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Submission to the Senate Community Affairs Committee Inquiry into the role of Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prostheses (PIP) breast implants

The AMA considers there is a critical need for device registries to be established in Australia. Such registries will need to be funded by government, as the AMA previously advised in its submission to the Committee in July 2011. The need for device registries has only been highlighted by the PIP breast implant incident.

The Committee's current inquiry considers the ability of the TGA to undertake or commission research in relation to specific areas of concern regarding devices, such as metal-on-metal implants (item (g) of the terms of reference).

The AMA considers that it is more important to look forwards, rather than look backwards. Sufficient evidence exists demonstrating that patient safety is best managed with the use of clinical registries. The National Joint Replacement Registry (NJRR) was instrumental in Australia being the first country to withdraw the DePuy metal-on-metal hip joint replacement device after a high rate of failure.

Implantable devices are likely to always have a failure rate. Clinical registries allow a robust assessment and comparison of devices, both in the short term and over longer time periods. They allow medical practitioners and the TGA to respond appropriately when there is a clear failure of a device that is beyond that of like products. For example, a breast implant registry could have provided early evidence of the failure rate of PIP breast implants compared to other breast implants.

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

Consideration should also be given to clinical registries being provided with the capacity to record information which would allow the registry operators to track devices to individual patients. This would assist in the case of device failure rates justifying patient recalls.

The NJRR is a premium example of a clinical registry that collects and provides high quality data on the performance of joint prostheses, and is internationally renowned. The NJRR allows the Australian Orthopaedic Association (AOA) 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 Australian Register of Therapeutic Goods.

The NJRR was established by the AOA with Commonwealth Government funding; it is operated however independent of government by the AOA. This ensures that the structure and nature of the registry is absolutely fit for purpose. An under-funded and under-resourced registry will not provide the appropriate data quality that would enable medical practitioners and the TGA to act with confidence when the data shows that a device has failed or precipitated other clinical concerns.

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.

If we are to improve post-market assessment of medical devices and patient safety in Australia, the AMA considers it is essential that sufficient, appropriately funded clinical registries be established for the broader range of clinical devices now available. This is particularly the case when the device is implanted in a vital organ such as neurological shunts and intra-cardiac devices.

The AMA considers there is a clear role for government to maintain funding to clinical registries that are established and independently operated by the relevant medical specialties as exemplified by the NJRR model. 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. We believe this is a cost that it is reasonable for the entire Australian community to share, rather than imposing it on those individuals whose lives have been saved or improved by medical devices.

In summary, the AMA considers the TGA's role in post-market regulation will be substantially strengthened by the introduction of more and relevant sufficiently resourced clinical implantable device registries. There is a clear role for the TGA to work with the specialty medical craft groups to develop or enhance implantable device registries to monitor device performance and to plan clinically appropriate and coordinated responses to device failures to the benefit of the Australian community.

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