the product group.

AQIS is currently re-evaluating the charging basis so as to more accurately categorise products. AQIS has advised that they have been monitoring evaluation and permit issuing times for the past three years and will use this data to simplify the categorisation and spread the costs as equitably as possible.

***Commonwealth Scientific and Industrial Research Organisation (CSIRO)***

- CSIRO support to Industry, when approved, is charged on a cost recovery basis that leads to excessive charging. This acts as a disincentive to industry.

***Department of Health & Aged Care***

- Maintenance of a Default Benefit List for prostheses
- Administration of the Default Benefits Scheme, including the proposed Expert Committee.

## Focus of this MIAA Response

In this response to your Inquiry, MIAA wishes to address particularly the fees and charges levied by the TGA and the disincentives associated with use of CSIRO support. To some extent, we wish to flag a developing concern with fees levied by the Department of Health & Aged Care for maintenance of the prostheses benefits list.

# 100% Cost Recovery by the TGA

The decision by the Federal Government in 1997 to shift all TGA budget costs to industry, in effect applied additional taxation on industry; legal advice to industry confirms TGA fees and charges constitute taxation. Prior to 1997, cost recovery from industry to meet TGA expenses had progressively shifted upwards to 50% of the TGA budget.

TGA fees and charges are applied under the provisions of the Therapeutic Goods Act and the Therapeutic Goods (Charges) Act 1989. The Therapeutic Goods Act has not been presented to the Parliament as an instrument of taxation, yet it acts in this way. A copy of the relevant legal advice will be tabled during the Public Hearings.

Each time TGA costs to industry are increased, this is the subject of amending Regulations in the Senate; no scrutiny is applied in the Parliament, nor is the impost assessed as an element of other taxation reforms. Fees and charges levied on industry increased by 30% to 50% in 1997 and again by 43% in 1999. In 1999 the 43% increase was passed to industry without regard to other government tax reforms underway concurrently, such as the introduction of the GST and reform of the FBT.

100% cost recovery for the TGA impacts at least six major industry sectors, representing more than 1,000 companies. The decision to have a Government agency (as opposed to a Statutory Authority) fully funded by Industry is almost unique, with the National Registration Authority (NRA) being the only known other agency to be funded in this way. As the decision to move from 50% cost recovery to 100% cost recovery was taken without consultation with industry, we do not understand why Government has singled out our industry for this additional taxation.

The decision to recover all TGA costs from industry by means of fees and charges, has exposed the TGA to sustained industry criticism over its inordinately high charges. At the time of writing, TGA has flagged additional planned fee increases. The TGA is not accountable to industry at all, unlike a Statutory Authority. TGA services to our industry are not measured by a Performance Agreement, despite repeated requests for such an agreement since early 1998.

The impact of 100% cost recovery is to make the TGA too expensive for many companies to use. Companies do not introduce new products to the Australian market (which is only 1% of the world medical devices market) where it is apparent that high up-front costs for evaluation and entry onto the Australian Register of Therapeutic Goods (ARTG) cannot be recovered in the often short market-life of the product. ***As a result consumers and the delivery of quality healthcare suffer and this situation may be expected to worsen.***

## TGA Role is in Contravention of Competition Principles

The TGA has a role as both the Government's Regulator and the sole Australian Conformity Assessment Authority. The continuance of this dual role has been announced as a feature of the Government's proposed amendments to the Therapeutic Goods Act. Retaining the conformity assessment role for the TGA is seen by industry as contradictory to Government's competition principles and at odds with the

recommendations of the Industry Commission Report No. 56 of 20th December 1996. This Report looked in detail at the Medical and Science industries. The first four recommendations of that extensive Study will have been disregarded if the TGA maintains a dual role.

However, Industry notes that any shift away from the TGA performing the conformity assessment role would need to be gradual, so as to allow the private sector capability time to develop. Nonetheless, there are several credible options for the development of a private sector capability, including the use of university biomedical engineering resources, where a predictable income stream would be welcomed. TGA capability would be required to continue during any transition of this function to the private sector.

**Comparative Costs of Product Entry to the Australian Market**

Speed of entry to market, consistent with safety, is critical for high technology, short-life products. So also is affordable entry, given the difficulties associated with recovering outlays in the small Australian market.

