

Submission to TGA:

Scope of regulated software-based products

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Executive Summary¹

The Medical Software Industry Association (MSIA) submission is threefold. It highlights unintended serious risks in the proposals, proposes a new carve-out principle and provides a viable alternative to achieve the joint aims of safety, efficiency, innovation and productivity in the interests of the Government and all Australians. The Australian health software industry record does not warrant more red tape, but it is understood that adoption of new technologies could benefit from a framework which we provide as an alternative to the TGA regulation. The objective is to meet the needs of Australia's dynamic health software industry and rapidly evolving healthcare system by minimising risks and duplication through standards and measured regulation.

Unintended Consequences

MSIA members have raised serious concerns about the impact and unintended consequences of the proposed regulation. The regulation has been described by some members as having "momentous" unintended consequences. The fact that there is no evidence of harm arising through the use of general health software in Australia, calls into question the need to extend the existing regulatory frameworks and safeguard.

The implementation of the proposals including the effect of anything less than the carve outs from regulation (exemptions and exclusions) recommended here would mean:

- many health software organisations which support healthcare providers to improve outcomes & efficiencies would be forced out of business²;
- long lasting negative implications for efficiency, research, innovation and competition;
- costs would rise significantly for health providers, being unavoidably passed on by software organisations;
- Health software industry and services productivity would be negatively impacted;
- the health care provider's experience (UX) would be diminished;
- some existing safeguards would be compromised,
- current health software based safety may be removed from products and implementation of new health software based safeguards development dropped or delayed in order to reduce regulatory burden &
- some entities being forced to move operations off-shore.

This submission provides the reasons.

¹ Proposed Carve Outs: Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019 (Amendment Regulations)

Submission in response to the TGA consultation paper provided on 30 March 2020 <https://www.tga.gov.au/consultation/consultation-scope-regulated-software-based-products>

² The cost of approximately \$100,000 plus 12 months' time was quoted by Dr Lee Walsh from the TGA in our 2019 Melbourne Forum.

New Carve out Principle

The MSIA recommends that the two carve out principles proposed³ (not duplicating existing oversight mechanisms and risk mitigation) be extended to include a third. This would be the principle of appropriate oversight by qualified health professionals versus the TGA which acknowledges that it does not “...get into clinical competence. We don’t know what products do or their risk profile.”⁴ Efficiency, innovation and safety demand detailed understanding of software and clinical practice.

Australian health professionals work in a complex ecosystem of regulation, policy, practice, and principle underscored by robust legislation and professional indemnity insurance. Our world ranking as #1 in outcomes and #2 in efficiencies is a testament to their professionalism⁵ and to the robustness of quality systems in healthcare service delivery. Not only is this shown to work, but is also reflected by the approach adopted by our closest trading partner, the USA in respect of the same issues through the Food & Drug Administration (FDA).⁶

Let’s build on this rather than undermine our health professionals skill by the proposed regulation which is not fit for purpose. The proposed regulation fails to recognise the vital role health professionals play in the use of health software. Australian health care is unique in many ways.⁷ It has an exemplary record in respect of safe adoption of software and should not follow other countries with dissimilar health care systems which have less robust results.

21st Century approach to achieve Harmonisation of Health regulation and Standards in Australia

The TGA has a specific mandate which means that it is looking at “information as harm”⁸, whereas the rest of the healthcare world⁹ considers “information as opportunity” to safely empower providers and their subjects. This divide needs to be bridged. The MSIA recommends an approach which will do this and leverage existing necessary government programmes¹⁰ at a time when fiscal restraint is key.

It is a seminal time in Australia’s history. Our Government has been a world leader in management of the COVID-19 pandemic. It has the mandate to set an agenda which not only addresses the safety challenges of existing and emerging technologies like Artificial Intelligence (AI), but also to respond to the desperately needed implementation of health software standards.

It is widely recognised by health experts in Australia and overseas that the most effective, safe and efficient way to manage health information is through standards and conformance in place of regulation. If our proposed direction is endorsed, the MSIA would be pleased to use this standards based work as a basis for developing

³ P11, <https://www.tga.gov.au/consultation/consultation-scope-regulated-software-based-products>

⁴ Statement by Tracey Duffy First Assistant Secretary Medical Devices & Product Quality Division | Health Products Regulation Group TGA, Australian Government Department of Health in the Minutes provided by the TGA on 24.04.20 [Attachment 1 - Draft Minutes of Meeting MSIA TGA 20 Apr 2020 V0.2](#)

⁵ Commonwealth Fund Report SOURCE 2019 Commonwealth Fund International Health Policy Survey of Primary Care Physicians

⁶ The FDA explicitly excludes health software from the FDA definition of SaMD because clinicians, not software developers, are trained to assess risk and provide treatment. Alignment with disparate health systems in the EU for the purpose of proving the benefit of regulation is unhelpful and specious, particularly given their different composition and legal codes.

⁷ Our federated Government, funding models, population spread and mix, private health insurance regulation, etc.

