Changes to premarket assessment requirements for medical devices

Submission
March 14, 2012

Therapeutic Goods Administration
PO Box 100
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Re: Submission

Changes to premarket assessment requirements for medical devices

General Electric (GE) welcomes the proposals outlined by the TGA in this paper with regards to the two key elements of the premarket assessment process.

GE’s Healthcare (GEHC) division provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, performance improvement and performance solutions services help our customers deliver improved patient care and health services. Our products and services include amongst others Diagnostic Imaging, Anaesthesia and Monitoring, Surgical Systems, Maternal and Infant Care and Healthcare IT. Our current healthcare portfolio is outlined below.
As a leading healthcare provider of medical devices to the Australian market for over 30 years, GE Healthcare appreciates the opportunity to provide our comments and input to assist in shaping the reform proposals.

GE Healthcare’s portfolio includes a range of medical device classifications including Active Implantable Medical Devices (AIMD). We are supportive of the overall need to further strengthen the process of premarket assessment for higher risk medical devices and our recommendations are as follows:

Proposal A: Increase scrutiny of conformity assessment

- Are the medical devices outlined above appropriate targets for greater premarket scrutiny?
- Have any other medical devices which should be included been missed?

GEHC believes that all relevant medical devices have been included in the proposal. We recognise and endorse that Class III/AIMD devices and products are appropriate targets for closer focus and TGA review with regards to premarket assessment, but not necessarily as proposed in the paper via the introduction of an incremental Level 3 assessment audit.

- What are the risks and benefits of this proposal?

GEHC acknowledges the benefits of improving community confidence and patient safety with the proposed increased scrutiny in levels of premarket assessment and the range of review of medical devices which are implantable or surgically invasive. Currently, pre-market assessments are already comprehensively completed in other markets such as Europe and the United States. As a result, some markets such as New Zealand leverage and recognise this international regulatory effort and have simplified their medical device regulatory processes thus benefiting business and consumers.

Clearly, additional investment in TGA resources and expertise will be required to support the proposed level and product range of assessments. Given medical device product issues have been very limited to-date we recommend that any increase in the level of scrutiny needs to be carefully evaluated with regards to current evidence and effectiveness in delivering increased patient safety. Product approval time-frame with regards to pre-market registrations is critical for GE as product life cycle and timely access to market may be impacted with the rapid and ongoing technology improvements. The current regulatory approval processes for high risk medical devices is already significantly lengthy (>6 months). Coupled with the anticipated increases in Level 3 audit fees of $12,000-15,000 the proposed reforms will add cost, complexity and create market delays for business. The risk is that the proposed increase regulatory requirements may actually discourage suppliers and medical device providers to introduce their innovative medical technology to the Australian market.
• Which elements of the proposal could be removed without reducing the premarket regulatory rigour of higher risk medical devices?

With regards to assessment of evidence of conformance certificates and the introduction of a new level of scrutiny, delays in bringing medical technology to the Australian market results from repeating pre-market assessment work already completed in other international markets.

As there are a number of 3rd party notified bodies recognised for their international expertise and consistent certification standards, we recommend that for high risk Class III/AIMD devices TGA considers accepting without further evaluation, conformity assessment certification from an identified number of international or European Notified Bodies that are approved by TGA as having completed sufficient regulator rigour for high risk devices. The benefit will be to reduce cost and regulatory complexity for industry in addition to improving timely access to new technologies for consumers.

As there is insufficient evidence to demonstrate that current TGA premarket assessments provide any additional patient safety outcomes for products already registered in Europe or US, other elements of the proposal that could be removed would be for TGA to consider automatically accepting European and US medical device registrations for all products lower than Class III. This initiative would significantly increase access to market for business and reduce compliance costs for both business and the TGA. Furthermore, such a change will permit TGA resources and expertise to be directed towards improved post market surveillance activities and monitoring longer term trends for medium and high risk medical devices following their introduction in Australia.

