The Submission of the Department of Industry, Innovation, Science, Research and Tertiary Education to the Senate Inquiry concerning *The role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prosthèse (PIP) breast implants.*

1. The Department of Industry, Innovation, Science, Research and Tertiary Education (DIISRTE) appreciates the opportunity to provide a submission to the *Inquiry into The role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prosthèse (PIP) breast implants*.

2. DIISRTE strives as a key priority to encourage the sustainable growth of Australian industries by developing a national innovation system that drives knowledge creation, cutting-edge science and research, international business competitiveness and greater productivity to improve social and economic benefits for the Australian community.

3. The impact of PIP breast implant failures on patients in Australia and overseas is regrettable. DIISRTE is seeking a proportionate response to the allegedly rogue behaviour of one overseas medical technology company.

4. DIISRTE considers that the relatively low risk of problems with the type of PIP breast implants that are legally available in Australia does not indicate that there is a problem with the level of regulation in Australia.

5. DIISRTE is concerned that overreacting to the particular details of this case may result in unnecessarily increasing the health technology assessment regulatory burden for all Australian medical technology companies without sufficient evidence of the need to do so.

6. Another risk or unintended consequence of overregulation may be Australians going overseas to access particular medical technologies that are either unregulated or are not regulated to the standard of medical technologies in Australia. This may impact negatively on the health of Australians and also on the Australian healthcare system.

7. As stated in previous submissions, DIISRTE supports a fundamental goal of the Review of Health Technology in Australia (HTA Review) to reduce regulatory costs of the current health technology assessment system while maintaining appropriate safety standards.

8. DIISRTE's concerns focus on the potential industry impacts of the cost (including compliance costs), speed and the regulatory burden associated with conformity assessment of medical technologies and the related regulatory framework. The current regulatory burden includes resourcing issues for small and medium businesses required to deal with regulatory change.'[1]

[1] DIISR 2010, *Submission to Reforms in the Medical Devices Regulatory Framework*, paragraph 12, p.2

9. DIISRTE maintains the position put in previous submissions that the Therapeutic Goods Administration (TGA), 'should be the sole Commonwealth arbiter of the safety of medical devices'[2] including approval of medical devices or implants, monitoring and withdrawal of devices considered to be defective or harmful. DIISRTE has previously proposed that the TGA should be responsible for setting criteria for appropriate third party conformity assessment and accredit appropriate third party conformity assessors and monitor them[3]. There is also strong industry support for the use of accredited third party conformity assessment bodies, approved and overseen by the TGA, for Australian manufacturers and companies seeking to sponsor medical devices in Australia.

10. As stated in its previous submission, DIISRTE, 'sees an opportunity to increase positive Australian health outcomes and improve the operating environment for medical devices companies through greater use of third party conformity assessment'.[4] Use of appropriate third party assessment has the potential to save considerable time and money for Australian medical devices manufacturers and their customers.

11. DIISRTE considers that the use of third party assessment bodies for Australian manufacturers and recognition of third party assessment are urgent areas of reform that have been recommended by various bodies, such as the Banks Review, since 2006.[5] These measures can improve the operating environment for medical devices companies through faster and non-duplicative assessment of the safety of medical devices by more appropriate use of third party conformity assessment bodies overseen by the TGA.[6]

12. DIISRTE has sought, 'greater use of and domestic alignment with, the international post-market surveillance mechanisms of comparable countries'[7] and has made statements in submissions regarding the need to, 'consider implementing post-market surveillance requirements to deliver fit-for purpose quality control regimes, including calibration of medical devices with a measuring function, for better health outcomes'.[8]

13. DIISRTE is aware that the TGA has proposed reforms to the medical devices regulatory framework and looks forward to their timely implementation.[9] Reforms include more effectively facilitating the recognition and reporting of adverse events by health practitioners and consumers, and promoting the easier use of the adverse

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[2] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation l, p.3
[3] DIISR 2010, Submission to Reforms in the Medical Devices Regulatory Framework, paragraphs 22-24.
[4] DIISR 2010, *Submission to Reforms in the Medical Devices Regulatory Framework*, paragraph 7, p.1
[5] Australian Government 2006, *Rethinking Regulation the Taskforce on Reducing Regulatory Burdens on Business*, Recommendation 4.19
[6] DIISR 2010, *Submission to Reforms in the Medical Devices Regulatory Framework*, paragraph 8, p.1
[7] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation p, p.3
[8] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation q, p.3
[9] Australian Government 2011, *TGA Reforms: A Blueprint for TGA's Future*

event reporting system. DIISRTE also notes the plan to ensure information on the key public access portal, the TGA website, is current, accurate, relevant, timely and up to date, and meets the needs of its audiences.

14. DIISRTE has noted the report and findings of the 2011 Senate Inquiry into the Regulatory Standards for the Approval of Medical Devices and understands that the Australian Government is currently considering its response to the recommendations of the Senate Inquiry.

15. The Government has a, 'strong commitment to microeconomic reform [which] includes an ambitious better regulation and red-tape reduction agenda. Sustained regulatory reform supports increased productivity and international competitiveness…'[10]. DIISRTE has submitted that it is of the view that reform to allow third party conformity assessment for Australian manufacturers is urgent.[11]

16. DIISRTE seeks any Senate Standing Committees on Community Affairs recommendations regarding the regulation of the medical technology industry to be:

- mindful of the impacts of the current burden of regulation in this area;
- proportionate and based on evidence concerning specific problems, rather than recommendations that are based on possible issues; and
- mindful of the risk or unintended consequence of unduly increasing regulation to the health of Australians.

[10] http://www.finance.gov.au/deregulation/index.html accessed on 12 April 2012.
[11] http://www.tga.gov.au/pdf/submissions/consult-devices-reforms-101130-submission-diisr.pdf accessed on 12 April 2012.