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Response

Productivity Commission Issues Paper: Right to Repair

Prepared by Stryker South Pacific

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Background

Established in 1941, Stryker Corporation is a Fortune 500 company that has led innovation in the global medical technology industry for more than 75 years, on a mission to make healthcare better for patients and care providers. Stryker's portfolio of 60,000 products and services range from reconstructive implants to state-of-the-art medical and surgical equipment, to neurotechnology and spine products. Stryker employs approximately 40,000 people worldwide, and its products and services are available in over 100 countries. In the early 1970s, Stryker was established in Australia. Headquartered in St Leonards, Sydney, Stryker Australia employs over 600 staff and is represented in every mainland capital city of Australia.

This history and pedigree in medical technology and the global healthcare market have given us a unique insight into the issues raised by the Productivity Commission in its "Right to Repair" Issues paper. We trust the Commission will find these responses useful and we would like thank you for taking the time to consider this response.

Contact

To discuss Stryker's submission, please contact:

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Stryker's response

In considering a consumers' ability to repair faulty goods and to access repair services at a competitive price, Stryker would strongly recommend the Productivity Commission **exclude medical technology** from consideration in a "right to repair", since such an inclusion would likely result in a number of negative outcomes:

- Consumers would face too high a risk due to the nature and class of products involved;
- There is too much risk involved in determining where legal liability exists for a device repaired by a third party;
- Consumers would face increased costs since a device not repaired to manufacturing standards would have its lifetime reduced;
    - This would also increase e-waste as more devices would need to be replaced.

In this submission, Stryker will concentrate its responses on requests for information 1, 2, 4, 5, and 8.

Information Request 1

In **defining a right to repair in an Australian context,** Stryker would urge the Commission to exclude medical technology due to the unacceptable level of risk involved. Medical device manufacturers have a legal responsibility to ensure their devices are safe and effective for use, and maintaining device history records under US Food and Drug Administration and Therapeutic Goods Administration regulations. It would be unclear when the legal obligation related to a medical device or health care equipment had been removed from Stryker (the manufacturer) and placed onto a third party (the repairer).

For example, in the event of a field action or recall, questions would arise as to which party would be legally responsible under current regulations, and who would be responsible for traceability, documentation and device history records.

To Stryker's knowledge, right to repair policies have not been implemented elsewhere in the world in relation to medical devices or healthcare equipment, particularly in the United States or Europe, which would limit the Commission's ability to observe the impact of such a policy on the medical technology sector and assess its possible implications for Australia.

Information Request 2

As noted above, in terms of examining **what types of products and repair markets the Commission should focus on**, Stryker would strongly urge the Commission to exclude medical technology. Not only would such an inclusion generate unacceptable risk, it would also have the likely impact of increasing prices for consumers, and generating higher levels of waste.

By way of illustration, Stryker's ProCare service extends the life of a device, ultimately reducing the costs to the consumer and reducing the need for replacement. However, if not repaired to manufacturing standards, the device's lifetime is reduced, leading to increased costs of repair, plus an increase in waste.

Information Request 4

Stryker's ProCare service provides plans to its customers to ensure their devices are available, either through the provision of loan equipment, preventative maintenance or service plans. This ensures that devices and equipment are repaired to the required standard and Stryker is able to retain legal obligations, particularly with regard to product recalls and record-keeping.

Information Request 5

In terms of **intellectual property-related barriers**, a right to repair policy in the medical technology sector would increase costs for third-party repairers and potentially customers due to the nature and cost of the fixtures and tools required to carry out repairs. Stryker's ProCare service does not reduce competition for repair services in the medical technology sector as Stryker offers training and parts where risk has been deemed acceptable.

Information Request 8

In considering what **policy reforms or suite of policies** would support a right to repair in the medical technology sector in Australia, any regulatory framework would need to unpick the complex issue of legal liability for devices and equipment in the context of product recalls and other legal obligations.

Conclusion

Medical devices and healthcare equipment occupy a unique place in the Australian market, ensuring the health and welfare of Australians and improving their quality of life. The risks of sub-standard repair to such technology extends well beyond an inability to make a phone call or view a website and literally become matters of life or death. This unacceptable risk is compounded by legal questions over liability and responsibility.

For these reasons, Stryker would strongly urge the Productivity Commission to exclude medical technology from any consideration of a right to repair.