TGA costs for evaluation of products and annual fees to maintain products on the ARTG, are the highest charges in the world, almost without exception. They are an order of magnitude above comparative costs in other countries with mature regulatory systems. Attachment 2 to this submission attempts to portray fairly the excessiveness of these charges. ***They are a major disincentive to the introduction of new technologies, to the detriment of healthcare delivery.***

These high charges are a direct result of a Government policy that obliges the TGA to recover all costs from industry, no matter that the bulk of TGA activity (and therefore expenditure) is not related to industry support.

It remains a sore point with industry that TGA, an agency fully funded by industry, is not accountable to that industry.

**An Alternative Model for the TGA**

Industry suggests there are various options that exist for improving the operations of the TGA, which would have the beneficial effect of lowering TGA budgetary costs, while encouraging private enterprise participation by progressively shifting the conformity assessment function to the private sector. Private sector conformity assessment includes recognition of appropriate overseas agencies, a feature that is planned for inclusion in the forthcoming Government legislation.

There is nothing radical about this proposal, it is essentially the same as the recommendations of the previously referenced Industry Commission Study. Product safety, consumer protection and product availability could all be enhanced by a progressive shift to this regime. The TGA would be able to focus on post-market surveillance and vigilance, rather than on pre-market product assessment.

In the short term, funding for the TGA should return to the agreed 50/50 arrangements that applied until 1998. 50% of current TGA costs would be recovered from Industry, which would in effect be paying fees-for-service, while Government would be seen to

be meeting the public interest and parliamentary support costs of its agency. Even with the resultant lowering of costs for industry TGA fees and charges would remain the highest in the developed world, but the current burden and disincentive to Industry would be reduced.

## CSIRO Costs

A major barrier to Australia gaining a proper return on its investment in the "clever country" is not a lack of good science or a lack of new start-ups, it is a lack of critical infrastructure.

Australia lacks the mature development and engineering sector. The DuPonts, the 3Ms and the multitude of supplier companies across the US that provide the start-ups and small ventures with the tools and materials necessary to grow to an established company do not exist in Australia. This infrastructure involves many disciplines and includes:

*scale-up of synthetic organic materials,*
*scale-up of biological materials,*
*scale-up of polymers and plastics*
*prototyping polymer extrusions,*
*prototyping large scale fermentation facilities,*
*fabrication of thin films of conductors and insulators*
*fabrication of small runs of application specific chips*
*small runs of mechanical and electronic prototypes.*

The absence of this infrastructure is resulting in Australia funding the high-risk early stage capability, which is then lost to overseas development. **A major return on Australia's investment is being made by US companies.**

The Commonwealth has already purchased much of the necessary infrastructure and placed it within the CSIRO. The investment in people, expertise, space and facilities has been substantial and continues at approximately $750M p.a. However, the arrangements under which CSIRO is currently structured, make it uneconomical for small to medium sized business to access. This appears to be a consequence of CSIRO loading its charges with overheads from across its organisation, most of which does not earn revenues. CSIRO's services are more expensive than accessing commercial service groups in the US.

MIAA has proposed to add an option to the support sought under a START grant to gain access to CSIRO staff, laboratory space and facilities for the period of an agreed project. Project management and team leadership would be the responsibility of the successful grant recipient. CSIRO staff with expertise central to the project goals would be seconded to the project for its duration. Technicians operating equipment as a service would participate in a number of projects depending on the needs each project has for that equipment. Base salary, loaded with sick leave, long service leave, superannuation and similar overheads typically amounting to 26% of the base salary would be paid from the grant funds to the CSIRO during the period of the secondment.

Existing staff of the START scheme would be used to administer the grants. The "return to Australia" requirements would be the same as in existing START contracts. Available capabilities within CSIRO are described within annual reports of the various

Divisions. These would be summarised and distributed as part of the START application package.

This option should stimulate a greater interaction between Government funded CSIRO staff and scientists and technologists from industry who are working at the development and commercialisation stages of the innovation cycle. Additionally, this will generate a more flexible career path for government funded scientists.

## Departmental Charges for Maintenance of Schedule 5 of the Default Table – Surgically Implanted Prostheses and Human Tissue Items List (The List)

Schedule 5 of the Default Table-Surgically Implanted Prostheses and Human Tissue Items List (The List) was established in August 1985. The List currently prescribes the Government determined, minimum benefit level payable by private health insurers for listed prostheses and human tissue items.

