Monash University’s School of Public Health and Preventive Medicine (SPHPM) welcomes the opportunity to submit a response to the Therapeutic Goods Administration’s (TGA) Consultation Paper on Draft Clinical Evidence Guidelines on Medical Devices. SPHPM is one of Australia’s leading academic public health institutions and houses expertise in epidemiology, biostatistics, evidence synthesis, clinical trials and clinical registries. This profile allows the School to be a key player in the clinical evaluation of drugs and devices.

We welcome the TGA’s efforts to provide clarity around the clinical assessment of medical devices within the Australian regulatory framework. As the custodian of two device registries, the Australian Breast Device Registry (ABDR) and the Bariatric Surgery Registry, SPHPM takes a considerable interest in this area. There is also considerable international interest in this area, with registries featured prominently in three major US reviews 1, 2, 3.

SPHPM considers the scope of the Consultation Paper to be comprehensive and sensible. We welcome the discussion of the need to incorporate data from clinical experience (post-market data) into the clinical evaluation report, but consider that this could have been expanded further. In regard to the clinical evidence required for submissions, we note that there were many references to case reports and spontaneous reports. This is weak evidence. A greater emphasis should be placed on data collected in a systematic manner through registries, which reflects “real world evidence”. We were pleased that the report noted that data from registries should be used whenever possible, but there was a strong reliance on overseas data. It provided little comment on the breadth of registry experience and expertise in Australia. Indeed, only the ABDR and the National Joint Replacement Registry were mentioned. This may reflect that the TGA has a limited understanding of how advanced Australia is in the registry space.

We note that the Commonwealth’s ‘Review of Health Technology Assessment in Australia 2009’ emphasised selective use of registries to collect post-market surveillance data (Recommendation 15), but this recommendation appears not to have been progressed. The importance of registries was echoed in the ‘Review of Medicines and Medical Devices Regulation’ in 2015, Recommendation 22, that “all high-risk implantable devices be included in a registry”. We feel that the Consultation Paper should align more strongly with these documents.

It is essential that registries adhere to ACSQHC guidelines, particularly with regards to proper governance and quality control. There is potential for outcomes on device safety to be confounded by differences in skills of the operators, for example, if a new device is preferentially used by less skilled operators. It is for this reason that device registries must always be combined as quality/safety registries. Furthermore we recognise the potential issues whereby a single group of patients are contributing to multiple registries. For this reason we have advocated that wherever possible a device registry is seen as an ‘add-on’ to an established disease registry. For example data on TAVIs could be collected much more efficiently if it were an add-on to an established cardiac procedures ‘quality of care’ registry. The ABDR is leading an international collaboration, the International Collaboration of Breast Registry Activities (ICOBRA), which looks to amplify the data on breast device safety through pooling of data from countries across the ICOBRA network. We hope that the TGA will also look more towards evidence from such collaborative initiatives.
We also note that with regards to MRI and device safety, there have been substantial advances in analytical modelling for complications of devices, and the document reflects this in the pre-market clinical evidence. Current registries do not systematically record MRI scanning of devices, which could provide real world evidence in this area.

The main reasons for slow progress in registries to date are high costs, need for adequate governance structures, quality assurance and qualified privilege. However, these issues are all currently being actively addressed. With regards to costs, co-funding of registries by all relevant stakeholders represents a 'risk-share' model that affords early access to patients but with the assurance of systematic monitoring of effectiveness and safety. Indeed, registries inform efficient healthcare planning and have the potential to be highly cost-effective and even cost-saving to the healthcare system.