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AdvaMed
Advanced Medical Technology Association

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The Advanced Medical Technology Association (AdvaMed) is pleased to offer this input to the Therapeutic Goods Administration regarding TGA's Discussion Paper of October 25, 2010 on Reforms in the Medical Devices Regulatory Framework.

AdvaMed has reviewed the Discussion Paper as well as the comments on it submitted by the Medical Technology Association of Australia (MTAA) in December 2010. AdvaMed fully supports and endorses MTAA's comments. These comments propose constructive solutions to the issues identified by the TGA in its Discussion Paper, bearing in mind the need to maintain the appropriate balance between protection of patient safety and access by those patients to innovative medical technologies. In particular, AdvaMed endorses MTAA's strong recommendation that further consultation be undertaken with the industry to ensure the workability of some of the reform proposals.

AdvaMed is the world's largest medical technology association. Based in Washington, D.C., AdvaMed represents international manufacturers of medical devices, diagnostic products and medical information systems.

On behalf of AdvaMed, I appreciate the opportunity to submit these comments.

Sincerely,

Philip R. Agress
Senior Vice President, Global Strategy and Analysis