



Submission in response to the TGA

Consultation: Changes to a number of Definitions & the Scope of the Medical  
Device Regulatory Framework in Australia

January 2019

18 February 2019

MSIA President – Robert Best

(07) 3292 0250 [president@msia.com.au](mailto:president@msia.com.au)

Inquiries to

MSIA CEO – Emma Hossack

+61411478799

[ceo@msia.com.au](mailto:ceo@msia.com.au)

## Executive Summary

The Medical Software Industry Association (MSIA) applauds the aim of the TGA to improve clarity and consistency and enhance the smooth functioning of the medical devices market in Australia. The objective of consistency with international regulation where possible makes commercial sense. It is however critical to be aware of the unintended consequences of regulating software when it is not a medical device.

The area is complex given the pace of technology and increasing interoperability between all systems. However, we are optimistic that a suitable direction can be adopted ultimately with appropriate consultation and engagement. We have recommended some consultation at our upcoming Forum on 22 March in Melbourne where we hope a representative from your Software as a Medical Device section can address our membership and hear the feedback.

In the mean time we propose that any further steps in respect of the definition of software be taken after further direct medical software industry consultation. Work done in the UK by the MHRA may be useful in informing the direction of the TGA, but Australia has significant differences as the number of software providers in the GP sector alone is over 30, whereas there are far fewer in UK. Likewise, the difference in the health system in the EU means that the EU regulatory framework cannot be adopted without significant localization.

## Introduction to the Medical Software Industry Association

The Medical Software Industry Association (MSIA) is Australia's leading industry body for providers of health software and a powerful force for innovation, productivity and better health outcomes for all Australians. Our members cover the digital management of Australians' healthcare from birth to death.

Our vision is to enable vibrant and innovative software organisations to achieve better health outcomes for all Australians and a more efficient world class health system for Australia. This vision is endorsed by Australia's National Digital Health Strategy Strategic plan, which aims to create "a thriving digital health industry delivering world-class innovation".

The MSIA represents providers across the spectrum of Australian health care services. with the 126-member companies ranging from Small and Medium Enterprises (SMEs) to large Australian and Public companies. Our members represent thousands of employees with an even larger referral network in the healthcare sector which is, of course, the largest employer in Australia.

Our members are responsible for almost 95% of the millions of transactions that occur through Medicare MBS and PBS annually. The MSIA represents providers across the full spectrum of Australian health care services

including:

- Aged and Community Services;
- Public and Private Hospital Services;
- Allied Health;
- Drug, Medicine and Decision Support;
- Prescription exchanges
- Practice Management;
- General Practice;
- Specialists;
- Aboriginal Health, &
- APPs plus many other specialty services.

### Health software

We understand from the consultations, that the Australian TGA does not intend to regulate software which is a very specific and complex market in Australia. Of concern to us is that the work our industry is currently involved in about interoperability over several government programs could inadvertently bring our industry under the regulation not only of existing regulators, but also the TGA which would result in an unsustainable regulatory burden.

For example, the Department of Health and the Australian Digital Health Agency (ADHA) is keen to see more consumer engagement and this of course will mean a proliferation of APPs and devices being used in conjunction with clinical information systems in the future. The MSIA members are keen to work with the Department and ADHA on these initiatives but remain concerned about the possibility of this converting their software into a medical device under the proposed changes to the definitions. Where a “medical purpose” begins and ends is not always clear. For example, some of our members are currently required by tenders to register with the TGA because of lack of understanding around this issue. This inhibits both productivity and innovation in health technology which is not in the interests of Australian healthcare or our economy.

Most of our member companies have many products, and so it is likely that products affected would run into the thousands. We understand that the TGA does not wish to capture software per se but believe an open and frank discussion with industry leaders would clarify the issues.

Our industry has an exceptional record in clinical safety. Our members pride themselves over the fact that their software plays such a critical role in the provision of healthcare in Australia. We applaud the intention of what the TGA is proposing and welcome a discussion on how a very specific exemption can be made in respect of health software which has been successfully and safely deployed for decades in Australia.

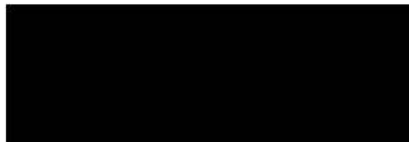
## Next Steps

Each quarter the MSIA hosts member Forums to discuss issues of concern, hear from Ministers and senior Department officials and hear about upcoming innovations.

Our next Forum is on 22 March in Melbourne. We propose that a presenter from your “Software as a Medical Device” section come and hear first-hand about the intricacies of our software and how this could impact the Australian Health Software Industry. One of the Governments 7 goals in Australia’s Digital Health Strategy is to create a “a thriving digital health industry delivering world-class innovation”. We are keen to work with all organisations to achieve this and avoid unintended consequences of unnecessary over-regulation.

Please feel free to contact me with any queries or suggestions and an invitation to our Forum will be issued today.

Yours Sincerely



**Emma Hossack**

BA (Hons), LLB, LLM

CEO



E: [ceo@msia.com.au](mailto:ceo@msia.com.au)

M: 0411478799

W: [msia.com.au](http://msia.com.au)