Queensland Government

Queensland Health

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Ms S Tang
Office of Device Authorisation
Therapeutic Goods Administration
PO BOX 100
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Dear Ms Tang,

Thank you for the opportunity to participate in the consultation process and provide feedback to the Therapeutic Goods Administration, regarding the *Reforms in the Medical Devices Regulatory Framework-Discussion Paper, 25 October 2010.* A summary of our responses are outlined in the attached table.

In April 2009, a *3rd Party Medical Device Assessment Proposal* was submitted to the Therapeutic Goods Administration regarding the *Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia* consultation paper from Queensland Health. Queensland Health would like to reiterate our commitment to this proposal and would be happy to meet and discuss the findings, directions or feedback that may have resulted as part of the review process. As you will note this proposal was a direct result of the work (including sterility testing) already being undertaken by the Centre for Healthcare Related Infection Surveillance and Prevention (CHRISP) Sterilizing Program with current registered medical devices.

Once again thank you for the opportunity to participate in the consultation process. If there is any opportunity for Queensland Health to participate in the detailed planning of these reforms please do not hesitate to contact Rosemary Steinhardt, CHRISP Sterilizing Program Manager by either email rosemary_steinhardt@health.qld.gov.au or phone 07 33289767.

Yours sincerely

Dr. Jeannette Young
Chief Health Officer
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Devices Regulatory Reform Proposals		
Proposal #	TGA Proposal	CHRIS Response and Clarification
Proposal 1	**1 Reclassification of joint replacement implants** A new classification rule is added to Schedule 2 of the medical device Regulations to reclassify all hip, knee and shoulder joint replacement implants from Class IIb to Class III medical devices.	1. The intent of this reform is understood and should be supported. However, it is not clear whether the ancillary related items/instruments remaining in Class IIb warrants a true recognition of the risk level applied? The real concern here is assurance that the implant and related items are recognised as a complete related set or system. Therefore, regardless of the split classification of items, the entire set/system is subject to Conformity Assessment (e.g. sterility testing). For example, where a set has a Class III item, then the whole system/set should be subject to the same assessment rather than having different levels of assessment or verification due to the different classification of the items in the whole set/system.
Proposal 2	**2A Use of third party assessment bodies for Australian manufacturers** That Subregulation 4.1(1) is removed from the medical device Regulations, so as to no longer require Australian medical device manufacturers to hold TGA conformity assessment certification.	2A. The intent of this reform is understood and should be supported in line with comments above.
	2B Increasing pre-market scrutiny for implantable medical devices **(i) Devices requiring a TGA Conformity Assessment Certificate to be issued** Subregulation 4.1(2) of the medical device Regulations be amended to require a TGA conformity assessment certificate to also be issued for all Class III and AIMD implantable medical devices. **(ii) Applications to be selected for auditing** Regulation 5.3 of the medical device Regulations be amended to require applications for all Class IIb implantable devices to also be selected for an application audit prior to inclusion in the ARTG.	2B. The intent of this reform is understood and should be supported in line with comments above.
	2C Recognition of third party assessment bodies **(i) Confidence building for EU Notified Bodies designated under the MRA** That the TGA commence discussions with the EC over a program of confidence building with the designated Notified Bodies under the MRA, which might include sharing of product assessments and observed audits of medical device manufacturers. **(ii) Recognising Australian third party assessment bodies** That further consultation be undertaken to investigate the development of a system whereby Australian based assessment bodies can be designated to issue conformity assessment certificates to Australian manufacturers.	2C (i). The intent of this reform is understood and should be supported. 2C (ii). The intent of this reform is understood and should be supported. Please refer to Division of Chief Health Officer previous proposal and consider future involvement during the system development phase.
Proposal 3	**3 Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices** **(i) amend the way in which a kind of device is included on the ARTG; and** **(ii) enhance the ability to identify devices that have been approved by the TGA for supply in Australia.**	3 (i) This is supported as experience has shown that some ARTG certificates have limited product information. 3 (ii) This is supported with a preference to upgrade the eBS ARTGD.
Proposal 4	**4 Publication of device product information on the TGA Website**	4 The intent of this reform is understood and should be supported. There is a great opportunity to inform consumers and healthcare facilities about the latest developments, product performance, reprocessing instructions etc via more of a Device Knowledgebase. This could be well supported by jurisdiction/facility product procurement and Medical Device review groups. It may also be worth aligning this with the National Product Catalogue.