25th May 2001

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

Dear Ms. Owens,

Re: Draft Report of Productivity Commission: Federal Government Cost Recovery

This letter is provided in response to your invitation for organizations or individuals to appear before Public Hearings in June. The Medical Industry Association of Australia (MIAA) has sought approval to appear at the Sydney hearings.

Firstly, MIAA commends the efforts of the Productivity Commission in unravelling the many complexities of cost recovery practices in use in the Federal environment. MIAA considers that the draft Report has identified all the issues of concern to industry. Further, we consider that the Report proposes some sound reforms for Government to take up that could result in improved efficiency, transparency, accountability, equity and fairness. Implementation of the proposed initiatives should enhance both public and industry confidence in the delivery of regulatory functions.

In the case of the TGA, implementation would not resolve some important conflict of interest issues, but we will address that later in this submission.

Proposal to Correct Matters of Fact in the Draft Report

In our view there are some errors of fact in the draft Report. These arise from a failure to define "**Therapeutic Goods**" and then to distinguish between the products of our industry and those of the pharmaceutical industry. This is an important distinction to make, as the overseas cost recovery practices discussed in Part G (G7) of the Report, are not correct for therapeutic devices. Also, the markets and the market behaviour for the different therapeutic goods are distinctly different.

MIAA represents suppliers, including manufacturers, of **therapeutic devices**, which includes diagnostics. This is a non-drug environment. **Therapeutic goods** are regulated separately by the TGA as prescription medicines, complementary medicines and medical devices. The Report frequently discusses therapeutic goods solely in terms of medicines, without differentiation. This leads to the erroneous statement in Part G7 of the Report, dealing with "prescription drugs and dietary supplements", that the MIAA and Awin submissions are incorrect in suggesting that no FDA fees are applied to the therapeutic devices industry. To the best of our knowledge,

confirmed by industry in the USA, no FDA costs are recovered from industry in relation to therapeutic devices, whereas some cost recovery is understood to occur in the pharmaceutical environment.

MIAA suggests that the Glossary be amended to define:

- "therapeutic goods" as separately regulated prescription medicines, complementary medicines and therapeutic devices, and
- "therapeutic devices" as inclusive of diagnostic equipment and diagnostic supplies.

MIAA suggests that the reference to MIAA and Awin submissions in G7 be removed, as it is both inaccurate and wrongly placed, given that the paragraph deals with prescription drugs and dietary supplements.

It will, or should be, apparent that the figures presented on ppG14-G15 for Canada and UK do not address therapeutic devices.

At page DI of the draft Report, paragraph 1, therapeutic devices should be specifically mentioned alongside those other products mentioned.

Other Comments

Nature of the Therapeutic Devices Market.

90% of therapeutic devices sold in Australia are imported. The market size is small at 1% of the world market. The Report recognises that it is possible for poor regulatory practice to act as a barrier to market entry; some examples of this are recorded. MIAA wishes to reinforce that our industry surveys show that companies routinely determine not to bring certain new products to the Australian market, as a direct outcome of high TGA entry costs, frequently slow approval times (though we concede the improvements that have been achieved) and small market size. There is a decreasing availability of certain therapeutic devices in Australia. The absence of these cannot always be addressed by the TGA Special Access Scheme, as product support may not be available.

MIAA considers that the Report fails to adequately recognise the extensive presence of high technology in the therapeutic devices market. The pace of technology advance demands a responsive regulatory system, consistent with public safety interests. The technology life of many of the higher technology products can be less than two years. The Report correctly recognises that the greatest threat to the availability of technology is reduced importing, rather than any constraint of local R & D.

Beneficiary Pays

Draft Recommendations 6.1 to 6.4 are strongly supported. Industry does not begrudge paying for effective and timely regulatory support, but as the draft Report notes, a substantial part of TGA activity is unrelated to regulatory support of industry. We note that consumers share a view that industry should not be expected to meet all TGA costs.[1]

[1] CHF Submission, 1st December 2000, page 5, Principle 7.

The issue of who is the "beneficiary" is clouded. Without question, industry benefits from certain regulatory functions. But, to suggest that TGA regulatory activity is delivered solely for industry benefit[2], is nonsense. There are shared benefits from regulatory practice, and these include the benefits afforded to consumers.

A difficulty for our industry is the nature of the market. 70 % of therapeutic devices are sold into the Public sector (States and the Commonwealth). Usually, volume items are sold by tender and contract. Thus, while prices may contain provision for review in certain circumstances (such as currency fluctuation), there is almost no capacity to pass on quickly, an upward shift in prices resulting from changed regulatory costs. This was a particular problem for our industry in 1997 when TGA fees and charges increased by 30%-50%, and again in 1999 when TGA regulatory costs for our industry increased by 43%.

