Private Healthcare Australia
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CHIEF EXECUTIVE OFFICER

18 April 2019

Medical Devices Branch
Therapeutic Goods Administration
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Consultation: Proposed changes to the classification of active implantable medical devices and their accessories

TGA team,

Thank you for the opportunity to provide input to the above consultation on behalf of the Private Health Insurance Industry (PHI) and their peak body Private Healthcare Australia (PHA).

Private health funds are the custodians of members' contributions and these are limited by affordability. As with all health system funding, these funds are a public good and are constrained. Our members expect that medical devices are safe and effective and implicitly place expectations on PHI funds to be a representative for them within health sector delivery. We thank the TGA for recognising this critical issue but also delivering proposed measures that are not onerous on manufacturers and sponsors within the AIMD category and its support technologies.

We support all aspects of this proposed consultation and change. While we recognise that components of the implantable devices have for some time been appropriately classified as Class III on a risk assessment, the external devices that are used to program these items should similarly carry the same classification due to their ability to influence an outcome. As a representative body for insured members we would be concerned about the risks associated with many of these devices and the potential for them to be hacked with associated ransom requests. While we are horrified that such activities could occur it shows the unique challenges any active device has, and as such we support all elements of their registration to be considered high risk.

Per your indication the companies that are likely impacted by such changes including Cochlear, Medtronic and Abbott, all of which we believe are well empowered to adjust to this reclassification, and will be required to do so in Europe in any case. Per our earlier TGA submissions we support the TGA's directive to align terminology and classifications with the EU under harmonisation. One area not discussed but relevant to articles such as the one on pacemakers is that Australia could be forced into receiving older more at-risk technologies if our classifications are not aligned to Europe.

In addressing the specific questions provided:

1) What impacts—including any that are unintended—do you anticipate the proposed amendments may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?

   The impact to suppliers should be minimal as it aligns with their global requirements, and a lengthy transition period is provided. We note that all companies in this space are major global technology companies. For patients covered by private health insurance they will have added safety in knowing the

TGA are as vigilant on tools that support the Class III related AIMD devices, recognising the impact these tools can have on a potentially negative outcome.

2) Are there any further issues and questions we should consider when implementing this change (including areas that can/should be clarified in our guidance)?

Following a recent article in The Australian newspaper 17/3/19 which discussed the status of insulin pumps in Australia, PHA received a number of responses from the general public on their own experience with insulin pumps and the services associated (including delays in replacements). Prompted by feedback such as that below (name withheld) and the realisation that these devices have a documented history of failing near to their warranty period, we believe these items should also be classified as Class III. This better reflects the risk they pose, particularly if a patient is not as vigilant as the one in the example below. It appears that the TGA classification of Medtronic insulin pumps and accessories is currently between Class I and IIb. We would encourage the TGA to consider if these devices should also be re-classified to Class III given the risk factors.

Subject:
Medtronic Pumps

Message:
Following The Australian's article quoting your Dr R David on 18 March, I advise my Medtronic Pump failed about 4 months after the Warranty expired and waiting on a replacement. As I was in Zimbabwe at the time, I was lucky to be carrying manual emergency supplies but had no long acting insulin for overnights until I reached Cape Town a couple of weeks later. I can only agree that built in obsolescence appears to be the culprit. Please keep up the good work.

3) Do you have any comments/views regarding all or some of non-implantable accessories to AIMD that are proposed to be reclassified to Class III? Is reclassification of these devices in Australia to Class III appropriate?

We support the proposal, due to the impact these components have on outcomes of high risk devices.

4) Do you have any comments regarding the transitional arrangements proposed in this paper?

We support linking the timing with changes in Europe to avoid unnecessary duplication of effort. We believe this is also sufficient time to amend registrations.

Thank you again for the opportunity to contribute to this consultation. As we have submitted in relation to previous TGA consultations, including that on inclusion of a UDI which was recently highlighted in the media, we see the TGA as being instrumental in improving safety for all Australians and as such endorse all measures taken. Like the TGA we hope not to see the type of outcomes and impacts on our members and member funds as occurred with PIP, meshes and ASR.

Best Regards

Craig Moy
Director of Access & Reimbursement
On behalf of Private Healthcare Australia and the Private Health Insurance Industry member funds