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

RE: PROPOSAL TO INTRODUCE A UNIQUE DEVICE IDENTIFICATION (UDI) SYSTEM

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 companies to be a representative for them within health sector delivery. This is reflected in the realisation, that, in the vast majority of cases the costs of revisions resulting from failed devices fall upon PHI member companies. This extends well beyond the device itself including hospitalisation, clinician fees and rehabilitation. All of these costs are invariably far higher in a revision setting. PHA notes that when a recall for a part occurs on your motor vehicle the manufacturer covers all costs related to this correction. This does not occur in the Australian health sector.

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."* The successful implementation of these reforms will in part address this trepidation.

I will respond to the specific questions of this consultation, however, in principle PHA and PHI member companies support the measures sought by the TGA in introducing a mandatory UDI system and the harmonisation of this with global counterparts. This is well overdue globally.

On a personal level from previous experience in the device sector, the ability to track impacted patients even with class 3 devices is sub optimal today. Often this involves sending recall communications to hundreds of surgeons and hospitals, when less than ten devices may be affected. This creates enormous inefficiency, wasted resource and a lack of confidence in the system. This was perhaps best highlighted in the recall of the Johnson & Johnson Depuy MoM ASR hip device. For many years the suppliers had resisted providing billing code/product/lot code data to the Australian Orthopaedic Association National Joint Replacement Registry. Under the unique ASR situation orthopaedic suppliers relented given the criticality of finding thousands of impacted patients.

**Though not specific to this inquiry PHA and member companies want to re-state that the Australian Private Health system by virtue of the Prostheses List is probably the only health system where the health insurer entrusted with their client's health, has no ability to identify what device has been implanted in their member. The TGA may or may not be aware that PHI companies only receive the PL billing code associated with a device. Many of these billing codes are generic to a supplier covering multiple implant designs. We would advocate additional consideration is given during this implementation of UDI that the PL billing code is linked to the UDI and by default the Manufacturers Product code (MPC) or GTIN is also known to PHI companies post-surgery. This would, as we understand it, be of great benefit to the Assessment Branch of the Department of Health as well, who also do not have a definitive list of MPC that sit behind the 10,748 PL billing codes in the private reimbursement framework.**

PHA want to flag two points of specific concern that relate to the gaps in current recalls noted above:

Firstly that with tens of thousands of clinicians implanting devices, all with their own surgical and business practices, it is NOT appropriate that the burden of client discovery weighs heavily on them. It is a commercial burden and outside of their core skill set. Again from experience, ***many clinicians are not empowered with resources or motivated to hunt through often paper records to chase what are effectively <u>needles in another clinician's haystack</u> caused by a lack of effective UDI management***.

Secondly the Australian medical device market is categorised by a broad diversity of suppliers from global multinationals such as J&J and Medtronic through to distributorships for international companies that may have a single employee/on-seller in Australia. When the ad-hoc burden of work falls on the local entity, these smaller providers are less capable and often less-inclined to act on device issues. Placing the burden of accountability back on the global manufacturer and ensuring it is built into the TGA process would remove this variability.

We support the outlined benefits for an effective UDI as listed on P6-7 of the consultation. Given these benefits are realised by the supplier, i.e. most notably reductions in medical errors and enhanced post market surveillance it is appropriate that implementation is covered through a cost recovery methodology as applied to the PL, ARTG, NJRR etc. The suppliers will realise these benefits through reduced administrative burden in unnecessary contact to clinicians and hospitals, as well as reducing the time selling defective devices and potential litigation that may follow.

**<u>In addressing the specific questions provided:</u>**

1) Do you agree with our proposal to establish the UDI System in Australia, taking the IMDRF UDI Guidance (when it is finalised) as the basis for informing Australia's regulatory and legislative requirements?

   *Yes, PHA supports this position. All efforts should be made to align/mirror the approach with other markets. The creation of unique needs may add significant cost and burden. Such costs have invariably found their way back to payers in the systems.*

2) The Australian UDI System will apply to all devices placed on the market except custom-made devices and certain other devices. For example, in Australia some products are regulated as devices while the same groups of products are not considered to be medical devices in some other jurisdictions. Also should UDI in Australia apply to Class I medical devices, particularly those other than Class Im (with measuring function) and/or Class Is (supplied sterile)? While it is highly desirable to align internationally, do you have proposals for possible exemptions from UDI requirements?

*PHA would encourage the TGA to focus on a risk/return consideration. Priority should be on high risk devices such as pacemakers, stents, neuromodulation devices and load bearing joints. These devices are also significant in cost, as such any additional burden of implementation cost per unit would be negligible. Given implementation and management cost per unit for a Class 1 device may be comparable to a Class 3, we would encourage the TGA's clinical and health economics team to assess the value of Class 1 inclusions (in particular if not supported in other harmonised markets). While addressing Class 3, implantable and 2A&B devices would be cost effective and of minimal inconvenience to suppliers; extending this to low cost, low risk Class 1 items, may result in a significant cost burden to the system, with limited meaningful savings in avoidable surgical costs. Suppliers of Class 1 devices are likely to seek relief on this from the TGA or other funding sources given the cost to sales price on these items.*

3) It is proposed to have the power to accredit one or more Issuing Agencies. What requirements should this accreditation be subject to?