⁸ P. 7 Consultation Scope of Regulated Software based products

⁹ Government, funders, health care organisations, innovators, insurers and researchers etc

¹⁰ E.g. The National Health Information Strategy, the ADHA Digital Health Strategy work on interoperability and standards etc.

a revised industry code of conduct to respond to new and emergent data-driven healthcare technologies.

*"We need to reimagine software regulation in ways that specifically align with the highly iterative and adaptable nature of its development."*¹¹

The MSIA has suggested specific clarifications and additions to the schedule of proposed carve-outs in Appendix 1 & 2 to assist the TGA.

The MSIA is grateful for the opportunity to respond to the consultation paper. We hope the TGA finds it constructive in developing an appropriate recommendation to the Minister. The MSIA remains keen to collaborate and assist the TGA as it navigates the health ecosystem and marketplace.

22 May, 2020

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¹¹ Danelle Miller, JD, Vice President of Global Regulatory Policy and Intelligence, Roche Diagnostics
<https://www.rochecanada.com/content/dam/rochexx/roche-ca/documents/articles/roundtable-with-danelle-miller-and-steve-burnell.pdf>

Unintended Consequences of proposed TGA regulation

Distinguishing Health Software from Medical Devices

The MSIA vision is to promote the value of technology to improve health outcomes. Our members welcome patient safety initiatives. Our submissions to the Therapeutic Goods Administration (TGA) on 29 March 2019¹² and again on 14 October 2019¹³ demonstrate this position which is the backdrop for this submission.

Integral to this is our vision is our clients trust in the safety and usability of our software¹⁴. The trust users have in our members software is warranted by an unblemished record of safety in Australia over the past 30 years.¹⁵ Whilst a testament to the health software industry¹⁶, a key reason for this is the fact that our members software is ultimately just one of many tools used by health professionals who make the ultimate qualified decisions about patient care and safety.

This record is in stark contrast to the numerous health and safety issues reported by the use of medical devices which are appropriately regulated by the TGA.¹⁷ That is not because of any lack of care, skill or rigour by manufacturers of traditional tangible medical devices. It is because the manufactured products are used directly by the providers and public relying on their stated fitness for use and purpose. Users are not expected to 'look under the hood' before they buy and use the products. The products stand alone. Users generally don't have the knowledge or skill to make informed assessment which is what the TGA rightly does. The TGA is experienced and qualified in this realm.

Software on the other hand provides some of the information to people which then becomes but a part of the knowledge, skill, instinct, and emotion which drives decisions. The so called "outputs" of the health software industry are radically different to the millions of products sold by the medical technology industry for this reason. The approach to regulation needs to reflect the difference. The TGA is not experienced or skilled to administer health software suitability, but other parties are. Other methods are available which will be covered by our proposed new principle to determine carve outs and address safety through standards.

¹² https://msia.com.au/wp-content/uploads/2019/04/MSIA_Submission_TGA-EH-1.pdf

¹³ <https://msia.com.au/wp-content/uploads/2019/09/MSIA-to-TGA-Carve-outs-20190911ejh2f.pdf>

¹⁴ In 2006 90% of GPs use a clinical software package DK McInnes, DC Saltman, MR Kidd. GPs' use of computers for prescribing and electronic health records. MJA 2006;185:88-91

¹⁵ The MSIA requested examples of harm to consumers from the TGA https://msia.com.au/wp-content/uploads/2020/04/SAMD-Proposed-Questions-For-TGA-Monday-20.04.20_ejhv2.pdf. The TGA was only able to provide examples of harm which arose through software which was not connected to a medical device. See TGA answers here [Safety and performance concerns with medical software apps](#)

¹⁶ The Australian software industry operates in an unusual market, a mix of Jurisdictions and private and public services. When it started there were not available standards for use in Australia, consequently some were developed, and existing ones were used. We have a patchwork of standards which are nonetheless carefully deployed but which could be made more efficient and robust by the proposed standardisation in our recommendation #3.

¹⁷ Also RC-2019-RN-01322-1, Class II, Consumer Level, Product Defect Correction, IBD Medical Dario Blood Glucose Tracker app. An in vitro diagnostic medical device (IVD), Android App Versions 4.3.0-4.3.2, ARTG 229859 RC-2019-RN-01358-1, —Class II, Product Notification (a non-recall action, however, a communication was still sent to customers), Abbott Australasia Pty Ltd FreeStyle LibreLink App when used with Android 10 Operating Systems, ARTG 233514

1. Possible unintended consequences

a. Loss of existing safeguards

Currently professional judgement is used to assess whether displayed information or prompts are appropriate and useful - or not. The health software products are not listed on the Australian Register for Therapeutic Goods (ARTG). Consequently the health professional or consumer exercise appropriate responsibility and care and are not reliant on a tick box affirmation of appropriateness for use.¹⁸

Whilst this could be considered an unnecessary impost on users, the TGA has confirmed that it does not get involved with the professional skill of the users or the detail of how the software works. This could give users a sense of false confidence. The TGA is arguably not as well placed to regulate health software as the entities the MSIA currently works with to formulate and maintain existing safeguards. These organisations have deep experience and knowledge in health in the use and safe deployment of software. They include the ACSQHC, the ADHA, professional Colleges like RACGP and RCPA together with Associations like the Pharmaceutical Society of Australia. Importantly the MSIA participates in work with Standards Australia, HL7 and other accredited standards bodies who participate in international standards development. This satisfies the TGA stated desire to align where appropriate with international standards.

