The Royal Australasian
College of Physicians

6 January 2011

Office of Device Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Via email: devices@tga.gov.au

Dear Sir/Madam

Re: The Royal Australasian College of Physicians (RACP) response to the discussion paper on *Reforms in the Medical Devices Regulatory Framework (25 October 2010)*.

The RACP supports the use of post-marketing safety surveillance for medical devices and support the recommendations in the discussion paper

The RACP supports the view that patients deserve to be fully informed about the benefits and risks of medical devices, and the medical device industry should be held accountable if they fail to achieve this standard. The RACP congratulates the Therapeutic Goods Administration (TGA) in developing a more streamlined approach to Industry Codes of Conduct.

The recently revised TGA website will provide information on the current Australian Government Health Technology Assessment in Australia (HTA) processes used to inform decisions about the registration of health technologies, and the reimbursement provided under these funding programs.

Mandatory recording of the detailed specifications of installed devices in existing healthcare datasets will be a necessary step in this evolution. Placing safety surveillance activities at a higher and more independent position within TGA is an excellent solution to this problem. This will make it possible to pool epidemiological expertise across several domains in which similar problems arise, such as pharmaceuticals, biological agents, and medical devices.

Complex medical devices are an increasingly prominent and vital component of the medical armamentarium. Health care providers and patients are awakening to the need for greater rigor in the evaluation and surveillance of all healthcare interventions.

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The RACP is willing to be involved in future discussion and developments. Please contact Mary Osborn, Senior Policy Officer, on (02) 9256 9606 or mary.osborn@racp.edu.au.

Yours faithfully

Dr Leslie E Bolitho AM
President-Elect

cc: Ms Shelley Tang
Acting Head
Office of Devices Authorisation