Predictability of future costs is an essential requirement for industry[3].

Draft Recommendation 6.8 proposes the concept of only passing on costs to industry when they are able to be "passed down" to final beneficiaries. When the Commonwealth and the States feature strongly as the "final beneficiaries", this can be difficult to accomplish in the short term.

Total Costs to Industry of Regulatory Activity

Chapters 3 and 6 of the draft Report address both costs to industry and parliamentary scrutiny of Agency costs (or the lack of it). However, we feel that the Report could be improved by noting the current inability of Government to take a holistic look at the costs industry faces. There is much "silo" activity occurring within government and agencies that culminates in additional costs for industry.

For example, during 2000, all industry struggled to deal with the impact and costs of the New Tax regime. At the same time, our industry sector faced a 43% increase in costs from the TGA, plus $680,000 in newly determined departmental fees (non-TGA) for the management of a Prostheses Benefits Schedule. The departmental fees for Prostheses Benefits management were small by comparison with the compliance costs for industry, which were estimated to have exceeded $1 million in the first year (additional staff, revised billing systems, etc). Parliament would have been unaware of the additional burdens facing our industry. DOHAC was itself unaware of the separate billing initiatives underway in the department until advised by industry.

This year industry faces additional costs from the TGA to meet increased rental charges for the TGA building at Symonston, a result of a DoFA-driven sale and leaseback policy. [4]

Seemingly small changes in charging regimes have a significantly adverse impact when summed and levied in a short space of time.

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[2] As recorded at Page 68 of the Draft Report

[3] This point was recognised by the Commission at Page 192 with reference to the Avcare submission.

[4] The increased costs for this are described at Page D13 of the draft Report.

Competition Policy

MIAA noted in its original submission that the TGA was operating without competition in its therapeutic device conformity assessment role. The lack of competition and the potential to introduce competition is noted on pp96-97 of the draft Report. MIAA wishes to reinforce that not only would private sector assessment of devices be a credible alternative, but it would remove potential conflict of interest issues wherein the TGA currently establishes regulatory standards then assesses products against them.

A separation of functions would truly harmonise Australian practice with Europe, where in many countries, private sector Notified Bodies conduct conformity assessment. No diminution of quality need result, provided (as in Europe) the regulatory authority audited the conformity assessment bodies.

Part D of the draft Report (ppD28-D29) could be improved by mention of the fact that the EU achieved competition and responsiveness in the therapeutic devices evaluation market by licensing of the private sector Notified Bodies.

Private sector conformity assessment could be expected to lead to the establishment of strategic partnerships between assessment bodies and industry, with responsiveness and cost effectiveness constantly under review. This cannot be accomplished under present arrangements while the TGA, as regulator, needs to be seen to be at “arm’s length” from industry.

Industry remains disappointed with Government's failure to embrace the key recommendations of the 1996 Industry Commission Report, in which separation of Regulatory and Assessment functions was recommended, as was the introduction of private sector competition.

A progressive shift of TGA conformity assessment functions to the private sector would be sensible.

Accountability of Agencies

Your draft Report has correctly identified that where full cost recovery is in place, as with the TGA and NRA, then accountability to the "bill payers" is difficult to achieve. The operation of the TGA TICC Committee is an example of inadequate accountability. The TICC forum offers an opportunity to exchange ideas and provide current information on industry issues and trends, but it fails to deliver a forum in which industry can expect to be given an opportunity to shape TGA business practices. Industry input can be and is ignored, and industry is not empowered in the TICC process to prescribe performance standards.

Recently, after more than three years of effort, MIAA abandoned efforts to reach a Performance Agreement with the TGA as it became clear that the TGA would not (or could not) agree to be bound by mutually agreed, reasonable performance measures.

Proposal: Efficiency Audit Committee (EAC)

While MIAA and other industry groups would like to achieve greater directional input to the TGA and improved performance reporting, we concede this is difficult to deliver. MIAA has argued for independent chairing of the TICC, with reporting from the Chair back to the Minister. This has been resisted.

As an alternative, the concept of an EAC is supported. As outlined in the draft Report[5] an EAC would offer more rigour and accountability than is apparent in the current TICC process.

Summary

MIAA appreciates the opportunity to raise these matters with the Commission. We would be pleased to provide further advice as required, or to address these issues during the Public Hearings in June.

Yours sincerely,

Brian Vale
Chief Executive Officer

[5] Chapter 5.3, page 107