Private Healthcare Australia
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Dr Rachel David
CHIEF EXECUTIVE OFFICER

15 February 2019

Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Re: Consultation on Definitions and Scope of Device Regulatory Framework

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 recognising the cost / return considerations in aligning the TGA and European definitions for devices. We note that much of this consultation is technical in nature relating to manufacturers of devices.

We will address as best the questions posed but would like to re-state some general principles we feel are critical and potentially need more attention in the Australian context.

The first is **reuse of Single Use Devices (SUDs).** We recognise that there has been development of guidelines in this area, yet remain sceptical that any re-use of a device designed for a single patient should be considered for re-processing. Single use devices are not designed for extensive cleaning access, nor are the components designed to accommodate ongoing use. While funding is limited across the health system including public health, the re-use of a SUD in a private hospital has a number of implications. Firstly, hospitals through bundled agreements are funded to provide new consumables. Secondly, costs resulting from infections and sub-optimal surgical interventions fall directly on the private health funds who paid for the new single use device to be used. With personal experience as a supplier of SUDs both the sponsor and the health fund bear the adverse risk, while the hospitals are a beneficiary through this re-use. Patients already question the value they receive from their private insurance, the thought they were receiving previously used disposable devices reflects poorly on all participants in the health system not just the hospitals.

Secondly the **reporting of adverse events and recalls**. Members have increased awareness and expressed concerns around the quality of device regulation and identification following high profile recalls within breast implants, pelvic mesh and joint replacements, often well after the suppliers and regulators were made aware of the issue. This was referenced as recently as late November in the Australian Financial Review – "*Probe exposes medical device failures.*" PHA and our member funds remain concerned that the mechanisms in place are currently not sufficient to report adverse events. **PHI funds currently do not have transparency on what implants have been placed in their members as hospitals only provide Prostheses List Billing Code details not the original manufacturers product code (MPC) / lot & batch number associated with surgeries, despite receiving this from the sponsor / device supplier on their invoices. We ask that urgent action is taken on this so that PHI can take a more active part in monitoring devices, including those flagged for recall that have been implanted in their members**.

We have real concerns again from personal experience that not enough is done to record adverse events with the TGA by hospitals, clinicians and suppliers, given the workload and oversight applied in accurate reporting. From a cost and confidence perspective in the TGA and the greater health system we believe this remains our largest issue for management in device regulation.

Finally products **without medical intended purpose**. As noted in this consultation, an increasing number of complex procedures are being performed in private clinics and consultant's rooms that have the potential for major risk for Australians. Costs associated with revision of these interventions often fall on PHI funds. Today these tend to relate to cosmetic surgery procedures, however with evolving medical technologies it is conceivable many current hospital / day surgery interventions may migrate to a non-medical setting.

We support the TGA in taking a more engaged position on these devices. As a lay person in the community not familiar with aesthetic procedures, the potential adverse event risks associated with cosmetic procedures justifies the need for greater regulatory intervention. Moreover most Australians would consider that such regulation is already in place and comparable to devices used in hospitals, for example: Patient loses sight from dermal filler operation

In addressing the specific questions provided:

1) Do you have comments about the proposed changes to the definitions (refer Appendix A)?

   We support the intent of the TGA position, particularly where alignment and harmonisation reduce cost or grey zones in interpreting requirements by suppliers.

2) Are you a consumer, patient, consumer advocacy group, healthcare provider, industry stakeholder, industry representative body or other?

   Private Healthcare Australia is the industry representative peak body representing the Private Health Insurance Industry who are stakeholders as payors in the health system.

3) Will you be affected by the proposed definition changes? If yes, how?

   Not significantly, unless it reduces adverse events, which would be a positive outcome.

4) What benefits or disadvantages might be there for patient, consumer or public health and safety in these proposed definition changes?

   Greater transparency around interpretation for sponsors/suppliers and potential for reduced cost in device registration with greater alignment of terminology with Europe thereby avoiding replication in submissions.

5) If you are an Australian business, please provide information on potential impacts relating to these changes including:

   – the number of products affected
   – benefits or disadvantages related to the safety and performance of your products
   – changes to administrative or regulatory obligations of sponsors
   – any operational impacts on your business costs that these changes may impose on your operations.

N/A

QUESTIONS: PRODUCTS WITHOUT INTENDED MEDICAL PURPOSE

6) Are you a consumer, patient, consumer advocacy group, healthcare provider, industry stakeholder, industry representative body or other?

Private Healthcare Australia is the industry representative peak body representing the Private Health Insurance Industry who are stakeholders as payors in the health system.

7) Are you affected by the proposal to regulate as 'medical devices' a prescribed list of specified groups of products that don't have an intended medical purpose? If yes, how?

Not specifically, but our member funds are potentially at risk of costs associated with these procedures. Similarly, our insured members consider their health funds to carry a duty of care in representing and protecting them from inappropriate risk.

8) What benefits or disadvantages are there for patients, consumers or public health and safety in regulating specified products without an intended medical purpose as medical devices?

Consumers most likely already expect that the TGA will act as a review body for procedures that are associated with significant risk such as cosmetic procedures. The health industry more than most encounters a significant gap between patients' technical understanding and what they are paying for. As such they will benefit from greater protection from regulatory oversight.

9) Would a prescriptive list of specified products that do not have an intended medical purpose regulated as medical devices simplify the regulatory expectations around such products?

Better regulation of procedures that generate risk for Australians would be more constructive than a list of what is not reviewed. As noted, the general public are often not empowered with sufficient expertise to assess these products on their own merits.

10) If you are an Australian business, please provide information on potential impacts relating to these changes including:

- the number of products affected
- benefits or disadvantages related to the safety and performance of your products
- changes to administrative or regulatory obligations on sponsors
- any operational impacts on your business
- costs that these changes may impose on your operations.

N/A

Thank you again for the opportunity to contribute to this consultation.

Best Regards

[redacted]

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