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Submission to the Senate Community Affairs Committee Inquiry into the Regulatory Standards for the Approval of Medical Devices

The arrangements for assessing and regulating medical devices in Australia have served Australians well. Australians have access to safe, quality health care and technologies at a reasonable cost.

Mortality rates have been lowered dramatically over the last 30 years. Health and medical research has made a huge contribution, as have advances in medical knowledge and technologies. The medical profession and the medical devices industry collaborate to develop cutting edge medical technology and improve existing products.

There will always be a tension between introducing new products to the Australian market and being certain that those products are safe and improve patient outcomes. This tension is mitigated by rigorous pre and post market assessment.

Pre-market assessment

The medical profession relies on the Therapeutic Goods Administration (TGA) pre-market assessment processes for listing products on the Australian Register of Therapeutic Goods (ARTG) to support high-quality clinical decision-making at the point of health care delivery. The medical profession's involvement in the TGA assessment processes ensures they are guided by medical opinion. Consequently, medical practitioners are able to confidently choose from a wide range of medical devices on the ARTG to make decisions about the optimal treatment for the patient, based on the patient's particular clinical circumstances.

Pre-market assessment processes need to strike a balance between keeping the regulatory costs down for organisations that seek to provide new devices, minimising the time it takes for new medical devices to be assessed and ensuring the assessment is systematic and comprehensive.

As technologies and international assessment processes change it is inevitable that assessment processes in Australia need to be refined to respond to these changes. The AMA supported the TGA's recent proposal to re-classify orthopaedic joint replacement implants from Class IIb to Class III devices. This will ensure that these devices, which are constantly utilising new materials and construction techniques, undergo a more rigorous assessment before they are listed on the ARTG.

Post-market assessment

As no pre-market assessment process is 100 per cent conclusive, it is important that post-market monitoring and evaluation is in place to ascertain the safety and clinical effectiveness of medical devices over time.

Post market assessment occurs through two mechanisms in Australia: through clinical registries and the reporting of adverse events. Both mechanisms can be strengthened.

The most effective mechanism for post-market assessment is through clinical registries. These registries allow a robust assessment of devices over long periods of time.

Clinical registers allow medical practitioners to identify problems early, respond appropriately and support clinical decisions about which devices are delivering the best patient outcomes in particular clinical circumstances.

The National Joint Replacement Registry (NJRR) is a premium example of a clinical registry that collects and provides high quality data on the performance of joint prostheses. The NJRR allows the Australian Orthopaedic Association to monitor the performance of surgeons against their peers. The NJRR information also assists the TGA to remove unsafe and non-performing devices from the ARTG.

If we are to improve post-market assessment of medical devices and patient safety in Australia, it is essential that more clinical registries be established for a broader range of devices, such as neurological shunts and cardiac devices.

Clinical registries are a valuable and cost effective way to undertake post-market assessment. The benefits to the Australian community, both in terms of individual health outcomes and overall health expenditure, and the public interest in guaranteeing independent governance of clinical registries, justifies Government funding for clinical registries. We note that while the Commonwealth's costs of the NJRR are met by a levy on device suppliers, these costs are passed on to patients. The role of the TGA in post-market regulation will be sufficiently strengthened by the introduction of more clinical registries. We believe this is a cost that the Australian community is willing to share, rather than imposing it on the individuals whose lives have been saved or improved by medical devices.

Reporting of adverse events could be streamlined to ensure busy medical practitioners can quickly and easily report an adverse event with a medical device to the TGA. Medical software companies could incorporate the ability for medical practitioners to compile the adverse event report using their medical practice software. Relevant information could be electronically incorporated into the TGA form and emailed directly to the TGA. This would reduce the time for completing and dispatching the form, which in turn would encourage more reporting to the TGA. Further, it is important that medical practitioners can see the value of reporting adverse events to the TGA by receiving information directly from the TGA about the quantity of reports of the same nature and what action has been taken in respect of the product that has been reported as being associated with adverse events.

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