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Submission to TGA consultations on Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia

Background

Monash University's School of Public Health and Preventive Medicine (SPHPM) welcomes the opportunity to provide a submission in response to the Therapeutic Goods Administration (TGA) consultation on *"Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia".*

The SPHPM is the University's principal source of skills in epidemiology, biostatistics and large scale clinical data-management. It has internationally recognised expertise in large-scale epidemiological studies, multi-centre clinical trials, clinical registries and evidence synthesis. The School provides a key resource underpinning translational research within the Faculty of Medicine, Nursing and Health Sciences.

The School houses four high risk implantable medical device registries including the Australian Breast Device Registry (ABDR) which collects data on breast implants, tissue expanders and dermal mesh; the Bariatric Surgery Registry (BSR) which collects data on gastric bands; Australian and New Zealand Society of Cardiac and Thoracic Surgery (ANZCTS) National Database which collects data on surgical and percutaneous cardiac valves; and Victorian Cardiac Outcomes Registry which collects data on percutaneous coronary interventions and implantable cardioverter defibrillators. The comments provided represent the views of the School's highly active clinicians and researchers in post-marketing surveillance of high risk implantable medical devices.

We have addressed the questions posed in the proposal below.

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Questions

1. Monash University SPHPM is strongly supportive of the proposal to establish the UDI system in Australia taking the IMDRF UDI Guidance as the basis for informing Australia's regulatory and legislative requirements.

2. We do not have proposals for possible exemptions from UDI requirements.

3. We do not have a comment on accreditation of issuing agencies.

4. We do not have a comment on which sponsor should enter the UDI into the AusUDID.

5. We support the TGA as the appropriate body to establish and manage the AusUDID.

6. The core elements common to all devices should be entered into the AusUDID as recommended in the IMDRF guidance section 9.2. High risk implantable medical device registries require data fields additional to these for the purposes of analyzing device performance. We recognize that adding these data fields to the AusUDID would make an unmanageably large dataset, most of which is unfilled. The solution to this is either that specific registries have their own separate device library, e.g. UK, Australia, Netherlands, or a coordinated system which is housed independently, such as the orthopaedic device libraries. We are currently working on an international device library for the Australian Breast Device Registry through the International Collaboration of Breast Registry Activities (ICOBRA). We suggest that the AusUDID be designed with secondary use by clinical registries in mind, so the data can be easily uploaded to these device libraries for use by registries. We would support a strong governance process in place for this.

7. We would suggest that the ARTG code be included as an extra field in the AusUDID so there is 1:1 mapping of the UDI and ARTG.

8. We believe alignment with the EU transitional times would be appropriate.

9. With regards to impact on stakeholders, we see this as an enormously beneficial move for high risk implantable device registries. It will allow patient level tracking of devices and

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will facilitate registries combining their datasets for post-marketing surveillance on a global scale.

We thank the TGA for the opportunity to comment.

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