It is highly likely that if the proposed regulation covered health software that some of these proven safeguards could be dismantled.

To avoid the proposed TGA regulation, some companies could change, or “dumb down” their products making them less intuitive and useful. The more the product resembles 20th Century tools like paper and lists, the less likely it is to be regulated. A number of features like alerts and pop up suggestions and efficiency measures would then be lost.¹⁹ This would also impact our nation’s productivity as well as our innovation which has now slipped several places to #22 in the World.²⁰

Software is necessarily iterative so the need for agile implementation is key. Changes are made and tested before implementation, and iteratively. Even Government Departments can be critical of the time that this vital step takes when there is an issue needing to be addressed. However, if this process was further complicated by review by the TGA, safety could be compromised.²¹

When assessing a clinical request for a new software safety feature, software developers would need to balance the cost, and delay the implementation of requirements that would require a change in TGA software product classification or TGA software reassessment. Examples would include:

- integration of bedside or portable monitor data into clinical records;
- integration with MyHR;

¹⁸ Drug Interaction Alerts in Software--What Do General Practitioners and Pharmacists Want? <https://pubmed.ncbi.nlm.nih.gov/22171864/>

¹⁹ SVHA clinicians (and patients) have benefited greatly from working with local medical software vendors to develop innovative solutions that meet our Australian clinical, patient experience and legislative requirements. A prime example is Episoft’s epi-me portal which has enabled infection alerts to be triggered from a patient’s submission to go directly to our pre-admission team giving them advanced notification of a potential virus risk. This has resulted in mitigating risks of infections to staff, efficiencies in time and effort and a better patient outcome through earlier preparation of their visit. Having a locally-built product means the security, reporting and legislative requirements protect our patient’s privacy and our Hospital’s reputation. It is vitally important that we safeguard and foster Australia’s medical software industry. Rebecca Ziffer, Project Manager – Clinical Systems, St Vincent’s Health Australia

²⁰ <https://www.globalinnovationindex.org/gii-2019-report>

²¹ Dr Toby Walsh, TGA advised MSIA Forum 22 March 2019 that this process could take months.

Unintended Consequences (cont.)

- integration of primary care desktops with the National Cancer Screening Register;
- Use of predictive analytics and/or AI to alert clinicians to potential impending patient deterioration in acute care and aged care settings; &
- MSIA member MIMS provides medicine information and clinical decision support data to approx. 100 medical software partners in Australia. Information is updated on a regular basis according to new clinical evidence continually gathered from multiple sources. This up-to-date information should reach health care workers without delay. Imposing regulations on the delivery of this data may result in clinical risks, especially in critical care environments.

b. Innovation

As foreshadowed the more useful and intuitive health software is, the more likely it is to be captured by regulation. This is because the draft assumes that health care professionals slavishly follow prompts and suggestions based on the analysis of health information collected. The reality together with the health software industry safety record are evidence this is not the case where appropriate training and oversight are in place. Should the draft premise be accepted, then perversely this will lead to some “dumbing -down” of software product to avoid untenable costs and delays to organisations and already hard pressed doctors who have become accustomed to intuitive interfaces.

AI covers “a broad range of technologies, involving complex tasks that would normally require human intervention. Machine learning is a subset of AI, and involves computers processing large amounts of data so that they can learn without being directly supervised”²² It is likely to provide some of the most extraordinary quantum leaps to healthcare in our time. It is complex and ever changing. Regulation would require the highest calibre of experienced experts – and AI should become heavily used – which would be virtually impossible for the TGA to accommodate. This is recognised internationally as an issue²³, ISO TC 215 has established an ad hoc Task Force (AHG2) which is due to report its findings on the standardisation requirements of AI in Healthcare in September 2020. This is why we recommend an alternative solution in Part 3.

In the meantime, concern by health software industry about the possible barriers to adoption through TGA regulation, may reduce industry appetite to embrace AI with profoundly negative consequences for our healthcare system.

Our health care providers and researchers are world class.²⁴ If the tools they need to hone personalised medicine and genomics are not available because of constraints on industry, they will look elsewhere for software. If we want to become the healthiest nation on earth²⁵ the health software industry has a critical role to play as the infrastructure which collects, stores, shares, transfers and manages the information.

²² <https://www.bsigroup.com/globalassets/localfiles/en-gb/about-bisi/nsb/innovation/mhra-ai-paper-2019.pdf>

²³ <http://www.imdrf.org/documents/documents.asp> - <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-200318-rrar-cab-cmdrr-n59.pdf>

²⁴ https://www.industry.gov.au/sites/default/files/May%202018/document/pdf/australia-2030-prosperity-through-innovation-full-report.pdf?acsf_files_redirect

²⁵ Ibid p.86

Hobbling Australia's health software industry with regulation which favours only the large multinational companies will raise the barriers for entrants and threaten smaller incumbents.

