

# Medical Industry Association of Australia

4<sup>th</sup> October 2005

Mr. Elton Humphery  
Committee Secretary  
Australian Senate  
Community Affairs  
Legislation Committee  
[community.affairs.sen@aph.gov.au](mailto:community.affairs.sen@aph.gov.au)

Dear Mr. Humphery,

## **Therapeutic Goods Amendment Bill 2005**

Thank you for the invitation to make a submission regarding the referenced Amendment Bill.

The Medical Industry Association of Australia (MIAA) is the peak industry body for suppliers and manufacturers of medical devices and *in vitro* diagnostics in Australia.

MIAA is of the view that the Bill and the General Principles closely interpret the objectives stated in the second reading speech. However, it does create a more punitive environment for industry and will add further to the costs of compliance by industry. Given these predictable costs (which will need to be absorbed at some point in the supply chain) and the potentially adverse impact on industry development in Australia, a regulatory impact statement should have been mandatory.

We believe that there are three areas in the Bill that require clarification:

- a) Is there a link between the Penalties Bill and the Therapeutic Goods Act, such that any penalty imposed (including an Infringement Notice) may trigger the "Fit and Proper Person" provision of the Therapeutic Goods Act?
- b) There may well be an issue with the protection against self incrimination. Although Section 31F only provides protection for an individual against self incrimination, it is unclear whether this extends to a corporate defendant.
- c) Sections 42YF and 42YH state that a person cannot be subject to a civil penalty where they are convicted of the offence and similarly, a person cannot be convicted where they have been subject to a civil penalty. However, it is unclear (and important) that if a person is the subject of criminal proceedings and has won, then they should not be subject to civil penalties (and vice versa).

Again, MIAA appreciates the opportunity to provide information for your consideration.

Yours sincerely,



Brian Vale  
Chief Executive Officer