Consultation submission cover sheet

This form accompanies a submission on:

***Regulation Impact Statement (RIS): Changes to premarket assessment requirements for medical devices* exposure draft**		
Name and designation	Lee Glanzmann - BSI Medical Devices	
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I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*		☐Yes ☒ No
I would like my name and personal details (phone and email contact, etc) to be removed from all documents prior to publication and not be included within the list of submissions on the TGA website.		☐Yes ☒ No
I would like my company's name to be removed from all documents prior to publication and not be included within the list of submissions on the TGA website.		☐Yes ☒ No

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: *(tick all that apply)*

Business in the therapeutics industry *(please tick sector):*

☐Prescription medicines ☐Complementary medicines ☐OTC medicines

☒Medical devices ☐Blood, tissues, biological ☐Other

☐Sole trader ☐Business with employees

☐Importer ☐Manufacturer ☐Supplier ☐Industry organisation

☐Government ☐Researcher ☐Professional body

☐ Consumer organisation ☐Institution (e.g. university, hospital)

☐Regulatory affairs consultant ☐Laboratory professional

☐Health professional – *please indicate type of practice*:

☒Other - *please specify*: EU Notified Body

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Monday, 03 June 2013

To whom it may concern,

RIS – Changes to premarket assessment of implantable medical devices

BSI would like the opportunity to provide the following comments in regard to the RIS on changes to the premarket assessment of implantable devices. All comments are detailed below. Should you require further information regarding these comments, please do not hesitate to contact me on the information provided in the coversheet.

Option 1: No immediate Action

Position: BSI does not support this option.

Comments: The current regulatory system hinders Australian manufacturers from selecting Notified Bodies that are capable of assessing medical devices for the Australian market. These Notified bodies are able to perform conformity assessments on European manufacturers. It is unclear exactly why this rule is in place.

Option 2: Changes to premarket assessment of medical devices

Proposal A: Increased scrutiny of conformity assessment as part of mandatory application audits prior to ARTG inclusion

Position: BSI supports the expanded range of products subject to mandatory audit

Comments: None

Proposal B: Publication of medical device regulatory decisions (including IVDs)

Position: BSI supports this, which is broadly in-line with greater calls for transparency in the EU.

Comments: None

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Proposal C: Removing the requirement for TGA conformity assessment for Australian manufacturers except for Class 4 IVDs

Position: BSI supports the proposal to allow manufacturers to have their conformity assessment certificates issued by a European NB rather than being limited to using the TGA. BSI also strongly supports the confidence building activities of notified bodies who review the high risk AIMDs and Class III devices.

Comments: BSI is of the opinion that removing the ruling will free up valuable resources at the TGA for them to reallocate to more important tasks such as enforcing regulations.

Reducing the audit level from level 3 to level 1 or 2 after confidence building has been established will allow the TGA to focus their attention on notified bodies that do not perform a sufficient review up to the standard that the TGA would express.

Additionally, the confidence building program will allow the TGA to gain a further insight into how notified bodies review high risk devices and may learn valuable lessons that can only be obtained by working with the best notified bodies. Australia does not have as broad an environment in the medical device industry to provide valuable work experience in high risk medical device design.

Option 3: Expand TGA mandatory conformity assessment for AIMD and Class III implantable medical devices and allow third party conformity assessment for other devices except for Class 4 IVDs

Position: BSI does not support this option

Comments: BSI is of the opinion that further scrutiny of AIMDs and Class III devices only doubles up on regulatory work. There is a wealth of talent and knowledge available in leading notified bodies that the TGA should better utilise.

Yours sincerely,

[redacted]

Digitally signed by Lee Glanzmann
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