MSIA submission to the TGA

In respect of Software as a medical device

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Executive Summary

The Medical Software Industry Association (MSIA) welcomes initiatives to improve patient safety which is of paramount importance to the membership and their clients. Clearly regulation of medical devices which can have life threatening effects is a specific and worthwhile focus for the Therapeutic Goods Administration (TGA) under the Therapeutic Goods Act 1989 (Cth). Consultation on the Act is sensible after 17 years because of advances in technology, and the MSIA appreciates the opportunity afforded by this public consultation to represent the views of member companies. This is the second submission by the MSIA in respect of this subject in 2019.

There are three proposed changes to the regime outlined in the Consultation: Regulation of software, including Software as a Medical Device (SaMD). The MSIA is only responding to the first, which is the recommendation to extend the classification rules for SaMD. The proposal to extend the definition of SaMD was described by industry experts as a "monolithic" change to the original intent and objective of the legislation at the MSIA Forum on 22 March 2019. The proposed change to the definition of "medical device" was generally viewed as having many unintended consequences which of themselves could impact patient safety and the fundamental delivery of medical software without evidence of commensurate benefit.

The Government has committed to digital health because of the promise it holds for better outcomes and efficiencies. Investment in software like MyHR and hundreds of health software products by industry has been premised on existing conditions and the record the health software industry has of providing high quality software for its users, which as clinicians take responsibility for the safety of their patients.

Most medical software products and platforms continue to be used to support or provide recommendations about prevention, diagnosis or treatment of diseases. This would bring them under the purview of the proposed recommendation. This broad definition is explicitly excluded from the FDA definition of SaMD in the USA for the sound reason that clinicians, not software developers, are trained to assess risk and provide treatment. This is quite different from the case of medical devices like pacemakers and their operating systems which of themselves could cause serious harm and require a strict regulatory system. Consequently, experienced qualified stakeholders including the Royal Australian College of General Practitioners and the Pharmacy Guild of Australia support the MSIA in this submission against the adoption of an extension to the definition of Software as Medical Device to cover virtually all the software which is developed by our membership.

We respectfully suggest that the first proposed change to the framework should be deleted.

If it is not deleted, we submit that a taskforce including the Medical Software Industry Association, the Australian Digital Health Agency, the Royal Australian College of General Practitioners (RACGP), Pharmacy Guild of Australia (PGA) and other leaders in health technology be engaged by the TGA to forensically examine and make recommendations about the proposed legislation and the likely unintended consequences for all Australians.

Medical Software Industry Association – Who we are.

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 through our clinician clients 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 over 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.

These include:v

- 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.

Our members software has safely and securely collected, managed and enabled the access and use of Australians health information for decades. There is evidence that the use of our heath software by clinicians has improved health outcomes. We are unaware of any evidence that of itself it has caused harm.

Health software is byzantine in its complexity: Reasons it should not be classified as a device subject to the TGA

In consultation we were advised that it was not the intention of the TGA to regulate software through:

New rules to **appropriately classify SaMD products according to the potential harm they could cause to patients**

However, having read the consultation paper, attending consultations and listening to the comprehensive presentation by the TGA representative Dr Lee Walsh on 22 March 2019, we are firmly of the view that the new rules, whether intended to or not, would cover virtually all software developed by companies except for "lifestyle Apps". This is a major concern for everyone interested in better and more efficient healthcare, not only because software use could be impeded, but also because it is ignoring the fact that health software is a tool deployed by highly skilled professionals.

Unlike devices, health software provides an array of functions which clinicians use with discretion or choose to ignore depending on their skilled assessment of the situation. Our software does not take the role of diagnosis which remains with health professionals. The proposal to increase regulation and cost, not only ignores the skill of the doctors, pharmacists and other professionals using our systems, but it is also being done without evidence of health software causing harm.

> *"GPs are qualified and skilled to assess and manage patients acute, chronic and potential health care problems. It is not the job of their software to do this but rather to assist in patient centred care by assisting in point of care decision making. The impost on General practice should this additional layer of regulation be imposed would be unacceptable and prejudice GPs ability to use technology at the very time when it should be encouraged to enable greater productivity and efficiency"*
>
> Dr Harry Nespolen, President RACGP March 2019

The role that clinician education and oversight plays in mitigating any perceived risks from clinical software has received little attention. The example provided on page 7 of the Consultation paper ignores the role of the clinician. Unlike medical devices, software in the main acts in a supporting capacity providing information in a timely manner that would otherwise remain captive in paper on bookshelves. Clinicians receive significant training in software that is specifically tailored to their clinical workflows and data needs. Whilst issues such as automation bias are difficult to guard against, research demonstrates that the benefits of clinical software far outweigh the risks.

"The best way of validating Dispensing Software is via the more than 10,000+ pharmacists that use it daily. Pharmacists are the experts in their field and no Official Body could honestly claim to provide the level of Software inspection that is carried out daily by these health professionals.'

David Phillips, Pharmacist

Founder Phillips & Phillips Pharmacy Computers

As with medication, the first step in understanding any need for stronger regulation would be establishment of a process and register for reporting any perceived harm or risk of harm from clinical software. Only once the magnitude and types of risks that are encountered are better understood, can a rational approach to governance and mitigation be formula.

Australia's health software industry has been a leader in introducing new safety features. These include such as electronic medication management in primary care, which independent research has demonstrated achieved and continues to achieve, a significant reduction in patient harm.

