



MEDIA RELEASE
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Fast-tracking innovation welcomed by medical technology industry

The Medical Technology Association of Australia (MTAA) welcomed the Government response to the Review of Medicines and Medical Devices Regulation.

The MTAA supports the Government's strategic and systems-based approach to achieve long-term sustainable reform to the regulation of therapeutic goods in Australia.

We are encouraged the Government accepted recommendations for the greater use of overseas assessment reports and for expedited access to innovative and life-saving products.

The MTAA welcomes the Government's decision to defer consideration of recommendations to establish registries "for all high risk implantable devices" pending further consultation with stakeholders.

However well-designed registries are extremely costly and careful consideration needs to be given to defining areas of high risk for selection and implementation of a registry.

If the intended purpose is to: diagnose, prevent, monitor, treat or alleviate a disease; or diagnose, monitor, treat, alleviate or compensate a handicap or injury; or investigate, replace or modify the anatomy or a physiological process; or control conception, the product is a medical device.

The MTAA is very supportive of Government's decision to reject the recommendation to delegate decision-making to a single person (the Chief Medical Officer), as this would slow the approval processes and lead to a significant backlog of applications.

Susi Tegen, Chief Executive of the Medical Technology Association of Australia said:

"We welcome the Government's response to the Review of Medicines and Medical Devices Regulation undertaken by Professor Lloyd Samson AO.

"In particular, we fully support the decision for greater use of overseas assessment to fast-track access to innovative and life-saving products, without compromising the integrity and safety of medical devices in Australia.

"We acknowledge a well-designed system can provide post-market safety for patients without compromising the overall safety and wellbeing of our regulatory system.

"Our members in particular the small-to-medium size companies complain about the avoidable red-tape, this report goes a long way to streamlining the regulatory burden."

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Did you know?

1. The medical technology industry currently employs more than 19,000 people and generates approximately \$12 billion in revenue.
2. The industry is highly skilled with over 52% of employees having a tertiary qualification, and 25% having a postgraduate qualification.
3. More than half of Australian medical device companies have grown from start-ups. 40% of all medical device businesses have been established since 2000.
4. In 2013-14, Australia exported medical devices to 167 different countries around the world for a total value of \$2.1 billion.
5. Medical technology (7.76%) is second only to Civil Engineering (8.5%) and pharmaceuticals in third (6.3%) when it comes to filing patents for innovative technology.

About MTAA

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

MTAA represents manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability. The range of medical technology is diverse with products ranging from familiar items such as syringes and wound dressings, through to high-technology implanted devices such as pacemakers, defibrillators, hip and other orthopaedic implants. Products also include hospital and diagnostic imaging equipment such as ultrasounds and magnetic resonance imaging machines.

MTAA members distribute the majority of the non-pharmaceutical products used in the diagnosis and treatment of disease and disability in Australia. Our member companies also play a vital role in providing healthcare professionals with essential education and training to ensure safe and effective use of medical technology.