Following a review of the List in June 1999, industry was advised of the new arrangements for the List in October 1999, which were to come into effect fully in February 2001. The new arrangements would mean no minimum benefit payable by health funds would be attached to prostheses items on the List, and benefit levels would need to be negotiated by the health fund either directly with suppliers or through a hospital or agent.

Also, there was to be the establishment of a new Supplementary List to include items that do not meet Departmental guidelines for inclusion on the Surgically Implanted Prostheses and Human Tissue Items List, but do offer health benefits to patients and potential savings to health funds or the Commonwealth.

An Expert Committee is to be formed to advise the Department on items proposed for the Supplementary list, based on the strength of evidence on new medical technologies aimed at improving health outcomes for patients, in terms of clinical effectiveness and cost-effectiveness.

The composition of the Expert Committee will consist of representatives from the Department of Health & Aged Care, and industry stakeholders including manufacturers/suppliers, private hospitals and health funds. The Committee will also include a health economist, consumer representative, and medical specialists as appropriate. A secretariat will be established within the Dept of Health and Aged Care to provide administrative and secretariat support to the Expert Committee.

The Department estimated a cost of $680,000 pa to support the operation of the secretariat to manage the List and the Expert Committee functions. During discussions with all players in Canberra in 1999, the Department determined that ‘industry’ should fund the operation of the secretariat. MIAA expected that all industry stakeholders impacted by the new arrangements (hospitals, funds, manufacturers/suppliers) would share this cost.

**This has not been the case** and in May 2000, manufacturers/suppliers **only** were charged retrospective fees for funding the new arrangements for the financial year 1999/2000. These charges were applied through fees for new applications and maintenance fees for existing items.

**It is clear that manufacturers/suppliers are unfairly bearing the costs for funding the new arrangements, while the other stakeholders, particularly the health funds, are the main beneficiaries.** Thus far, MIAA member companies have accepted these costs without substantial protest, in the hope that there would be rapid development of the Secretariat, the Expert Committee and the new arrangements. That has not happened. MIAA has made clear that no further costs will be paid until this occurs and that income already collected by the Department for an expressed purpose has been expended for that purpose

## Conclusion

MIAA expresses appreciation for the opportunity to lodge this submission and remains ready to provide supporting documentation or to address any questions of detail.

Yours sincerely,

Brian Vale
Chief Executive Officer

**Attachment 1**

# MIAA MEMBERSHIP

3M Health Care
Abbott Australasia Pty Ltd
Abbott Diagnostics Division
Acute Care Systems Pty Ltd
Alaris Medical Systems
Alcon Laboratories (Aust) Pty Ltd
Allergan Aust Pty Ltd
Ambri
AMS American Medical Systems
Ansell International
AstraZeneca
B Braun Aust Pty Ltd
Bard Aust Pty Ltd
Bausch & Lomb Aust) Pty Ltd
Baxter Healthcare Pty Ltd
Bayer Diagnostics
Beckman Coulter Aust Pty Ltd
Becton Dickinson Pty Ltd
Beiersdorf Aust Ltd
bioMérieux Aust Pty Ltd
Biomet Aust Pty Ltd
Bio-Rad Laboratories Pty Ltd
Biotronik Asia Pacific Pty Ltd
Boots Healthcare Aust Pty Ltd
Boston Scientific Corporation
Clinical Data (Aust) Pty Ltd
Cochlear Limited
Coloplast Pty Ltd
ConvaTec
CSL Biosciences
DePuy Aust Pty Ltd
Device Technologies Aust
Endocorp Pty Ltd
Endotherapeutics Pty Ltd
Faulding Healthcare Pty Ltd
Fresenius Australasia Pty Ltd
Gambro Pty Ltd
GE Marquette Medical Systems
Genzyme Australasia Pty Ltd
George Walck & Associates
Guidant Australia & New Zealand
Healthmed Marketing Aust Pty Ltd
Helena Laboratories (Aust) Pty Ltd
Hipokrat Australia Pty Ltd
Hospital Supplies of Australia
Hydron Pty Ltd
Immuno Diagnostics
Integrated Sciences Pty Limited
Johnson & Johnson Medical
Johnson & Johnson Pacific
Johnson & Johnson Research
KCI Medical Aust Pty Ltd
Kimberly-Clark Aust Pty Limited
Link Orthopaedics Australia Pty Ltd
Linvatec Aust Pty Ltd
Maersk Indoplas Pty Ltd
Mathys Aust Pty Ltd
Medical & Optical
Medical Specialties Aust Pty Ltd
Medtronic Australasia Pty Ltd
Micro Diagnostics Pty Ltd
Microgenics Diagnostics Pty Ltd
N Stenning & Co Pty Ltd
Ocular Sciences Aust
OPSM Instruments
Organon Teknika (Aust) Pty Ltd
Ortho-Clinical Diagnostics
Osteotech Pty Ltd
Pacific Medical Pty Ltd
Pharmacia Australia Pty Limited
Promedica Pty Ltd
Psiron Limited
Roche Diagnostic Aust
SSL Australia Pty Ltd
Sanofi Pty Ltd
Smith & Nephew Pty Ltd
Smith & Nephew Surgical Pty Ltd
Sofamor Danek Aust Pty Ltd
Steritech
St. Jude Medical Aust Pty Ltd
Stryker Aust Pty Ltd
Sulzer Technology Corporation
Terumo Corporation
Tyco Healthcare Aust Pty Ltd
Ulco Medical
Van Leer Flexible Packaging
VidaMed Pty Ltd
Waite & Co Pty Ltd
Welch Allyn Aust Pty Limited
Wesley Jessen/PBH
W.L. Gore and Co
Xomed Aust Pty Ltd
Zimmer