The MSIA appreciates the concerns around consumer facing health APPs which are not moderated by qualified practitioners and which could cause harm. We welcome the work being done by the mHealth APPs Project Reference Group which aims to promote innovation in health service delivery through increasing the adoption and use of mHealth APPs that are safe and have the potential to improve health outcomes. This work is being done in consultation with the ACSQHC and its draft National Safety and Quality Digital Mental Health (NSQDMH) Standards, Cth. Additional safeguards exist through Standards based processes for Health software quality and safety:

ISO TC 215 Adhoc working group on AI in Healthcare software – this group is looking at emerging issues and recommending future standards development requirements

ISO TC 215 ISO 82304-2 – Safety and quality of Health Software Apps

These in conjunction with the work done by the Australian Alliance for Artificial Intelligence in Healthcare (AAAIH) safety and ethics working group²⁶ provide strong assurance of an appropriate safety and governance framework in this area.

c. Cost & Productivity & Competition

“Our mental health assessment team at Healthscope have been using EpiSoft's assessment app for many years now. There have been many benefits to using the app but the most notable from a safety perspective has been the ability for the assessment team to capture and safely transfer clinical data from locations outside of the hospital, for the intake team to be able to quickly see the priority of the admission on the worklist and to have access to a legible, fully populated assessment with validated data”

Aaron Fowler, Application Change Manager

Healthscope

Digitisation of Australia's health system happened several decades ago with a successful combination of clinical entrepreneurs,²⁷ practice incentive payments and innovators who saw the opportunity for the health system to be streamlined in line with other industries.

Apple is becoming a health company²⁸ along with many other large software and technology companies. The benefit of this are many, but the risk to Australian industry is that if these companies do not have the same imposts imposed upon them as our own Government places on Australian companies, the price signals will prejudice our market. Without question the cost of this regulation would be prohibitive and is avoidable.

²⁶ Chaired by Prof. Farah Magrabi

²⁷ Dr Frank Pyefinch a GP from Bundaberg started Best practice to improve the practice of GPs.

²⁸ P.17 https://www.industry.gov.au/sites/default/files/May%202018/document/pdf/australia-2030-prosperity-through-innovation-full-report.pdf?acsf_files_redirect

"It is vitally important that we maintain and protect a viable Australian medical software industry. Working with a small, Australian based software company has been enormously beneficial as they understand the unique needs of an agile Australian healthcare organisations and have been able to quickly respond to the challenges affecting our innovative healthcare company. We chose an Australian based company for this exact reason, and we have not been disappointed."

Julie Adams, Pharmacist

MD Chemo@Home

Furthermore, our position would become analogous to that of other industries like the print media, taxis and hotels. Although we may offer comparable services, companies from overseas could compete without the restraint of regulation. The playing field would not be remotely equal. This could be overcome if our third proposition was to be accepted.

If we operated within the international standards framework it would open up markets for Australian developed products rather than having barriers imposed which would have to be re-engineered for export.

2. New Carve Out Principle – Clinical Oversight

"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

MSIA member

Australians trust in health professionals who "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..."²⁹ This trust, skill and experience has worked to date in the context of existing frameworks. It should be extended rather than replaced with an Administration which acknowledges that it lacks the knowledge about software products and doesn't get involved with the context of settings and clinical competence with which they are deployed.³⁰

The role of the TGA is "to administer a regulatory framework that addresses the safety, performance, and quality of (the design, construction and supply) medical devices in Australia."³¹ It performs this role successfully, but to enable it to understand the health software industry which it proposes it should regulate, skill it with the requisite resources and future proof it, would take years and be expensive. If it was the only option, then it would have to be done. However, we have in place many existing and highly skilled Australian and international organisations with which the MSIA works. These should be leveraged to ensure that the approach is calibrated to meet any real or perceived risks.

It is because of this well-founded Government and community trust in our health

²⁹ Dr Harry Nespolen, president RACGP in support of the March 2019 submission p.4 https://msia.com.au/wp-content/uploads/2019/04/MSIA_Submission_TGA-EH-1.pdf

³⁰ See TGA minutes dated 20.04.20 p.5 [Attachment 1 - Draft Minutes of Meeting MSIA TGA 20 Apr 2020 V0.2](#)

³¹ Section 4 Therapeutics Goods Act 1989.

professionals that some of the usual conformance requirements of ePrescribing, for instance, could be modified during COVID-19 to assist Australians through a risk-based approach. “Do no harm” is the touchstone for health professionals – health software has assisted and not jeopardised this priority. Research has demonstrated that our software processes assist clinicians without in any way impeding their curation of all the relevant indicators and evidence.³²

Health providers successfully navigate a complex regulatory environment consisting of privacy regulators³³, competition and consumer protection regulators³⁴, jurisdictional specific legislation and a regulatory framework for consumer protection. In addition the AIHW draft National Health Information Strategy, the Australian Digital Health Strategy 2018 and their own professional bodies all have comprehensive rules and guidelines. Importantly, consumer safety is embedded as policy in established health care delivery services.

