Submission to TGA consultations on Alignment with European medical device regulatory framework – Up-classification of surgical mesh, patient implant card

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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 "Alignment with European medical device regulatory framework – up-classification of surgical mesh, patient implant card". SPHPM is the University's principal source of skills in epidemiology, biostatistics and large scale clinical data-management. It has expertise in large 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.

We are in strong support of the TGA's efforts to streamline processes by aligning with the European Union regulatory requirements in reclassification of implantable surgical mesh to Class III (high risk), and the introduction of a formal requirement for medical device manufacturers to provide patients implant cards and product information directed at consumers in Australia.

The answers to the questions posed are below.
We cannot foresee any unintended consequences that may arise from the application process. We support the short six-month notification period.

We very strongly support the use of device identification cards for medical devices. As well as allowing information on medical devices to be easily communicated to new health care providers, this improves patient autonomy by improving their knowledge on their medical device, and also allows patients to check if any issues have been identified with their devices. We also support the adoption of the Unique Device Identifier in Australia in conformity with European Regulations in the future. The Unique Identifier will improve the ease and quality of data collected on devices by registries.

Patient ID cards could be issued by an associated device registry instead of by the device manufacturer. We believe that classification as a Class III device should require manufacturers to financially contribute to an appropriate device registry so that systematic post-market surveillance can be undertaken in order to identify poorly performing devices earlier than would be achieved through spontaneous reporting. The issuing of device ID cards by registries may allow for their timelier delivery than currently achieved through manufacturers, and further would act as an incentive for clinicians to report to registries, thereby improving the ability of registries to monitor device safety. The registry can also be a centralised site where

patients can check up whether there are any safety issues associated with their particular device, or facilitate notification of patients if required. Registries can also store information perpetually in case the device manufacturer ceases to exist. Patients would be able to easily replace lost device ID cards through the registry.

Unintended consequences – the main issue would be that industry would not have lists of the patients using their device, however registries would house this information.

We thank the TGA for the opportunity to comment.