## Comparative Assessment Costs – 2000

## (All data in Australian $, exchange rates as at November 6, 2000)

As the regulatory systems of countries vary widely, it is difficult to compare the cost of gaining marketing approval for products across different countries. However, the following table describes the known costs levied by regulators for the processing and evaluation of products.

Where differences apply between high and low risk products in one country and not in others, these have been included (e.g. high risk and low risk diagnostic products are differentiated in Canada, annual charges for high and low risk products are differentiated in Australia)

### Product Evaluation Costs and Annual Maintenance

| Country | High Risk | Low Risk | Diagnostics | Annual Charges |
|---|---|---|---|---|
| Australia | $64,000 | $240 | $12,400 | High risk - $900<br>Low risk - $450 |
| Canada | $18426 | $254 | High risk- $10,665<br>Low risk $560 | $127 |
| USA | Nil | Nil | Nil | Nil |
| UK | Nil (NB) | Nil (NB) | Nil (NB) | $197 |

N.B. = Notified Body

**Notified Bodies** are the private sector conformity assessment companies used in the UK, Europe and occasionally, the USA. Fees charged by these bodies are determined by negotiation with the manufacturers they support. Thus, their costs are not shown in the above Table. Usually, these costs fall well below TGA levels. Comparative examples, Commercial in Confidence, can be provided on request.

In the USA, while FDA support is free of cost, the sponsor is able to streamline the regulatory process by having an independent body evaluate their product and then presenting the report to the FDA. This considerably shortens the time to market and can be advantageous in terms of sales versus evaluation costs.

Although the regulatory authorities in the EU charge minimal fees to maintain a product on the market (e.g. costs provided for the UK), sponsors must have their products evaluated by an approved Notified Body. As stated above, this cost is subject to negotiation between the manufacturer (or sponsor) and the Notified Body. Many factors are considered in this negotiation besides the time required for evaluation:

- number of products to be evaluated per year
- familiarity of the Notified Body with the manufacturing plant
- discounts due to number of facilities using the same Notified Body

The following table provides one set of figures for an identical new product application which was reviewed by the competent authorities and/or Notified Bodies in the countries indicated. This Table compares the relative market sizes and shows the volume of sales required to recoup initial fees.

| **Country** | **Fees ($A)** | **Sales to recoup fees (1)** | **Relative market size (2)** |
|---|---|---|---|
| Australia | $76,000 | $486,000 | 1% |
| Canada | $19,800 | $123,000 | 2% |
| Europe | $12,800 | $81,000 | 26% |
| USA | Nil | N/A | 43% |
| Japan | $11,100 | $71,000 | 15% |

Notes:

1. The estimates of sales to recoup fees are based on 36% company tax and 10% net profit on sales after tax
2. Medical device market estimates made by Health Industry Manufacturers Association USA in 1999