Queensland Government

Queensland **Health**

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Ms Shelley Tang
Director
Medical Device Conformity Assessment Section
Office of Devices, Blood and Tissues
Thereapeutic Goods Adminstration
Department of Health and Ageing

Dear Ms Tang

Discussion paper: *"Reforms in the Medical Devices Regulatory Framework – October 2010"*

I am writing in response to the invitation on the TGA website to provide feedback on the Discussion Paper "Reforms in the Medical Devices Regulatory Framework, October 2010.

Queensland Health is committed to providing quality care and safe interventions using the highest quality products available to health care consumers. To be able to fully comment upon the reforms, there are questions in relation to the possible impact that reforms have upon the regulatory framework surrounding the quality of implantable devices.

Reclassification of joint replacement implants

It is noted that ancillary components for hip and knee replacements, such as screws, wedges, plates and surgical instruments have been omitted from the proposed reclassification. The proposal does not provide the reason ancillary components will not be subject to the same scrutiny as the component part. Ensuring that all products made available to consumers during the course of medical intervention are of the highest quality standards is paramount. Will there be a risk that patients will be subjected to ongoing revision as a result of the omission to reclassify ancillary components?

Use of third party assessment bodies for Australian manufacturers

The paper proposed Sub regulation 4. 1(1) is removed from the medical device regulations thereby removing the requirement for Australian manufacturers to hold Therapeutic Goods Administration conformity assessment certification.

The proposal does not detail the expectations of the Therapeutic Goods Administration in terms of the quality standards of third party assessors. It is also unclear which authority will fully regulate these third parties or how third parties will guarantee quality of product. Failure to take these factors into careful consideration may pose a risk to consumers through revision or recall when the product does not conform to acceptable levels of quality or safety standards. Will the Therapeutic Goods Administration provide a regulatory function to ensure that third party assessors are high quality assessors? What are the requirements for third party assessors to guarantee the product is safe and that any risk to the consumer is fully disclosed and publicly accessible?

We welcome improvements to the way in which medical devices will be included in the Australian Register of Therapeutic Goods (ARTG) and enhancing identification methodologies for approved devices. We would suggest that this model field would be ideal way to identify components to enable improved availability to search the ARTG.

Thank you for the opportunity to respond to this paper.

Yours sincerely

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