The MSIA proposes that in the context of extensive existing regulation and pseudo-regulations as well as several national health strategies and frameworks, that the health providers are the most qualified people to determine what tools they use and how they should be used. To be clear, the MSIA is in favour of appropriate regulation of consumer facing APPS which have the potential to cause harm through information which has not been clinically validated.³⁵

Health care providers have significant regulation. Their use of health software together with many existing regulations, embedded practices, principles and policies mitigates any possible risk.

The equivalent to the TGA in one of our closest allies and trading partners the USA recognises this. The FDA explicitly excludes health software from the FDA definition of SaMD because clinicians, not software developers, are trained to assess risk and provide treatment. Alignment with disparate health systems in the EU for the purpose of proving the benefit of regulation is unhelpful and specious, particularly given their radically different legal codes and relative relationship with Australia.

Numerous regulations and pseudo-regulations exist today. There are also several national health strategies and frameworks³⁶ which will complement the international standards work with which our industry seeks to align. We have a solid track record. It is in this context that the MSIA recommends that clinical oversight of health software which is not specifically excluded or exempted from TGA regulation, be carved out from regulation on the basis of risk mitigation if it is subject to the use of a qualified health care practitioner.

“We need to be able to answer clinical questions at the point of care.”³⁷

32 Drug Interaction Alerts in Software--What Do General Practitioners and Pharmacists Want? <https://pubmed.ncbi.nlm.nih.gov/22171864/> Quality improvement of Prescribing Safety: aPilot study in primary care-reusing UK electronic health Records <https://bjgp.org/content/69/686/e605>; Improving Quality and Safety of Care Using “Technovigilance”: An Ethnographic Case Study of Secondary Use of Data from an Electronic Prescribing a Decision Support System <https://onlinelibrary.wiley.com/doi/abs/10.1111/1468-0009.12021>;

33 The OAIC through the Privacy Act 1988.

34 The ACCC through the Australian Competition and Consumer Act 2010 .

35 Saba Akbar, Enrico Coiera,, Farah Magrabi; Journal of the American Medical Informatics Association, Volume 27, Issue 2, February 2020, Pages 330–340, Concerns with consumer-facing mobile health ; <https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/evaluation-of-mobile-health-applications-is-regulatory-policy-up-to-the-challenge/06CA7101361A567361F1E9CBB094A362>

36 Including but not limited to the National Safety & Quality Digital Mental Health Standards, the National Digital Health Information Strategy, the National Health Data Asset Steering Group, the proposed standards and accreditation of Australian health software as proposed by the ADHA in its response to the ANAO audit within 2 years & the RACP work known as PITUS

37 Professor H.C. “Moon” Mullins • Chair of Family Medicine • The University of South Alabama, USA

This is possible. It's not dangerous. We should enable and not hobble this functionality

3. Standardisation – the 21st Century Approach to software regulation

There is an underlying philosophical divide between positions held by the health software industry and the TGA. The health software industry develops software through imagination and intellectual rigour to solve complex information flows with agile solutions responding to user needs. It is then refined multiple times through entities like the ACSQHC and multiple user settings³⁸ before release. The TGA refers to manufacture³⁹ and outputs which are more akin to widgets and indeed are tangible and can be mass produced. The rules for each are radically different and governance of emerging technologies like AI present significant challenges as the benefits are high, but so are the perceived risks. Consequently having a fit for purpose organisation and approach is crucial and has been recognised as the way forward by the Medicines and Healthcare Products Agency (MHRA) in the UK⁴⁰ and the US Food and Drug Administration (FDA) in the U.S.⁴¹

The complexity of digital health has resulted in inconsistencies in the TGA consultation paper.⁴² This underlies an inherent lack of understanding of the health software industry, the role of our stakeholders in both the development and utilisation of health software and the inevitable effect on innovation and competition in Australia. If adopted it will add an enormous and avoidable cost burden on Government, industry and tax-payers.

Fortunately there is an opportunity to solve the problem of safety and interoperability. This is through standardisation. Standardisation would achieve efficiencies and safety as well as respond to the concerns of the Australian National Audit Office in respect of third party interactions with the MyHR.⁴³ The ADHA has provided in its response an agreement to attend to these issues so a solid start and owner of the work is already in place.

Standardisation can be carried out in conjunction with the work of other entities such as the ADHA and the Australian Commission of Safety and Quality in Health Care (ACSQHC) which will otherwise be duplicated.⁴⁴ Imprecise regulation will hamper productivity, innovation and add cost to health care providers when they can least afford it. Standardisation is a far more effective solution for Government and industry. Qualified experienced groups and entities already working together, like the Australian Digital Health Agency (ADHA), the Royal Australian College of General Practitioners (RACGP), Australian Medical Association (AMA) IT-14, HL7 Australia and Int, Standards Australia, Australian Alliance for AI in Healthcare,(AAAIH) the Pharmacy Guild of Australia (PGA), Digital Health Commonwealth Research

38 RACGP, PSA, RCPA, ADHA, AAPM, PGA, PHNs, AMA, Jurisdictional and Commonwealth governments, ADHA, Universities etc

39 Literally made by hand - or automation - not a relevant term to be used in the context of intellectual outputs
Manufacture – to make by hand from the Latin Manus – hand ; Facio – to produce..

