Our Ref: GEN-2010-2480

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Dear Sir/Madam

**Stakeholder Consultation**

**Discussion Paper - Reforms in the Medical Devices Regulatory Framework (25 October 2010)**

GlaxoSmithKline Australia (GSKA) appreciates the opportunity to comment on the TGAs Discussion Paper - Reforms in the Medical Devices Regulatory Framework. GSKAs specific comments on the four device regulatory reform proposals are provided below.

**Proposal 1 - Reclassification of Joint Replacement Implants**

GSKA does not have any comments on this proposal.

**Proposal 2 - Third Party Assessment Bodies and Supporting Reforms**
**Proposal 2A – Use of third party assessment bodies for Australian manufacturers**
**Proposal 2B – Increasing pre-market scrutiny for implantable medical devices**
**2B(i) – Devices requiring a TGA Conformity Assessment Certificate to be issued**
**2B(ii) – Applications to be selected for auditing**

GSKA does not have any comments on these proposals.

**Proposal 2C – Recognition of third party assessment bodies**
**2C(i) – Confidence building for EU Notified Bodies designated under the MRA**
**2C(ii) – Recognising Australian third party assessment bodies**

GSKA does not have any comments on these proposals.

**Proposal 3 - Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices**

**3(i) – Amending the way a kind of device is included on the ARTG**

GSKA fully supports the following TGA proposals as it will allow the TGA, healthcare providers and consumers to easily identify devices that have been approved by the TGA for supply in Australia:

- Within the application form, sponsors will be required to itemise the devices and/or various models that are supplied under the same ARTG entry.
- On the public view of the ARTG, the list of devices identified by model number or trade name per ARTG entry will be published.
- Sponsors will be required to submit an application to vary the existing ARTG record to add a new model of that kind of device.

The proposed transition period of 12 months to vary existing device entries on the ARTG at no cost to the sponsor seems reasonable.

However, post the transition period the requirement to lodge a variation application to register a new model or trade name of device will be an additional ongoing cost to sponsors. This cost should therefore be minimal and reflective of the amount of data submitted by sponsors and the time taken by the TGA to assess the submitted data.

**3(ii) – Enhancing the identification of approved devices**

GSKA fully supports TGA's proposal to include the ARTG number on the information that accompanies a medical device. However, we believe the location of this ARTG number should be limited to the outer packaging of the device. For example, if a device is provided in a carton, the ARTG number should be mandated on the carton only. This approach will reduce artwork costs associated with updating current packaging. Furthermore, depending on the type of device, it may not be practicable to print the ARTG number on the physical device or immediate packaging.

The inclusion of the ARTG number on the packaging will allow easy identification of medical devices that have been approved by the TGA for supply in Australia.

We request the TGA considers extending the implementation timeframe from 12 months to 24 months for adding the ARTG number to medical devices based on the following factors:

- The packaging of medical devices tends to be shared across a number of countries and therefore adding the ARTG number on the packaging could take a long time to implement if each country sharing the pack needs to obtain regulatory approval.
- The lead times for updating packaging can take up to 3 months, if not more, depending on the site of manufacture and frequency of manufacture of the device.
- Write-off costs of existing packaging should be minimised wherever possible, particularly for low volume devices that are manufactured infrequently.

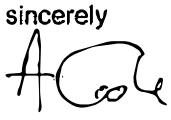
**Proposal 4 - Publication of device product information on the TGA Website**

GSKA does not support the development and publication of equivalent documents to the AusPAR, PI and CMI for all medical devices.

Currently, only prescription medicines (i.e higher risk medicines) are required by the TGA to have an AusPAR, PI and CMI published on the TGA website. There is no requirement to write an AusPAR nor to publish the PI and CMI for OTC products which are generally recognised to be lower risk medicines. The same approach should therefore be applied to medical devices. That is, the development and publication of such documents should be restricted to higher risk classification devices such as Class III and AIMDs. The TGA only assesses these devices and so in line with being transparent on the evaluation and decision making process, this would be justified. Lower risk classification devices such as Class I and II medical devices are not assessed by the TGA and therefore should be exempted.

Please do not hesitate to contact the undersigned should you require clarification on any of the issues raised.

Yours sincerely



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