AUSTRALIAN MEDICAL ASSOCIATION
ABN 37 008 426 793
T | 61 2 6270 5400
F | 61 2 6270 5499
E | info@ama.com.au
W | www.ama.com.au
42 Macquarie St Barton ACT 2600
PO Box 6090 Kingston ACT 2604

AMA submission – TGA proposed alignment with European medical device regulatory framework

mmdr.consultation@tga.gov.au

The AMA supports a comprehensive product vigilance system in line with international best practice, and the development of proactive product vigilance strategies that enhance the robustness of post market surveillance processes and improve data linkages.

The AMA therefore fully supports the TGA's plans to bring Australia's medical device regulations in line with European regulations, including the requirement for patient implant cards and information leaflets to accompany all implantable medical devices.

The provision of details to patients may help not only in post market monitoring but in clinical practice such as providing crucial information to radiologists. For example, a radiologist may receive a request for an MRI scan in a patient with an implantable device such as a cardiac pacemaker, but the details of the implant are not known. As some of these devices are not MRI compatible, it can be a time consuming process to obtain the implant details, often delaying the scan for several days. In urgent cases this becomes a critical issue.

However the key issue, as the TGA points out in the consultation paper, is how to ensure the patient receives the implantable device identification information and then, most importantly, keeps it.

AMA members report that patient retention of current manufacturer-supplied 'patient cards' is variable. For example, patients supplied with pacemakers appear to keep their implant information more reliably than patients who are given cards with the details of their breast implants. In the latter case, the Australian Breast Device Registry provides a reliable back-up for patients who don't retain this information, however, registries are not available – or warranted – for all implantable devices.

The TGA's proposed education strategy may be effective in increasing surgeons and hospitals passing on implantable device information to patients, but given the likely low patient card retention rates, there may be minimal benefits resulting from this measure.

Ideally, information about a patient's implantable device should be entered into a patient's My Health Record (MHR) so that it is always readily available when needed by both health professionals and patients. Once MHR switches to an 'opt-out' system, it has enormous potential to provide a reliable, easily accessible record of key information about a patient's implantable

device. AMA members report they already record implantable device details into a patient's MHR if they have one.

Although the TGA has stated that entering implantable device information into MHR is beyond its remit, it clearly has an important role in guiding the functionality of the database so that it becomes searchable for implantable medical devices.

AUGUST 2017

[redacted]