40 <https://bmcmmedinformdecismak.biomedcentral.com/articles/10.1186/1472-6947-10-21>

Identification of Features of Electronic prescribing systems to support quality and safety in primary care using a modified Delphi process

41 <https://www.bsigroup.com/globalassets/localfiles/en-gb/about-bsi/nsb/innovation/mhra-ai-paper-2019.pdf>

42 E.g. the MyHR is carved out despite its agreed capability to cause patient harm through the display of pathology results.

43 This work is also required to address the concerns of the ANAO audit response to the implementation of the MHR by the ADHA <https://www.anao.gov.au/work/performance-audit/implementation-the-my-health-record-system>

44 This is being looked at by the ADHA as a part of its Digital Health Strategy and the ANAO response [SMD Report Version 1.0 final](#) Executive summary of 21 pages) [SMD Executive Summary Report Version 1.0 final](#) and a supplemental version [SMD Supplement Version 1.0 final](#)

Collaborative (DHCRC) OAIC could all be called upon to contribute where appropriate in their field of expertise.

The equivalent to the TGA in one of our closest allies and trading partners the FDA in the USA recognises the value of using appropriately skilled regulators for health software. The FDA explicitly excludes health software from the FDA definition of SaMD because clinicians, not software developers, are trained to assess risk and provide treatment. Alignment with disparate health systems in the EU for the purpose of proving the benefit of regulation is unhelpful and specious, particularly given their different composition and legal codes. Where possible it is useful for Australia to have alignment with the regulatory processes of one of it's largest trading partners.

Conclusion

The MSIA proposes an evidence based, fiscally responsible approach to ensuring future safety, efficiency, innovation and productivity for health software. The approach to regulation must match our world-class healthcare system. Our proposal is based not on a desire to escape regulation, but a need for carefully articulated standardisation as a means to achieve not only improved safety, but also a magnitude of efficiencies and cost savings for the Government, healthcare provider organisations and all Australians.

This is not to say the status quo should continue. The MSIA is keen to leverage the existing foundations for standardisation of software which have commenced to provide a more robust framework for the benefit of all parts of the health system every day. Furthermore, when the next crisis hits, the constraints imposed by lack of interoperability will evaporate to be replaced by targeted responses which can be implemented without first undergoing hugely expensive lengthy processes to link services together.

The health software industry has runs on the board. It works with dozens of stakeholders across the nation and internationally. Never before has this industry's ability to coalesce and get things done been so evident as during the Bushfires and the COVID-19 pandemic. Australia should not now jeopardise the safe innovation, productivity and efficiency which it has enabled. We need to avoid the unintended consequences of this regulation, empower health professionals and facilitate the benefits of standards over regulation. Australia has the opportunity of a moon shot. Let's take it.

Appendix 1

The MSIA has adopted the TGA draft lists and incorporated comments, proposed additions and alterations as tracked changes

List of Software considered to be a medical device as per the definition⁴⁶:

- Diagnosis of an individual's disease or condition. Examples include; software intended to provide screening of skin cancer by checking skin for signs of cancer with instant results on consumers phone; and software intended to provide information (analysis of a coronary angiogram) for the purpose of the relevant health professional making a diagnosis of arterial stenosis.
- Monitors an individual's disease or condition. Examples include; software intended to analyse physiological signals to monitor a disease or condition, for example, an app that processes data from a mobile ECG device to detect heart arrhythmias of a person; and software intended to monitor the state of eyesight deterioration, of a person, over time.
- Provides therapy to an individual. An example includes; software intended to use a patient's image sets to provide an individual treatment plan for radiation therapy of lung cancer.
- Controls other medical devices. Examples include; a smartphone app intended to control or adjust a hardware medical device, such as an implanted spinal stimulator, through Bluetooth or Wi-Fi features; a smartphone app intended to calculate insulin dose volume of an infusion pump based on a patient's blood glucose levels; and, software intended to analyse a person's cardiac arrhythmias and automatically or semi-automatically treat the patient by administering a controlled electric shock (defibrillation) to the person in order to re-establish a normal cardiac rhythm.
- Is an accessory to a medical device. An example includes; a smartphone app intended to be an accessory to a glucose meter that reads blood test strips and plugs into a smartphone to display and store the results.
- Recommend or specify a treatment or intervention specific to an individual. An example includes; software intended to specify or recommend to an eye surgeon whether or not to undertake a particular form of laser eye surgery.
- Software used to generate virtual anatomical or physiological models. An example includes; software intended to generate a patient's anatomical model by processing images provided by a CT or MRI scan.

Commented [EH1]: Is it not possible for software like this to be used in telehealth consultations in which case the Dermatologists oversight in respect of skin cancers would be adequate?

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Commented [EH2]: Some proviso should be added to exclude monitors like this which are used with clinician oversight

Commented [EH3]: Should there be clarification that software which provide efficiency tools to patients are excluded?

Commented [EH4]: Presumably as long as such a result can be over-ridden by a clinicians decision and oversight it would be exempted?

