

31 July 2008

Regulatory Burdens – Manufacturing and Distributive Trades Productivity Commission GPO Box 1428 Canberra City ACT 2601

**Dear Commissioners** 

Additional Comment on Draft Research Report on Annual Review of Regulatory Burdens on Business – Manufacturing and Distributive Trades

I write with reference to the Commission's Draft Research Report, specifically the Draft Responses set out in Chapter 4 as they impact medical devices (also known as medical technologies).

The Medical Technology Association of Australia (MTAA) generally supports the Draft Responses which reflect the long history of review and recommendations to enable reform of regulation and assessment for funding of medical technologies. However MTAA would like to use this opportunity to propose a broader statement in Draft Response 4.7. MTAA would like to see the Draft Response reflect the need for a more architectural or structural review of the place of medical technology, including an assessment of Health Technology Assessment. MTAA is of the view that the current system is inflexible and out-of-date, incapable of effectively and efficiently assessing the evidence-based merit of approving and funding innovative technologies.

MTAA also proposes the use of the term 'medical technology' as there are many technologies such as diagnostic imaging equipment that might not meet the traditional definition of a 'medical device'.

MTAA therefore proposes a rewording of Draft Response 4.7 as follows:

A comprehensive and independent public review of the means by which medical technologies are assessed for use in the Australian healthcare system. A review of Health Technology Assessment processes for medical technologies should proceed as soon as possible. Outcomes should include:

 a framework for the development of policies for access to, and use of, medical technologies

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- a streamlined process for the regulation and assessment for funding of medical technologies to remove duplication and overlap in current arrangements
- a transparent, timely and evidence-based process for assessing safety and performance and suitability for public funding and reimbursement by private health funds.

MTAA appreciates that the Commission's focus is on regulatory burdens on business but as the Commission has previously noted, the systemic challenges for the medical technology industry reach beyond mere regulatory barriers. The barriers are evidenced by the failure of healthcare policy to adapt to a rapidly evolving industry and its technologies which will form a critical component of the future of healthcare delivery in Australia.

I look forward to seeing the final Report.

Yours sincerely

Anne Trimmer

Chief Executive Officer