*The TGA and aligned global bodies would have greater scrutiny and control through a reduced number of well assessed accrediting agencies. PHA would support the selection criteria determined by the TGA. Prior evidence has shown that low cost accrediting/notified bodies in some countries may not deliver to requirements.*
*https://www.telegraph.co.uk/news/health/news/10042607/Experts-call-for-transparency-over-medical-devices.html*

*https://www.telegraph.co.uk/news/health/news/9626756/Faulty-medical-implants-investigation-Patients-health-put-at-risk-by-unscrupulous-EU-regulators.html*

4) Sponsors will be required to have an agreement with the device manufacturer to legally enter the required UDI information into the AusUDID - what should be taken into account when making the legislative amendments to clarify these responsibilities? For example, where more than one sponsor has pre-market authorisation for the device?

*The process needs to be robust and consistent, each sponsor should be required to enter the data or where a potential conflict exists to do so then the entity holding the TGA listing would be required to do so (i.e. Emergo). The legislative framework must offer security for Australians and be consistent to other harmonised markets. The inclusion of a UDI mechanism is well overdue, had it been in place a decade ago issues with Meshes, PIP and hip devices may have been addressed earlier.*

5) It is proposed that the TGA establish and manage the AusUDID. Are there any concerns with this proposal? Are there alternative organisations that could establish and manage the AusUDID? What are the advantages and disadvantages of these alternatives?

*PHA would support this being managed by the TGA through a cost recovery mechanism imposed on device suppliers. The TGA are the empowered authority including through the ARTG to approve devices for sale. The TGA are beyond reproach of financial short cuts as has been seen in private notified bodies in the past. The TGA is the appropriate management body when enacted by federal legislative change. Critical to success for the TGA will be employing sufficient staff so as not to delay the current and future functioning of the health system.*

6) What core data elements and other relevant information should be entered into AusUDID?

*PHA would support the TGA recommendation on inclusions to AusUDID. Without restating the list on P13 of the consultation the EU list provides a suitable base, with any additions identified as critical by the TGA from the IMDRF recommendations.* ***PHA would also seek inclusion of PL billing data*** *(as noted PHI currently have no cross reference of devices impacted for their members, invoices submitted from hospitals for payment only contain PL billing codes and not the MPC/GTIN from the manufacturer).*

7) How should we link the ARTG and the UDI database? What information should they share?

*The TGA has clearly engaged with Eudamed, alignment of process supporting multinational suppliers would be logical, assuming it meets all TGA needs. Transparency remains a core gap in the Australian health system. As noted above the existing PL has no transparent data link to the suppliers MPC.* ***PHI members cannot currently identify which members have been affected by recalled devices. The inclusion of the UDI should accompany/contain a required link between MPC, ARTG and the PL benefit code. This offers full transparency and opens additional data sets to the TGA including patient records held within PHI.***

8) Should different transitional arrangements be implemented for different classes and categories of devices? Is the alignment with EU transitional times appropriate?

*For the benefit of suppliers and the Australian public it is logical to implement this in parallel with the European time frames. As noted PHA would caution that an appropriate review is considered for the cost vs benefit of inclusion of Class 1 devices (only), ensuring all cost recovery methodologies are assessed and established before implementation. The Australian public would not support an extended period of transition for high risk devices given the obvious benefits of transparency and reduced chance of an adverse event.*

9) What impacts (including unintended impacts) do you anticipate for you and other stakeholders?

*As noted above, the group currently engaged but less skilled in device identification are clinicians and their consulting practices. Reducing the burden on clinicians with respect to device identification would be seen as a positive step and is likely to reduce cost and delays compared to the current model. Hospitals should have competency to introduce such changes, the inclusion of a UDI would also reduce burden on them compared to the current model. For global suppliers this will align practices and should reduce the need to send recall notifications to all surgeons and hospital sites that have implanted the product over its lifetime. For PHI the increased transparency including on a global level, may allow early identification of at risk procedures and for PHI/PHA to work with the TGA and suppliers to mitigate risks. Australia has world leading device registries, the inclusion of UDI data should also aid in theory with early identification and targeting of defective devices.*

10) Are there any other issues and questions we need to consider when implementing this change?

*PHA foresee the determination of funding as critical. Potential cost implications on these devices are of concern if they place additional burden on Australians. Particularly with the proposed inclusion of Class 1 devices. Similar issues are found with some registries where they seek to capture clinical data on lower cost items, where the administration burden is significant against the device price. The TGA may be best advised to focus on Class 2 and above and following a period of review thereafter to assess the risk/cost trade-off of adding Class 1, particularly if some Australian items in this class are not involved in global harmonisation. The regulatory staff competency of suppliers focused in Class 1 devices may be different to those operating in higher registration categories. The TGA should assess this competency before committing to a 2025 deadline.*

PHA support the commitment to this critical change for the Australian health system. The benefits are well defined, while the majority of costs will already be completed at the manufacturers site (noting >90% of medical devices in Class 2 and above are manufactured overseas).

**While the tangible cost savings are well articulated by the TGA, the confidence this step provides to Australians in the wake of media on PIP, ASR and J&J pelvic mesh products should not be understated. Most Australians do not have experience or even the capacity to understand the technology that will be used on them. They carry genuine fear about the unknown of surgery, they should feel confident that those managing the approval of the devices and those that manufacture them are as up to date and transparent as possible on that device's performance.**

**This process change is also an ideal time to introduce mandatory reporting of the devices used including Manufacturing code (MPC) in parallel with PL billing codes. This along with the UDI change will allow PHI to track within their own records the performance of devices and support registries and the TGA to identify early device concerns. This would be an additional data set available to the TGA, that could previously not be provided due to the decoupling of device and billing codes on invoices supplied to PHI by hospitals.**

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

Best Regards

[redacted]

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