



Productivity Commission

Inquiry into the Right to Repair in Australia

Submission by Medtronic Australasia Pty Ltd
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ABOUT MEDTRONIC

Making healthcare better is our priority, and we believe medical technology can play an even greater role in improving people's lives. As a global leader in medical technology, services and solutions, Medtronic improves the health and lives of millions of people each year. We believe our deep clinical, therapeutic and economic expertise can help address the complex challenges — such as rising costs, ageing populations, and the burden of chronic disease — faced by families and healthcare systems today.

But we can't do it alone. That's why we're committed to partnering in new ways and developing powerful solutions that deliver better patient outcomes. Medtronic provides a wide range of products, therapies and services with the emphasis on providing a complete continuum of care to diagnose, prevent, treat and monitor chronic and acute conditions.

Our technologies encompass several areas, including:

- Cardiac Rhythm Disease Management (pacemakers, defibrillators);
- Cardiovascular (heart valves, surgical ablation, coronary & endovascular stents);
- Neurovascular (revascularisation and embolisation technologies) ;
- Venous (endovenous therapy);
- Diabetes (insulin pumps & continuous glucose monitoring);
- Neuromodulation (neurostimulation including brain, spine & sacral and intrathecal baclofen pumps);
- Spine & Biologics (fixation & stabilisation plates, rods & screws);
- Surgical Technologies (ear, nose & throat and cranial implant, surgical and navigation equipment); and,
- Surgical Innovations (stapling, trocars and access instruments) and Surgical Robotics.

Since the late 1940s, we have been working with others to alleviate pain, restore health, and extend life. We are now among the world's largest medical technology, services and solutions companies, employing more than 85,000 people worldwide, serving physicians, hospitals and patients in more than 160 countries.

Introduction

Thank you for the opportunity to provide a submission to the Productivity Commission's "Right to Repair" draft report. As the Commission has noted, this is a complex and multifaceted policy area.

"Right to Repair", depending on what and how it is implemented, could have significant impacts and risks both on the patients our products serve, and also on the existing regulatory regime that covers medical devices throughout their product lifecycle. As noted by the Department of Health in its submission to the inquiry, the medical technology sector currently operates within a comprehensive regulatory framework covering product safety and effectiveness pre and post market.

Given the broad patient and health implications regarding medical technology, and the regulatory requirements already covering these products, we believe it prudent that medical technology not be considered as part of this inquiry process.

We note the inherent complexities, particularly as they relate to medical technology, and would be happy to assist the Commission wherever possible as it finalises its recommendations and findings.

Right to Repair and the Safety of Medical Devices

Strong existing regulation

To ensure the continued safety and effectiveness of health restoring and life-saving medical devices, Medtronic believes medical devices should be excluded from consideration from "Right to Repair".

Medical devices designed, manufactured, and serviced by the manufacturer are categorically different than consumer and other goods in that they are regulated by the Therapeutic Goods Administration (TGA) throughout their lifecycle to ensure safe and effective operation for an intended use. The Therapeutic Goods Act (1989) and the Therapeutic Goods (Medical Devices) Regulations (2002) set out the regulatory requirements for medical devices in Australia, with sponsors responsible for the ongoing safety and efficacy of their medical devices across the medical device life cycle.

Patient Safety Risks

"Right to Repair" could present dangerous unintended consequences for the patient with the key concern that it may compromise patient safety.

The provision of product repair information and tools to third party repairers of medical devices creates uncertainty and a lack of confidence in the device's ability to perform its intended therapeutic and life-saving purpose. Highly sophisticated healthcare technology, such as patient monitoring systems, ablation systems, personal programmers for neurostimulators, insulin pumps and external defibrillators, are manufactured, repaired and calibrated to exact specifications, and clinicians and patients can confidently use them knowing that any repairs are managed by the manufacturer under strict guidelines and regulations with advanced training of personnel. The repercussions of a medical device failure due to inadequate and inexperienced repair are serious for the patient and their families and may have severe

consequences, even death. third party repair may also lead to misdiagnosis and inaccurate results, increased costs to the healthcare system and increased device down time.

Third party repair and servicing lacks transparency, traceability and accountability. Third party repairers may fall outside the jurisdiction of the TGA.

In addition, the provision of access to manuals, tools and diagnostic software does not necessarily ensure that the works are carried out appropriately and maintenance records are kept in compliance with quality standards. In the event of a recall, under current TGA regulations, legal responsibility for documentation and traceability remains with the sponsor of the device and not the third-party repair company. Therefore, the sponsor may be unaware of any modifications made by the third party and can cause further significant risk of not getting the device corrected as required by the field action.

Cybersecurity

According to the recently published TGA Medical Device Cyber Security Guidance for Industry, 'enabling medical devices to be cyber-secure is a requirement for regulatory compliance in Australia.' Allowing third parties to repair regulated, safe and complicated medical devices, can result in potential breaches in cybersecurity and can lead to increased harm to patients through cyber vulnerabilities. The responsibility of the medical device sponsor/manufacture is to strengthen the cybersecurity of medical devices by controlling the repair and maintenance of these highly technical devices, and protect the patient from the unauthorised access and misuse of the device, its function and its stored information.

Conclusion

Medical devices are important therapeutic and life-saving technologies and it is in the best interests of the patient and clinicians for any maintenance and repairs to be managed by the manufacturer/sponsor who have strong governance and expertise of domain knowledge in their owned technologies. The TGA sets a strong regulatory framework to uphold safety which medical technology companies are required to comply with, and in the case of Medtronic strongly support.

Given the significant ramifications that could result if a "Right to Repair" approach was applied to medical technology and how this would interact with the effectiveness of the current regulatory regime managed by the Therapeutic Goods Administration, Medtronic recommends that the Productivity Commission exclude medical devices and medical technology from the consideration of the 'Right to Repair'.

We would be happy to provide additional information to the Commission.