Commented [EH5]: It should be clarified that some software particularly in allied care can create an anatomical model to assist the provider with their clinical notes and explanations to patients. These need to be clearly excluded from the section

⁴⁶ Consultation: Scope of regulated software-based products V1.0 March 2020 p.12

Appendix 2

The MSIA has adopted the TGA draft lists and incorporated comments, proposed additions and alterations as tracked changes

Software that is not a medical device under the current application of the Therapeutic Goods Act⁴⁷

Software products that are not intended to have a therapeutic purpose fall outside the scope of the definition of a medical device. Software would not be considered a medical device if, for example, it is intended solely for:

- Educational or general information purposes
- Displaying or recording information
- Managing data
- Enabling communication
- Encouraging a healthy lifestyle

Software products for the following intended purposes are not considered to be a medical device because these functions do not fit the definition of a medical device:

- Administrative support of a health or other care facility including aged care, disability care, allied care, indigenous care or prison care facilities including the processing and maintenance of financial records, claims or billing information, appointment booking and schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilisation or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow.
- Management of prescription information, including real time prescription monitoring or electronic prescription exchanges. Examples include software that is intended to provide electronic medication chart, electronic prescribing, dispensing, and support healthcare professionals to research, order, check and record administration of medicines; and software that is intended to provide secure and safe transmission of prescription information between doctors and pharmacists.
- Medication/adherence (treatment regimens) - Examples include; software intended to provide information on drug-drug interactions; and software intended to help patients improve medication, ordering, delivery & adherence.
- to serve as electronic patient records, including patient provided information to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart so long as:
 - such function is not intended to interpret or analyse individual patient records, including medical image data, for the purpose of diagnosis, prevention, treatment etc. of a specific disease or condition.

Commented [EH6]: The MSIA is presuming that this means the software is excluded.

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Commented [EH7]: Alternatively perverse result that professionals could turn to Google

Commented [EH8]: This is confusing. Why else do patients visit doctors other than for treatment etc? The record is one of many tools used for this. Be it an aide memoire or otherwise it is all used for these purposes or why keep it?

⁴⁷ Consultation: Scope of regulated software-based products V1.0 March 2020 p.13

- Electronic patient record keeping – examples include software that that helps individuals interact with these records or enables individuals to organise their health information (this includes manual patient recording of blood glucose, asthma attacks, blood pressure, etc.).

- Patient facing APPs which provide clinically valid information from systems like MHR, Hospital EMRs & PAS. Clinical and pharmacist information systems, all of which are the source of information from the MvHR which is excluded;

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- Clinical workflow and support - software to support health professional. Examples include software that is intended solely to display or print medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical-practice guidelines).
- Used for education, training, or guidance - Examples include; online textbooks, clinical guidance materials (including decision trees) for health professionals,
- software intended to help patients to self-manage diseases/ conditions through the provision of educational information.

Commented [EH9]: Please clarify whether any suggestions /algorithms about information displayed would disqualify the system from being excluded

- for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results. Findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyse clinical laboratory test or other device data, results, and findings. This includes secure messaging software extraction tools which enable the transfer of information from one system to another;

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- Processing tools (transferring, storing, converting formats, archiving, encrypting data) – Data platform that is intended to provide secure information storage and exchange data between applications.
- Communication tools (e.g., between healthcare professionals, patients, pathology labs). Examples include; telemedicine, video-conferencing software; and an online health platform that is intended to help patients to find healthcare providers, book appointments and obtain online consultations via tele-conferencing.
- Health information management/database systems – Examples include; a database (including search and query functions) intended to be used for storing health-related information and records; an application that provides library functions such as the retrieval of records by matching record metadata against record search criteria; and software that is intended to electronically receive, collect, store, transform and distribute data within or between healthcare facilities to support the administrative and clinical activities. Software intended to be used in hospitals or other care settings to aggregate information from different systems.
- for maintaining or encouraging a healthy lifestyle – Health and lifestyle apps including software intended to record fitness, wellness or to encourage a healthy diet or lifestyle without claiming to treat, prevent, manage, or predict susceptibility or risk of contracting a disease, condition, etc.; or to provide rehabilitation for a disease, condition etc.

- Software intended to extract data from clinical trial or patient records for population-based analyses
- Monitoring or management of Health IT systems – Monitoring uptime, cyber threats, performance, load on networks, servers, etc. in health environments (unless as an accessory to a medical device).
- Medi-alerts an example might be fall detectors not intended for the purpose of monitoring a disease or condition (such as Multiple Sclerosis).
- Standard IT equipment where the manufacturer is not making any therapeutic claims – Desktops, monitors, accessories; tablets, mobile phones, smart watches. (Note that if a manufacturer takes commodity hardware and packages it with claims about having a therapeutic purpose then it becomes a medical device in most jurisdictions. It is the intended purpose/use—not the form—in which something is presented that is the determiner of whether something becomes a medical device or not.)
- Travel medicine tools - Software intended to provide up to date travel vaccination advice and individualised vaccination scheduling.
- Predictive analysis – Software intended to predict whether a person ends up in an emergency department in the next 30 days or other useful efficiency or warning measure such as falls management, medication management, impending clinical deterioration, etc. by extracting information from the patient's health records.
- Archetype editor – Software intended to be used by clinicians to develop and edit archetypes for use in both point-of-care and research settings.