For the last 15 years, MSIA has been co-operating with Pharmaceutical Defence Ltd to assist vendors develop the warning software and to assist with the coordination, authoring and distribution of advice to the dispensing software providers in relation to issues of medicine safety particularly those associated with potential dispensing errors.

Subsequently, all dispensing vendors incorporate the PDL pop-up system into their software which highlights a potential issue when a vulnerable drug is selected for dispensing.

For example:

- Coveram/Reaptam multi-ingredient medicine issues associated with the incorrect product selection
- Oxycontin reformulation
- Methotrexate dosage alerts - a lifesaving alert for medicine to be taken weekly - NEVER daily
- Clozapine Program

Our industry was also involved in the work associated with the introduction of barcode scanners integrated with the dispensing function to double check that the medicine selected from the shelf was consistent with the medicine on the doctor's prescription. Again, there are many lifesaving examples which have resulted from the introduction of this initiative. Again, our software was only a tool which the pharmacist could use to assist in exercising their overriding clinical decision.

Further regulation would be an unnecessary impost given the success of the existing programs and could lead to increased risk on account of its negative effect on prompt response to required changes identified by clinicians and the advances in evolving medical knowledge.

Regulation is a blunt tool applied to this internationally highly competitive industry with complex interoperability and strong links with government programs. For instance, many government programs are dependent on software being responsive to changes in government policy on a month to month basis. Programs such as PBS and MBS would need to be restricted to single annual updates as they would trigger re-accreditation requirements which would otherwise impose a crippling burden.

The MSIA was advised that even simple changes to a line of code would need to be submitted and would not be assessed for months. Some software platforms have the capacity for clinicians to create their own archetypes to improve their practice. The proposed changes would prevent this and other innovations and make healthcare less accessible and equitable, as it would affect patient's ability to claim, and impact on clinician's ability to claim appropriately and legally. The proposed change would impede the would prevent the flexibility and responsiveness of our industry to policy or practice changes consequently it would be impossible for health providers to respond to government changes within appropriate time frames.

Government driven software changes in primary and secondary care such as secure messaging, adoption of health identifiers, consistent clinical terminology (SNOMED, AMT) and similar future initiatives, would struggle to overcome the barrier of re-accreditation which would follow their implementation. This would postpone (possibly indefinitely) the uptake of capabilities intended to significantly improve patient outcomes.

For instance, MyHR has been built by the government to make health information more accessible for consumers and providers. The Australian Digital Health Agency claims MyHR will provide information to enable the support and recommendation about treatment, diagnosis and prevention to improve health outcomes. It is a system which covers over 90% of Australians and could be covered by the new definition. The effect could be devastating in the cases where as recently the system needed to be swiftly changed to comply with new privacy requirements.

Medical software has successfully provided reliable tools to assist the clinicians who are responsible for Australia ranking number one in the world for clinical outcomes[1] Industry works closely with the Department of Health, Department of Human Services, the Australian Digital health Agency, the RACGP, the PGA, the AIHW, all the Jurisdictional Health Departments and many others including the Australian Commission on Safety and Quality in Healthcare. Our record for products which help clinicians to produce world class health system is unblemished.

No evidence has been provided that significant patient harm has occurred due to the design and manufacture of Australian Health software.

[1] https://www.commonwealthfund.org/chart/2017/health-care-system-performance-rankings

Negative Impacts of Proposed change to the definition of software as a medical device: Productivity, Efficiency, Innovation & Clinical Safety

The quoted time and cost to obtain Conformity Assessment Certification under the TGA was 12 months and a minimum of $100,000.00 per product. Each assessment for change after that would also involve significant time and resources. This would be applicable even though benefit for such an impost are not clear and not backed up by evidence given the safety record of existing companies. The cost would be fatal to many health software companies which not only support health providers, but also support the national health infrastructure.

> *"We certainly would not want to see unintended consequences having an impact on the availability, cost and timeliness of the software that is vital to the operation of modern Australian community pharmacy dispensaries."*
>
> George Tambassis, the National President of the Pharmacy Guild of Australia

Innovation and productivity would be stifled at the very time the economy and ageing population needs better technology. Health industry digitisation lags other industries by 16% according to our National Chief Economists recent paper[1] Healthcare is Australia's second largest employer and increased digitisation would result in billions of dollars of savings. Not only would the proposed change prevent these savings being realised, it would also increase the cost of compliance and disable companies from further innovation. It would also result in many companies ceasing operation.

These unintended consequences would include negative clinical impacts. This is because health software provides significant efficiencies to provision of service. Services including Hospitals, GPs, Pharmacies, Aged Care, Allied Health, Disabilities and Indigenous health care services all rely on health software to process their work. Reduction of these services and increases to their pricing could have devastating impacts.

[2] http://www.abs.gov.au/websitedbs/D3310114.nsf/home/ABS+Chief+Economist+-+Full+Paper+of+Measuring+Digital+Activities+in+the+Australian+Economy

Summary

The Australian health software industry has an international reputation for quality. There is no evidence of software risking patient outcomes. Our software does not replace clinicians, it is a tool they deploy using their professional judgement.

COAG supports the Australian Digital Health Strategy which includes stimulating Australian software industry. The proposed regulation would not only make that impossible, but it would also result in the exit of many companies from the marketplace, thus reducing customer choice, productivity, competition and opportunities for innovation.

The MSIA has support of major stakeholders in Australia's health landscape in the PGA and RACGP. We respectfully submit that the TGA accept our submission and contact us should any further clarification and consultation be required