Proposal B: Publication of TGA Regulatory Decisions

• What are the risks and benefits of this proposal?

• What limits may be applied to the publication of decisions, including which medical devices to which it might apply, or the way in which implementation might be phased in?

GEHC appreciates and is supportive of the benefits to business, consumers and patients on improving the transparency and accountability of the TGA’s decision making processes. Additional investment in TGA resources will also be required to implement the publication proposal, thus the incremental effort to administer and update the additional information proposed needs to be evaluated versus the value and use of having such detailed information publically available.

The risks and concerns that need to be considered with the publication proposal include:

➢ Ensure no further increase in current and approval time-frames times or regulatory costs to business for bringing medical devices to market.
The feasibility in keep the information updated on a real-time basis, in particular if an application is initially rejected and then subsequently approved for inclusion on the ARTG at a later point in time once additional evidence or supplementary information has been received. This may result in confusion and possibly concern, particularly for consumers not familiar with regulatory processes.

For rejected applications, how the confidentiality of submitted information will be managed and what content is released in the public domain where intellectual property is involved. Furthermore following consultation, arrangements and provisions need to be made available to a manufacturer or sponsor where for commercial in confidence reasons they do not endorse their rejected application to be published at any point in time.

With regards to the additional information proposed and given the potential risks and concerns outlined above we recommend initially publication is limited to applications for inclusion on the ARTG only, given this is the decision which enables a medical device to be supplied in Australia with conformity assessment decisions excluded from publication (on the basis of our earlier recommendation that TGA accepts conformity assessment certification from an identified number of international or European Notified Bodies that are approved by TGA as having completed sufficient regulator rigour for high risk devices). We believe this will avoid potential confusion with regards to what is actually approved in the market and facilitate the rapid access of relevant and updated regulatory information for business, clinicians, consumers and patients.

Proposal C: Abolition of requirement for TGA conformity assessment for Australian manufacturers of low risk medical devices

GEHC currently does not manufacture medical devices in Australia. However we endorse the proposal given it will enable limited regulatory resources to be focused on higher risk medical devices and to reduce overall regulatory burden on lower risk devices. The proposal is consistent with our above recommendations that TGA leverage pre-market work and conformity assessment certificates already issued by European notified bodies to further streamline the current premarket medical device assessment process.

Summary

GEHC commends the TGA in embarking in the reform agenda to improve premarket regulation and transparency and proactively engaging with stakeholders in this important project. We are supportive of the need to further strengthen the overall process of premarket assessment for higher risk medical devices.

GEHC recognises the broader reform environment for medical devices currently underway and the extensive effort required to implement these reforms. With the review of the development of a responsive and cost-effective regime for jointly regulating therapeutic products in Australia and New Zealand currently underway and given insufficient evidence is available that increased premarket assessment improves patient safety outcomes we recommend that the TGA:
1. Does not proceed with the implementation of an additional Level 3 audit assessment for Class III/AIMD devices at this point in time.

2. Considers removing processes for medical devices which duplicate the comprehensive work already completed internationally to improve speed to market, increase access for consumers and reduce regulatory effort. Automatic acceptance of European and US registrations for all products lower than Class III and acceptance of 3rd party conformity assessment certificates from TGA designated agencies for all Class III/AIMD medical devices will result in significant benefits.

3. Redirects scarce regulatory resources to strengthen post market surveillance of medical devices and high risk products introduced into the market. Increasing post market surveillance and timely monitoring of manufacturers trends will in the longer term assist in improving overall public safety outcomes. GEHC suggests further effort and investment is focused in this area.

4. Continues further consultation with regards to publication of additional information related to applications and considers effort required to administer such updated information, in addition to the business impact of the transparency proposals following patient safety implications.

We look forward to ongoing consultation with regards to this initiative over the coming months.

In the meantime, if you have any questions regarding this submission or GE Healthcare, please do not hesitate to contact me directly on (02) 9846 4695 or eddy.mcfadden@ge.com

Yours sincerely,

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