- Software which has one or more than one of the listed exclusions.

Commented [EH10]: Why is it ok to be excluded for a whole population of which an individual could be one part, but not also allowed if the extraction is for that individuals analysis? E.g. I could extract data about a nursing home and use it to decide to give them all a flu shot, but a system that did that for just one person is not allowed? Does the legislation need further clarity to avoid this anomaly?

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Software that could be potentially excluded or exempted from regulation

There may be some other types of software that while being medical devices in law could be excluded, or exempted, from the regulatory framework based on whether:

- It is considered that the software product does not pose significant harm to the individual (e.g., due to inappropriate use of the product); and/or
- There is an alternative mechanism of oversight in place.

Commented [EH12]: Should there be any specification here? I.e. radiology, path or lab system?

There may also be some software products where there is ambiguity as to whether it would be a medical device or not. In these circumstances an exclusion may be considered to provide clarity in relation to what would not be regulated as a medical device.

Based on the carve-out principles, an exemption should be provided for software products that implement existing, approved, hospital policies and processes, in an auditable and explainable manner. Software that does this is adhering to the 'no harm' principle above, as the policy and processes implemented are already approved, and the software is just an implementation of approved policies and processes in an electronic way.

There should be an exemption for software products that propose options to health care professionals (for example, Natural Language Processing and Clinical

Decision Support) where the recommendation is validated by a health care professional. This is covered by the principle above, which states that a carve-out is possible 'where any risks associated with their use and performance (e.g. risk of misdiagnosis or inappropriate treatment) can be appropriately mitigated'. The health-care professional's review and validation the recommendation is the risk mitigation in this instance.

Potential software exclusion/exemption, where it may be considered that the software poses no potential for significant harm to a patient

This principle involves identifying products that—while being medical devices in law—are considered to pose no significant threat of harm to a patient through their intended performance or failure to perform. This requires careful consideration of the basis for deeming that a product poses no potential for significant harm to a person.

Software used by consumers

Some software is used by consumers to manage ongoing conditions or chronic diseases. While some of these may currently be considered medical devices, if their inappropriate use would not result in significant harm to the patient they may potentially be excluded or exempted from regulation as a medical device. Patient information and health management:

- helps patients self-manage a specific disease/ condition; assists in managing own health as well as providing education information.
- helps patients manage stress for mental health; for example, providing daily motivational tips to promote a positive mental outlook, directing mindfulness activities
- monitors a condition, providing the condition is mild or self-limiting. Note that monitoring is separate to diagnosis and is specifically included legislated definition of a medical device (section 41BD, Therapeutic Goods Act 1989). There would need to be further analysis of which conditions could be excluded or exempted from the software regulatory regime and which ones could not be – similar to the development of restricted representations that do not allow the advertising of products for serious conditions to the general public.

Note: There is risk associated with excluding or exempting particular forms of product, rather than particular intended purposes. For example, if software that monitors a particular condition is excluded or exempted, that would create inconsistent regulation because other types of products that monitor similar conditions would still be regulated.

Software used by health professionals

- Software that provides “class-based analyses” rather than patient-specific diagnosis or management

Software that analyses a group of patients for common trends or diagnostic indicators e.g. breast density and cancer propensity could be excluded or exempted, while software that performs patient-specific analyses/ diagnoses/

treatment recommendations – e.g. radiotherapy dosage plan, would be regulated as a medical device

Potential software exclusion/exemption, where adequate alternative mechanisms of oversight exist

This principle would apply if it can be demonstrated that there are already adequate alternative mechanisms of oversight for software-based medical devices and risks associated with their use and performance (e.g., risk of misdiagnosis or inappropriate treatment) can be appropriately mitigated.

It is recognised that some software-based products may be embedded in the delivery of a health service and therefore be subject to other systems of regulatory or pseudo-regulatory oversight. Thus, there may be other, adequate controls already in place rendering TGA regulation unnecessary in certain circumstances.

Examples of software that could potentially be excluded or exempted might include:

- Lab Support Software that is intended to be used in an accredited pathology/[radiology](#) laboratory

Laboratory information management software (LIMS) that is intended for the input, storage and retrieval of clinical information or data; and reporting of clinical information does not usually meet the definition of a medical device. Some modules of LIMS, including some algorithms developed within the laboratory, may perform some functions that do meet the definition of a medical device. It may be possible to exclude these cases when they are supplied to/ used in a NATA/[RCPS](#) [or other](#) accredited laboratory.

- Clinical Decision Support Software

It is proposed that Clinical Decision Support software [should](#) be excluded or exempted from regulation when:

- it is not intended to acquire, process, or analyse a medical image or a signal from a hardware medical device or an in vitro diagnostic device, and
- it is intended for the purpose of displaying, analysing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines), and
- it is intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition, and
- it is intended for the purpose of enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not [the intent that such health care professional rely primarily](#) on any such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

Commented [EH13]: Any recognised accreditation body should be permitted to avoid third line forcing and fair competition

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Commented [EH14]: What other reason could it be used for other than treatment. Please explain.